

Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur

Proposed Syllabi and Scheme of

Master of Pharmacy

(Semester, Credit & Grade system)

2012-13

Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur

M. Pharm. Syllabus

Credit-grade based performance and assessment system (CGPA)

Features of the Credit System

With effect from Academic Session 2012- 2013

FEATURES OF THE CREDIT SYSTEM

- Master's degree would be of 80 credits each.
- One credit course of theory will be of one clock hour per week running for 15 weeks.
- Two credit course of theory will be of two clock hours per week running for 15 weeks.
- Four-credit course of theory will be of four clock hours per week running for 15 weeks.
- One credit course of practical will consist of 2 hours of laboratory exercise for 15 weeks.
- Two credit courses of practical will consist of 4 hours of laboratory exercise for 15 weeks.
- Four credit course of practical will consist of 8 hours of laboratory exercise for 15 weeks.

FIRST TWO SEMESTERS SHALL HAVE 5 THEORY COURSES, 2 PRACTICAL COURSES AND 1 SEMINAR FOR EACH SEMESTER

- 3 Theory courses x 4 credits = 12 credits
 - 2 Theory courses x 2 credits = 04 credits
 - 2 Laboratory courses x 4 credits = 08 credits
 - 1 Seminar x 2 credits = 02 credits
- Total = 26 credits**

EVERY STUDENT SHALL COMPLETE 80 CREDITS IN A MINIMUM OF FOUR SEMESTERS.

FIRST TWO SEMESTERS WILL HAVE 26 CREDITS EACH, THIRD SEMESTER WILL BE OF 08 CREDITS AND FOURTH SEMESTER WILL BE OF 20 CREDITS.

- Two semesters 2x 26 credits = 52 credits
 - Third semester 1x 08 = 08 credits
 - Forth semester 1x 20 = 20 credits
- Four semesters total credits = 80 credits**

SCHEME OF SYLLABUS AND CREDIT SYSTEM

The syllabus for the first semester includes three (03) theory courses common to all M. Pharm. Specializations, one theory course of respective specialization and an elective subject, so consist of total five theory papers and two laboratory courses and one seminar. Two credits have been allocated for seminar. Marks out of 50 will be allotted. Evaluation of seminar shall be done by three internal Examiners appointed by the Head/Principal of the Department/Institute based on scientific contents, communication, representation and skill in oral presentation.

The syllabus for the second semester includes two (02) theory courses common to all M. Pharm. Specializations, two theory course of respective specialization and an elective subject, so consist of total five theory papers and two laboratory courses and one seminar. Two credits have been allocated for seminar. Marks out of 50 will be allotted. Evaluation of seminar shall be done by three internal Examiners appointed by the Head/Principal of the Department/Institute based on scientific contents, communication, representation and skill in oral presentation.

The syllabus for the third semester includes one theory course of respective specialization and an elective subject, so consist of total two theory papers and one seminar. Two credits

have been allocated for seminar. Marks out of 50 will be allotted. Evaluation of seminar shall be done by three internal Examiners appointed by the Head/Principal of the Department/Institute based on scientific contents, communication, representation and skill in oral presentation. The topic for the research envisaged for the dissertation shall be assigned to him/her within one month from the date of commencement of third semester.

One elective subject can be chosen by minimum 8 and maximum 12 students of a particular college/institution during a semester. Each student has to clear three different elective subjects during his/her course of studies from the list given in Annexure-I

Total four credits have been allocated for the seminar on dissertation on completed research work for dissertation prior to thesis submission in fourth semester.

Scheme for Marks Distribution of Seminar on Dissertation (Semester IV)

CONTENT	MARKS	CREDIT
1. Introduction, justification, scope of dissertation work, organization of materials, methods and references.	25	01
2. Experimental work, observations, results and conclusion	50	02
3. Presentation skill, questioning and defending	25	01
Total	100	04

- Twelve credits have been allocated for the dissertation work.

Scheme for Marks Distribution for Dissertation Work

CONTENT	MARKS	CREDIT
1. Introduction, information retrieval system	50	02
2. Experimental work	100	04
3. Scientific content	50	02
4. Results / Conclusion	50	02
5. Organization of Scientific materials, dissertation thesis and references	50	02
Total	300	12

- Four credits each have been allocated for the Viva-voce on dissertation.

Scheme for Marks Distribution for Viva-voce

CONTENT	MARKS	CREDIT
1. Reading research paper and depth of knowledge on work topic	50	02
2. Discussion	25	01
3. Report	25	01
Total	100	04

- One credit = 25 marks; two credits = 50 marks and four credits = 100 marks.
- Four credits (theory) = 100 marks

Internal Examination (20 marks) External Examination (80 marks)

- Four credits (Practical) = 100 marks

Internal Examination (20 marks) External Examination (80 marks)

The Internal Assessment marks for theory should be based on Class Test and Attendance as follows:-

a) Class Test - 15

Marks will be based upon average marks of two Class Tests.

b) Attendance - Mark/s

75% to 80% - 1
81% to 85% - 2
86% to 90% - 3
91% to 95% - 4
96% to 100% - 5

Academic calendar showing dates of commencement and end of teaching, internal assessment tests & term end examination shall be duly notified before commencement of each semester every year by the affiliated colleges.

- Credit system offers more options to students and has more flexibility.
- Students can get requisite credits from the concerned colleges where she/he is mutually permitted on terms mutually agreed to complete the same and be eligible to appear for term end examination.
- The term end examination, however, shall be conducted by the RTM Nagpur University, Nagpur in the allotted centers.
- The research project shall be compulsory.
- These activities, including preparation of the result-sheets for the students, would be co-ordinated by the Departmental Examination Committee comprising Course in-charges and HOD or Head of the institution.
- Grades-Marks for each course would be converted to grades as shown in Table 1.

Table 1: Conversion of marks to grades in credit system

Marks Obtained	Grade	Grade Points
100-85	A ⁺	10
84-75	A	9
74-65	B ⁺	8
64-60	B	7
59-55	C	6
54-50	D	5
49 and less (internal)	FR	0-Failed (Clear course)

- A student who passes the internal tests but fails in Term End Examination of a course shall be given FR grade.
- Student with FR grade in a course would be granted credit for that course but not the grade for that course.
- Grade points earned in each paper shall be calculated as – Grade points obtained (vide Table 1 above) x Credits for the paper.

The computation of Semester Grade Point Average (SGPA) and Cumulative Grade Point Average (CGPA) of an examinee shall be as given below:-

The marks will be given in all examinations which will include college assessment marks and the total marks for each Theory /Practical shall be converted into Grades as per Table I. SGPA shall be calculated based on Grade Points corresponding to Grade as given in Table I and the Credits allotted to respective Theory / Practical shown in the scheme for respective semester.

SGPA shall be computed for every semester and CGPA shall be computed only in IV semester. The CGPA of IV semester shall be calculated based on SGPA of all four semesters as per following computation :-

SGPA	=	$C1 \times G1 + C2 \times G2 + \dots + Cn \times Gn$
		$C1 + C2 + \dots + Cn$

Where C1 = Credit of individual Theory / Practical
 G1 = Corresponding Grade Point obtained in the Respective Theory / Practical

CGPA	=	$(SGPA) I \times (Cr) I + (SGPA) II \times (Cr) II + (SGPA) III \times (Cr) III + (SGPA) IV \times (Cr) IV$
		$(Cr) I + (Cr) II + (Cr) III + (Cr) IV$

Where, (SGPA) I = SGPA of I Semester
 (Cr) I = Total Credits for I Semester
 (SGPA) II = SGPA of II Semester
 (Cr) II = Total Credits for II Semester
 (SGPA) III = SGPA of III Semester
 (Cr) III = Total Credits for III Semester
 (SGPA) IV = SGPA of IV Semester
 (Cr) IV = Total Credits for IV Semester

CGPA	Final Grade
9.0 – 10	A+
8.0 – 8.9	A
7.0 – 7.9	B+
6.0 – 6.9	B
5.5 – 5.9	C
5.0 – 5.4	D
4.9 and less	FR (Failed)

Final Mark List will only show the grade and grade points and not the marks.

CGPA equal to 6.00 and above shall be considered as equivalent to First Class which shall be mentioned on Grade Card of IV Semester as a foot note.

ACADEMIC CALENDAR AND TERMS

The terms and academic activities of the college affiliated to RTM, Nagpur University under CGPA shall be as prescribed by the University for respective academic session.

Beginning of First Term (Semester I and III) : As per University academic calendar

Vacation : As per University academic calendar

Beginning of Second Term (Semester II and IV) : As per University academic calendar

Draft Syllabus Prescribed for Master of Pharmacy

The several courses leading to the Master Degree of Pharmacy covers following subjects namely

1. Pharmaceutics
2. Pharmaceutical Chemistry
3. Pharmacology
4. Pharmacognosy
5. Biotechnology
6. Quality Assurance
7. Industrial Pharmacy
8. Pharmacoinformatics
9. Clinical Pharmacy
10. Natural Products
11. Pharmaceutical Management

SCHEME OF TEACHING AND EXAMINATION

APPENDIX-A

Pharmaceutics

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MPH-S4	Advanced Pharmaceutics	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MPH-6	Seminar (I)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MPH-S9	Product Development and Formulation	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MPH-S10	Novel Drug Delivery Systems	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MPH-12	Seminar (II)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-III	S3/301	MPH-S13	Biopharmaceutics and Pharmacokinetics	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MPH-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MPH-16	Dissertation		24									
					06	28	30		05	120				
Semester-IV	S4/401	MPH-17	Dissertation		24									300(12)
	S4/402	MPH-18	Seminar on Dissertation											100(4)
	S4/403	MPH-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MPH-S : Subject specialization in pharmaceutics

APPENDIX – B
Pharmaceutical Chemistry

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MPC-S4	Advanced Pharmaceutical Chemistry-I	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MPC-6	Seminar (I)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MPC-S9	Advanced Pharmaceutical Chemistry-II	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MPC-S10	Advanced Pharmaceutical Chemistry-III	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MPC-12	Seminar (II)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-III	S3/301	MPC-S13	Advanced Pharmaceutical Chemistry-IV	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MPC-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MPC-16	Dissertation		24									
					06	28	30		05	120				
Semester-IV	S4/401	MPC-17	Dissertation		24									300(12)
	S4/402	MPC-18	Seminar on Dissertation											100(4)
	S4/403	MPC-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MPC-S : Subject specialization in pharmaceutical chemistry

APPENDIX–C

Pharmacology

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MPL-S4	Advanced Physiology & Pathophysiology	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MPL-6	Seminar (I)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MPL-S9	Advanced Systemic Pharmacology	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MPL-S10	Advanced Pharmacology & Pharmacotherapeutics	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MPL-12	Seminar (II)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-III	S3/301	MPL-S13	Molecular Pharmacology and Toxicology	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MPL-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MPL-16	Dissertation		24									
				06	28	30		05	120					200(8)
Semester-IV	S4/401	MPL-17	Dissertation		24									300(12)
	S4/402	MPL-18	Seminar on Dissertation											100(4)
	S4/403	MPL-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MPL-S : Subject specialization in pharmacology

APPENDIX-D

Pharmacognosy

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MPG-S4	Advanced Pharmacognosy and Phytochemistry	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MPG-6	Seminar (I)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MPG-S9	Standardization of Natural Products	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MPG-S10	Herbal Drug Formulation and Development	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MPG-12	Seminar (I)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-III	S3/301	MPG-S13	Selected Topics in Pharmacognosy	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MPG-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MPG-16	Dissertation		24									
				06	28	30		05	120					200(8)
Semester-IV	S4/401	MPG-17	Dissertation		24									300(12)
	S4/402	MPG-18	Seminar on Dissertation											100(4)
	S4/403	MPG-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MPG-S : Subject specialization in pharmacognosy and phytochemistry

APPENDIX–E

Biotechnology

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MBT-S4	Fundamentals of Biotechnology	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MBT-6	Seminar (I)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MBT-S9	Molecular Biology	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MBT-S10	Fermentation Technology	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2	4	10		02	40			25		50(2)
	S2/206	MBT-12	Seminar (II)											50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-III	S3/301	MBT-S13	Advanced Tissue and Cell Culture Techniques	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MBT-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MBT-16	Dissertation		24									
				06	28	30		05	120					200(8)
Semester-IV	S4/401	MBT-17	Dissertation		24									300(12)
	S4/402	MBT-18	Seminar on Dissertation											100(4)
	S4/403	MBT-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MBT-S : Subject specialization in biotechnology

APPENDIX-F

Quality Assurance

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MQA-S4	Pharmaceutical Validation	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MQA-6	Seminar (I)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MQA-S9	Quality Assurance of Cosmeceuticals	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MQA-S10	Novel Drug Delivery Systems	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MQA-12	Seminar (II)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-III	S3/301	MQA-S13	Quality Management	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MQA-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MQA-16	Dissertation		24									
				06	28	30		05	120					200(8)
Semester-IV	S4/401	MQA-17	Dissertation		24									300(12)
	S4/402	MQA-18	Seminar on Dissertation											100(4)
	S4/403	MQA-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MQA-S : Subject specialization in quality assurance

APPENDIX-G

Industrial Pharmacy

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MIP-S4	Advanced Industrial Pharmacy-I	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MIP-6	Seminar (I)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MIP-S9	Advanced Industrial Pharmacy-II	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MIP-S10	Advances in Drug Delivery Systems	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MIP-12	Seminar (II)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-III	S3/301	MIP-S13	Industrial Process Validation and Production Management	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MIP-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MIP-16	Dissertation		24									
				06	28	30		05	120					200(8)
Semester-IV	S4/401	MIP-17	Dissertation		24									300(12)
	S4/402	MIP-18	Seminar on Dissertation											100(4)
	S4/403	MIP-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MIP-S : Subject specialization in industrial pharmacy

Pharmacoinformatics

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MPI-S4	Information Technology	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MPI-6	Seminar (I)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MPI-S9	Bioinformatics	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MPI-S10	Molecular Biology	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MPI-12	Seminar (II)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-III	S3/301	MPI-S13	Selected Topics in Pharmacoinformatics	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MPI-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MPI-16	Dissertation		24									
				06	28	30		05	120					200(8)
Semester-IV	S4/401	MPI-17	Dissertation		24									300(12)
	S4/402	MPI-18	Seminar on Dissertation											100(4)
	S4/403	MPI-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MPI-S : Subject specialization in pharmacoinformatics

APPENDIX-I

Clinical Pharmacy

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MCP-S4	Advanced Clinical Pharmacy & Pharmacotherapeutics-I	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MCP-6	Seminar (I)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MCP-S9	Advanced Clinical Pharmacy & Pharmacotherapeutics-II	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MCP-S10	Clinical Research	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MCP-12	Seminar (II)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-III	S3/301	MCP-S13	Community & Clinical Pharmacy	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MCP-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MCP-16	Dissertation		24									
				06	28	30		05	120					200(8)
Semester-IV	S4/401	MCP-17	Dissertation		24									300(12)
	S4/402	MCP-18	Seminar on Dissertation											100(4)
	S4/403	MCP-19	Viva-voce											100(4)
													500(20)	
														2000(80)

MC-S : Subject common to all branches

MCP-S : Subject specialization in clinical pharmacy

APPENDIX-J

Natural Product

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MNP-S4	Industrial Pharmacognosy	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MNP-6	Seminar (I)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MNP-S9	Natural Products & Bio-organic Chemistry	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MNP-S10	Standardization of Natural Products	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MNP-12	Seminar (II)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-III	S3/301	MNP-S13	Selected Topics in Natural Products	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MNP-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MNP-16	Dissertation		24									
				06	28	30		05	120					200(8)
Semester-IV	S4/401	MNP-17	Dissertation		24									300(12)
	S4/402	MNP-18	Seminar on Dissertation											100(4)
	S4/403	MNP-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MNP-S : Subject specialization in natural product

Pharmaceutical Management

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MPM-S4	Pharmaceutical Management-I (General and Personnel)	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2	4	10		02	40			25		50(2)
	S1/106	MPM-6	Seminar (I)											50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MPM-S9	Pharmaceutical Management II (Production)	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MPM-S10	Pharmaceutical Marketing Management	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MPM-12	Seminar (II)		4									50(2)
				16	20	80	40	13	320	16	160			650(26)
Semester-III	S3/301	MPM-S13	PharmaProduct Management	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MPM-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MPM-16	Dissertation		24									
				06	28	30		05	120					200(8)
Semester-IV	S4/401	MPM-17	Dissertation		24									300(12)
	S4/402	MPM-18	Seminar on Dissertation											100(4)
	S4/403	MPM-19	Viva-voce											100(4)
													500(20)	
														2000(80)

MC-S : Subject common to all branches

MPM-S : Subject specialization in pharmaceutical management

Syllabus Prescribed for Degree of Master of Pharmacy in Pharmaceutics

Semester-I

Subject code: MC-S1

Subject: ADVANCED ANALYTICAL TECHNIQUES

THEORY:

60 Hours (4 hrs. /week)

1. **Chromatographic Techniques:**

Classification of chromatographic methods based on mechanism of separation and their basic principles.

Gas chromatography: Instrumentation, column efficiency parameters, derivatisation methods, applications in pharmaceutical analysis.

Liquid chromatography: Instrumentation in HPLC, normal and reversed phase packing materials, column selection, mobile phase selection, efficiency parameters, applications in pharmaceutical analysis.

Thin Layer Chromatography overview. Instrumentation and applications of HPTLC giving emphasis to use of TLC- Densitometry in the standardization of some Medicinal Plants.

Recent advances in Chromatography like LCMS, HPTLC MS, LC MS-MS

2. **UV-Visible Spectroscopy:**

Basic principles, Instrumentation, Electronic transitions. Concept of chromophore and auxochrome, Effect of conjugation, solvent and pH. Instrumentation. Multicomponent analysis. Woodward-Fieser rules for calculating absorption maximum for unsaturated hydrocarbons. Difference and derivative spectra. Interpretation of spectra, Qualitative and quantitative analysis of drug molecules.

3. **Infra-Red Spectroscopy:**

Basic principle, Interaction of infrared radiation with organic molecules and its effect on bonds. Instrumentation- Dispersive IR and FT-IR spectrophotometers. Sample preparation & Sample handling. Interpretation of IR spectra. Fermi Resonance. Brief note on Attenuated Total Reflectance. Qualitative and quantitative applications of IR.

4. **Nuclear Magnetic Resonance Spectroscopy:**

Fundamental principles of NMR. Instrumentation. Chemical shift concept, spin-spin coupling and decoupling, shielding and deshielding, solvents. Pascal triangle, signal multiplicity in PMR. Spin-spin and spin-lattice relaxation, Nuclear overhauser effect, Interpretation of PMR, ¹³C NMR.

5. **Mass Spectrometry:**

Basic principles and instrumentation. Ionization techniques, mass spectrum and its characteristics, molecular ion, metastable ions, fragment ions; fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks.

6. **Thermal Methods:**

Thermogravimetry, Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

RECOMMENDED BOOKS:

1. Skoog, DA, Holler, FJ, Crouch, SR. Principles of instrumental analysis. 6th ed., Baba Barkha Nath Printers, Haryana, 2007.
2. Silverstein, RM, Webster, FX. Spectrometric identification of organic compounds. 6th ed., John Wiley and Sons (Asia) Pvt. Ltd., Singapore, 2005.
3. William Kemp. Organic Spectroscopy, 3rd ed., Palgrave, New York, 2006
4. Connors KA. Text book of Pharmaceutical analysis, 3rd ed., John Wiley and Sons, Singapore, 2004
5. Willard HH, Merritt LL, Settle FA. Instrumental methods of analysis, 7th ed., CBS Publishers and Distributors, New Delhi, 1986
6. Sharma BK. Instrumental methods of chemical analysis, 25th ed., Goel Publishing House, Meerut, 2006.
7. Beckett, AH, Stenlake, JB. Practical Pharmaceutical Chemistry, Part I and Part II, 4th ed., CBS Publishers and Distributors, New Delhi, 2004.
8. Ewing, GW. Instrumental methods of chemical analysis, 5th ed., McGraw Hill Book Company, New York, 1985.
9. Houghton P, Mukherjee PK. Evaluation of Herbal Medicinal Product, Pharmaceutical Press, London, 2009.
10. Kalsi, P S. Spectroscopy of Organic Compounds, 2nd ed., Wiley Eastern Ltd., Delhi

Subject code: MC-P1

Subject: ADVANCED ANALYTICAL TECHNIQUES

PRACTICAL:

8 hrs. /week

1. UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures and isobestic point in case of mixtures.
2. Estimation of single drug (raw material/ formulation) by colorimetry involving different reagents. (minimum of 4 experiments)
3. Estimation of single drug (raw material/ formulations) by UV spectrophotometry. (minimum of 4 experiments)
4. Estimation of multicomponent formulation by UV- Spectrophotometer in formulations (minimum of 4 experiments)
5. Effect of pH and solvent on UV Spectrum of certain drugs. (Minimum of 2 experiments)
6. Calibration of IR Spectrophotometer using polystyrene film and checking the performance of the instrument.
7. Interpretation of structure of drugs by Infra red spectra. (Minimum 4 compounds).
8. Experiments based on the application of derivative spectroscopy. (Minimum of 2 experiments)
9. Standardization and dissolution studies of solid dosage form (Minimum of 5 experiments)
10. Experiments using HPLC: Determination of chromatographic parameters- capacity factor, selectivity, resolution, efficiency of column HETP, asymmetric factor.
11. Estimation of drugs in biological fluids by HPLC (minimum 2 experiments)
12. Experiments based on application of HPTLC for quantification of Berberin from *Berberis aristata* and Andrographolide from *Andrographis paniculata*.

Subject code: MC-S2

Subject : RESEARCH METHODOLOGY & BIostatISTICS

THEORY:

30 Hours (2 hrs. /week)

Research Methodology

- 1. Introduction:** Meaning & Objectives of research, types of research: basic, applied action & patent oriented research, approaches to research; research methods, research process; criteria for good research, common problems, nature and significance of research problems, qualitative & quantitative research methods.
- 2. Selection of Research Topic:** Selection of research problem, literature review, evaluation of research problem, research design; meaning, concept & features of research design, experimental design, plan of research work.
- 3. Methods & tools of research**
Reliability and validity of research tool, Qualitative and quantitative studies, Primary & secondary data collection method, Preparing questionnaire and opinionnaire, identification of sources of information, searching and classifying information; organization of data collection, processing & analyzing of data & information. Limitations & sources of error.
- 4. Preparing a research proposal**
Format of research proposals: finding related literature, Individual & Institutional research proposals, submitting research proposal to funding agencies.
- 5. The Research Report/Report writing**
Style manuals, format of research report, The thesis or dissertation, style of writing, typing the report, reference form, pagination, tables, figures, evaluating a research report, summary, references.

Biostatistics

- 1. Descriptive Statistics:** Classification of variable, Summary of measures of location: median and mean, Properties of the sample mean, Summary measures of dispersion: interquartile range, variance, standard deviation, Properties of sample variance and standard deviation, Graphic representation of data.
- 2. Estimation and Hypothesis testing:** Null Hypothesis, confidence level, Point & interval estimation, concept of hypothesis testing & types of error, Student 't' test, Chi-Square test.
- 3. Analysis of Variance:** Analysis of variance (one way & two way), Repeated measures designs, factorial designs, univariate ANOVA post hoc tests, analysis of covariance (ANCOVA), repeated measures analysis, multiple regression, and power analysis.

RECOMMENDED BOOKS:

1. B.D. John, A.L. Brown and R.R. Cocking, 1999. "How People Learn: brain, mind, experience and school". Washington, DC: National Academy Press.
2. J.R. Fraenkel, N.E. Wallen, 2008. "How to Design and Evaluate Research in Education", 7th Ed. Boston: McGraw-Hill.
3. K.E. David, 2009. Curriculum Development for Medical Education: A Six-Step Approach, 2nd Ed. The John Hopkins University Press. ISBN 0-8018-9367-4.
4. N. Peter, 2009. "Leadership: Theory and Practice." 3rd Ed. Thousand Oaks: Sage Publications.
5. G. Bordage, B. Dawson, 2003. Experimental study design and grant writing in eight steps and 28 questions. *Medical Education*, 37(4): 376-385.

6. C.R. Kothari, 2004. "Research Methodology". 2nd Ed. New Age International (p) Limited, Publishers.
7. D. Montgomery, 2000. "Design of Experiments". 5th Ed. Wiley Interscience.
8. K.P. Willkinston, L. Bhandarkar, "Formulation of Hypothesis". 3rd Ed. Himalaya publishing, Mumbai.
9. Schank Fr, 2008. "Theories of Engineering Experiments". 2nd Ed. Tata McGraw Hill.
10. D.C. Montgomery, 2009. "Introduction to SQC" 6th Ed. John Willy & sons.
11. Cochran & Cocks, 1957. 2nd Ed. "Experimental Design" New York, John Willy & sons.
12. J.W. Best and J.V. Kahn, 2006. "Research in Education". 10th Ed. PHI publication.
13. Adler and Granovky, "Optimization of Engineering Experiments", MIR Publications.
14. S.S. Rao, 1983. "Optimization Theory & Applications". 2nd Ed. Wiley Eastern Ltd. ND.
15. P.D. Kulkarni, 1986. "Independent Study Techniques", TTTI Chandigarh.
16. C. B. Gupta, Introduction to Statistical Methods.
17. C. E. Weatherborn, A first course in Mathematical Statistics.
18. LD Fisher, GV Belle, Biostatistics: A Methodology for Health Sciences. 2nd Edition. Wiley Interscience .2004.
19. Sanford Bolton. Pharmaceutical statistics- Practical and clinical applications. 4th edition, publisher Marcel Dekker Inc. New York.

Subject code: MC-S3

**Subject : DRUG REGULATORY AFFAIRS
THEORY**

60 Hours (4 hrs. /week)

1. Aims, objects and salient features of following legislations affecting pharmaceutical industry.
 - a) Industrial Development and Regulation Act 1951.
 - b) Consumer Protection Act
 - c) Pollution and Environmental Control Act..
2. Legislation
 - a. To Regulate the profession of pharmacy – The Pharmacy Act 1948
 - b. To control the advertisements, excise duties & prices of drug The Drugs and Magic Remedies Act & Rules (Objectionable advertisements) The Medicinal & Toiletry preparations (The Excise Duties Act- 1955 & Rules 1976).
 - c. To control the operations relating to dangerous drugs & opium. Narcotic Drugs & Psychotropic Substance Act 1985.
3. Standard institutes & certification agencies like ISI, BSS, ASTM, SO, WHO, US-FDA, UK-MCA, TGA. Australian TGA guidelines. US-FDA, CDER guidelines
4. Intellectual Property Rights Law:
 - a) Indian Patent Act 1970 and amendments there under,
 - b) Copyright (Indian) Act
 - c) Guide lines for filing patents in countries like US & UK.
 - d) Good Clinical Practice Guideline, Good Laboratory Practice Guidelines, GMP Guidelines
5. Drug Master File. Preparation of Site Master File, Master Formula Record and DMF Procedure for filing of Patent.
6. Management of Intellectual Property in Drugs & Pharmaceuticals
7. Drug Regulatory Agencies of the following countries with focus on historical perspectives, organization structure activities & responsibilities: India, US, Europe and Japan
8. Drug and Cosmetics Act 1940 & rules 1945 with amendments, Prevention of Food Adulteration Act 1954.

9. Study of compendia – Evolution, Study of parts of compendia like: Policies, General notices, Monographs, Comparative picture of IP, USP, BP, EP & GP.
10. New Drug Application (NDA), Investigational New Drug Application (INDA), Abbreviated New Drug Application (ANDA).
11. Material Safety Data Sheet (MSDS) preparation and Industrial Safety & Health

RECOMMENDED BOOKS: -

1. Forensic Pharmacy by B.S. Kuchekar, A. M. Khadatare and S. C. Jitkar, 6th Ed., Nirali Prakashan
2. Drugs and Cosmetics Laws by Krishnan Arora, Professional Book Publishers, New Delhi
3. Mittal B.M., A Textbook of Forensic Pharmacy, 9th Ed., Vallabh Prakashan
4. James Swarbrick, James C Boylon, Encyclopedia of Pharmaceutical Technology, 2nd Ed. Marcel Dekker Inc.
5. Deshpande S.W., Drugs and Cosmetic Act.1940
6. Bubuarm N.R, Whatever one should know about patent, 2nd Ed., Pharma Book Syndicate
7. Gnarino Richard A, New Drug Approval Process, 3rd Edition, Marcel Dekker Inc
8. Deshpande S.W, Drug and Magic Remedies Act 1954.
9. P. Warayan, Intellectual Property Laws, Eastern Law House.
10. Drug and Cosmetic Act 1940, Eastern Book company by Vijay Malic, 11th Ed. Patents for Medicine, by N. B. Zareri, Indian Drug Manufacturers Association (IDMA)
11. Pharmacy Law and Ethics by Dale and Appelbes, The Pharmaceutical Press, Joy Winfield.
12. Guidelines of various countries like MCA, TGA, ICH.
13. GLP regulation by Alen Hirsch Vol 38 Marcel Decker series.
14. GMP for pharmaceuticals forth edition by S. Willing, J. Stocker Marcel Decker series 1997.
15. I.P., B.P., U.S.P. International Pharmacopoeia

Subject code: MPH-S4

Subject : ADVANCED PHARMACEUTICS

THEORY:

60 Hours (4 hrs. /week)

1. **Preformulation Studies:** Timings and goals of Preformulation, Pre-formulation methodology, solid state properties, partition coefficient, solubility, dissolution, crystal form and stability, Thermal Analysis, X-ray diffraction:- Techniques to generate & characterize amorphous & crystalline forms, compatibility tests, dissolution of drug substances and dosage.
2. **Kinetic Principles and Stability Testing:** Order of reaction, influence of pH, temperature, Acid - base catalysis. Effect of Ionic strength on degradation, Complex reactions, amide hydrolysis, Ring alteration, Oxidation - reduction, Chemical & Physical stability of dosage forms, Influence of packaging components on dosage form stability. Overages and ICH guidelines.
3. **Excipients:** Overview of excipients used in formulations. Factors affecting the selection. Introductory aspects of drug-excipient and excipient, package interactions.

Study of newer excipients like cyclodextrin, ion exchange resins, film coating materials, superdisintegrants, directly compressible vehicles, surfactants- micelle formation, liquid crystal phase, thickeners. Standardization of excipients.

4. **Polymer Science:-** Introduction and classification ,preparation methods of synthetic polymers, Molecular weight determination , Thermal characterization and rheology of polymers. Introduction to biodegradable & biodegradable polymers.
5. **Diffusion & Dissolution:** Concept and importance of dissolution. Steady state diffusion. Determination of diffusion coefficient & its importance. Concept & importance of dissolution. Dissolution test, Historical development & USP dissolution test. Dissolution model like Hixson-Crowell, Higuchi's Model. Drug release modeling through polymer matrix & laminates. Concept of membrane controlled delivery & its importance in dosage form design.
6. Optimization Techniques in Pharmaceutics, Formulation and Processing Optimization parameters, statistical design, and other application.
7. **Quality Control :** Process of dosage forms : Process control ; Control of quality Validation, Control of manufacturing Process, Statistical quality control, control charts, sampling plans, Automated & process control, Dosage form control, Testing programme & method, Product identification systems, Adulteration, Misbranding, maintenance of records, Bioavailability, Bioequivalence, manufacturer's reliability, Manufacturer/drug information profile.

RECOMMENDED BOOKS:

1. Lachmann and Libermann, Theory and Practice of Industrial Pharmacy. Third edition, Varghese Publishing House.
2. Leon Lachmann, Pharmaceutical dosage forms: Tablets Vol. 1-3. Third Edition, Marcel Dekker.
3. Leon Lachmann. Pharmaceutical Dosage forms: Disperse systems, Vol, 1, 2, 3. Second edition. Marcel Dekker
4. Gillbert and S. Banker. Modern Pharmaceutics.. Fourth Edition. Volume 121.
5. Remington's Pharmaceutical Sciences. Vol.I-II, 21 st Edition.
6. H.S. Bean & A.H. Beckett .Advances in Pharmaceutical Sciences Vol. 1-4.
7. Alfred Martin, Physical Pharmacy. Fifth Edition, Published by B. I. Waverly Pvt. Ltd.
8. Rawlins. Bentley's Textbook of Pharmaceutics. Eight Edition
9. Sidney H. Willig. Good manufacturing practices for Pharmaceuticals: A plan for total quality control. Second Ed.
10. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
11. D.P.S. Kohli and D.H. Shah. Drug formulation manual. Third Edition, Eastern publishers, New Delhi.
12. P. P. Sharma. How to practice GMPs. Fifth Edition, Vandana Publications, Agra.
13. Fra. R. Berry and Robert A. Nash. Pharmaceutical Process Validation. Vol-129, Second Edition. Revised and Expanded.
14. Evans, Anderson, Sweeney and Williams Applied production and operations management.
15. M. Gibson, 2001. "Pharmaceutical preformulation and formulation"1st Ed. Informa Healthcare.
16. A. Hickey, 2009. "Pharmaceutical process engineering" 2nd Ed. Marcel Dekker, Inc

17. J. Swarbrick, 2007. Encyclopedia of Pharmaceutical Technology, Third Edition, Volume 1-6, Informa Healthcare.
18. R. Sheskey and Quinn, "Pharmaceutical excipients" Pharmaceutical Press.
19. M. Chaubal, "Excipients development for. Pharmaceutical, Biotechnology, and Drug Delivery System". Informa Healthcare.
20. S.C. Sweetman. Martindale-The complete drug reference. 37th Edition, Vol. A and B, Pharmaceutical Press, UK.

Subject code: MPH-P4

Subject : ADVANCED PHARMACEUTICS

Practical:

8 hrs. /week

1. Preformulation studies on tablets.
2. To study the decomposition kinetics of any three drugs.
3. To study the effect of copper ions on the ascorbic acid stability in solution
4. To determine the aqueous solubility of given drug sample at various temperature and report its thermodynamic parameters.
5. To study the dissolution kinetics of given drug.
6. To study the effect of pH (2, 4, 6 and 8.0) on the apparent partition coefficient of a drug in n-octanol- water buffer system.
7. To study the dissolution kinetics of immediate and extended release dosage form (any five).
8. To study the effect of temperature on rheological behavior of poloxamers.
9. To study the effects of pH on rheological characteristics of carbopol gels using Brookfield viscometer.
10. To determine the best compatible additive for aspirin tablets using at least five known tablet components.
11. To study the diffusion of drug from topical gel using Franz diffusion cell.

Semester-II

Subject code: MC-S7

Subject: VALIDATION and cGMP

THEORY:

30 Hours (2 hrs. /week)

Validation

1. Definition, Government regulation, scope and advantage of validation, relationship between validation and qualification, validation master plan, FDA 21 CFR Part 11, qualifications of utilities and process equipments (protocols & reports for DQ, IQ, OQ, PQ).
2. Validation of medical devices, biotechnology processes, pharmaceutical ingredients, air handling and HVAC systems, sterile and non sterile areas, aseptic processes and sterilization methods, purified water system, distilled water and water for injection.

cGMP

1. Concepts and Philosophy of cGMP in manufacturing, processing, packaging, and holding of Drugs.
2. Organization and Personnel: Responsibilities, qualification, experience, training, personal hygiene and clothing.
3. Buildings and Facilities: Location, design, plant layout, maintenance and sanitation, environmental control, utilities and services like gas, water, control of contamination and maintenance of sterile areas.
4. Raw materials: Purchase specifications, selection of vendors, control on raw materials and finished dosage forms.

RECOMMENDED BOOKS:

1. Pharmaceutical Process Validation, Edited by Robert A. Nash, Alfred H. Wachter, Vol. 129, Marcel Dekker Inc.
2. Good Manufacturing Practices for Pharmaceuticals by Sidney H. Willing and Murray M. Tuckerman, Vol. 16, Marcel Dekker Inc.
3. Encyclopedia by pharmaceutical technology edited by James Swarbrick, James C. Boylan, Marcel Dekker Inc. gtg
4. How to practice GMPs by Sharma PP, 3rd Ed., Vandana Publication.
5. Drug and Cosmetic Act and Rules (Government of India).
6. Current Good Manufacturing Practices by Potdar MA, Pharma-Med Press, Hyderabad.
7. Pharmaceutical Quality Assurance by Potdar MA, Nirali Prakashan, Pune.

Subject code: MC-S8

Subject: BIOLOGICAL EVALUATION

THEORY:

60 Hours (4 hrs. /week)

1. Principles of Pharmacological and Pre-clinical Evaluation of drugs. Commonly used laboratory animals in pharmacological research, limitations of animal tests Standard techniques used in laboratory animals, euthanasia of experimental animals, Regulations for laboratory animal care and ethical requirements.

2. Bioassays: Basic principles of bioassays, official bioassays, experimental models, design of bioassays.

3. Toxicology: Principles of toxicity evaluations. Safety evaluation of new drugs in animals including acute, sub-acute, sub chronic and chronic toxicity. ED50 and LD50 determination, special toxicity test like teratogenicity and mutagenicity. Various guidelines for toxicity studies. International guidelines and regulatory agencies for toxicity studies like ICH, OECD, FDA, WHO etc.

4. Modern Methods of Pharmacological evaluations: Radioligand binding assay, patch clamp, stereotaxic technique and ELISA. Recent advances in transgenic and genetically modified animals for drug screening and other sophisticated methods

5. Alternatives to animal screening procedures: Cell line - handling, maintenance and propagation of cell lines, their uses and limitations. In-vitro testing of drugs.

6. Preclinical Evaluation: Preclinical models employed and organization of screening of new drugs of following categories:

- i) Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotics, nootropics, antiparkinsonian agents, analgesics, antipyretics.
- ii) Anti-inflammatory agents, anticonvulsants, local anaesthetics, CNS stimulants.
- iii) Cardiac glycosides, antiarrhythmic, antihypertensive, antianginal, anti-atherosclerotic,
- iv) Antiulcer agents, Laxatives, Bronchodilators, antitussives,
- v) Diuretics.
- vi) Histamine antagonists.
- vii) Muscle relaxants, Anticholinesterases, anticholinergics, adrenolytics.
- viii) Hypoglycemics, antifertility agents, androgens.
- ix) Anti-thyroid agents, Dermatological agents, Antitumor agents.
- x) Anthelmintics, Antimalarials, Antileprotics.
- xi) Drugs used for glaucoma, cataract and eye inflammation.

RECOMMENDED BOOKS:

1. Laurence D R and Bacharach A L, Evaluation of Drug Activities: Pharmacometrics, Academic Press, London & New York.
2. Nodine J H and Siegler P E, Animal and Clinical Pharmacological Techniques in Drug
3. Evaluation, Year Book Medical Publishers Chicago.
4. Turner R A and Hebborn P, Screening Methods in Pharmacology, Vol I & II, Academic Press, New York, 2009.
5. Vogel H G, Drug Discovery and Evaluation, Pharmacological Assays, Springer-verlog Berlin Heidelberg, 2007.

6. S. K. Gupta, Drug screening methods, Jaypee Brothers Medical Publisher (P) Ltd, New Delhi 2005.
7. Sheth U K, Dadkar N K and Kamat U G, Selected topics in Experimental Pharmacology, Kotari Book Depot, Mumbai.
8. Jann Hau, Handbook of Laboratory Animal Science, Animal Models, Vol I and II. CRC Press 2004 3rd edition.
9. Perry W L M, Pharmacological Experiments on Isolated preparations, E & S Livingstone, London.
10. Burn J H, Practical Pharmacology, Blachwell Scientific Co., Oxford.
11. Parmar N S and Shivkumar, Pharmacological Screening Methods, □ Sciences 2006.
12. Thomson E.B. Drug Bioscreening, John-Wiley and Sons, New York, 1990.
13. Review articles published in various medical and pharmaceutical journals and CPCSEA, OECD, FDA, WHO, ICH guidelines from respective website.

Subject code: MPH-S9

Subject: PRODUCT DEVELOPMENT AND FORMULATION

THEORY:

60 Hours (4 hrs. /week)

1. **Fundamental Aspects of Product Development:** Studies of wettability, solubility, dissolution, and absorption, surfactant and hydrocolloids and their role in drug delivery and targeting.
2. **Pilot Plant Scale-up Techniques:** Purpose and functions, concepts of pilot plant for development and control. Planning for pilot plant, size of pilot plant. Organization and personnel, basic consideration in developing the process for production of pharmaceutical dosage forms. Pilot plant study design for tablets, tablet coating, capsules, liquid orals and semi-solids.
3. **Designing of Oral Pharmaceuticals:** Formulation, evaluation, stability Studies and recent advances in dosage form; tablet, capsule, suspension, emulsion; microencapsulation, advances in coating techniques. Advances in pelletization techniques
4. **Development of Parenterals:** Concepts, formulation, evaluation of large and small volume parenterals, environmental control and quality assurance in manufacturing.
5. **Ophthalmic Preparation:** Introduction, Physiology of eye, formulation consideration and evaluation of ophthalmic products (ointments, suspension, eye drops, contact lenses, occuserts etc.), container and closures.
6. **Suppositories:** Selection of suppository bases, characteristics of bases, formulation, preparation, evaluation and packaging of suppositories, stability studies and recent development.
7. **Dermatological Preparations:** Anatomy and physiology of skin, mechanism of absorption through skin including mathematical treatment, formulation and evaluation of ointments, creams, paste, gels including herbal cosmetic creams.

Note: The designing and development of dosage form should be covered at advanced level considering recent advances in dosage form technology

RECOMMENDED BOOKS:

1. Remingtons "Pharmaceutical Sciences" 21st edition.
2. Lachman "The Theory and Practice of Industrial Pharmacy" 3rd edition, Varghese Publisher.
3. M. E. Aulton, Pharmaceutics "The Science of Dosage form design". Second Edition.
4. Husa's Pharmaceutical dispensing; a textbook and reference manual on drug development, pharmaceutical compounding, and dispensing. 6th Edition, Editor: Eric W. Martin. Managing editor: John E. Hoover.
5. Gillbert and S. Banker. Modern Pharmaceutics.. Fourth Edition. Volume 121.
6. J. Swarbrick, 2007. Encyclopedia of Pharmaceutical Technology, Third Edition, Volume 1-6, Informa Healthcare.

Subject code: MPH-S10

Subject: NOVEL DRUG DELIVERY SYSTEMS

THEORY:

60 Hours (4 hrs. /week)

1. Fundamentals of controlled release drug delivery systems :

Fundamentals and Rationale of Sustained / controlled drug delivery, factors influencing the design & performance of sustained/ Controlled release products, Drug Targeting, Use of polymers in controlled release of active agents, Pharmacokinetic / Pharmacodynamic basis of controlled drug delivery systems, regulatory requirements.

2. Oral drug delivery: Formulation, fabrication and evaluation of various oral controlled drug delivery systems including dissolution and diffusion controlled delivery systems, gastro retentive, colon targeted and pulsatile drug delivery. TIMERx, MASSRx & COSRx, Procise technology, RingCap technology, Theriform Technology, Accudep Technology, THREIFORM Technology, DissoCube IDD Technology, Zydis Technology for poorly soluble drugs, Orasolv & Durasolv technology, Egalet Technology, Buccal Mucoadhesives, Periochips.

3. Parenteral controlled release system: Scope, terminology & techniques used, injectable controlled release, formulation. Implantable drug delivery, microspheres, liposomes & their quality control.

4. Mucosal drug delivery models: Buccal, rectal, nasal & vaginal drug delivery. Mechanisms of transports of drugs through mucosal routes, penetration enhancers, formulation development, in-vitro, ex-vivo and in-vivo methods of evaluation (for each route).

5. Transdermal drug delivery system: Permeation through skin including mechanism, permeation enhances, In-vitro skin permeation, technologies for developing transdermal drug delivery system, mechanism of release kinetics, evaluation of transdermal drug delivery systems.

6. Ocular Drug Delivery: Transport of drugs through ocular tissues, approaches to improve ocular drug delivery.

7. Site specific drug delivery system: Active & passive targeting, resealed erythrocyte, monoclonal antibodies, drug targeting by particulate carrier system, drug targeting to brain, lung & colon.

8. Protein & peptide drug delivery system: Physical aspects, biochemistry of protein drug (structure, properties & stability- Mechanisms of destabilization. Techniques of stabilization of Proteins and Peptides.) General methods of analysis of protein & peptide drugs, barrier to transport & Pharmacokinetics, different route of delivery, practical considerations. Importance of pre-formulation & formulation considerations, toxicity immunogenicity, stability & regulatory perspective.

9. Regulatory consideration in controlled release: Demonstration of safety, efficiency & controlled release nature. WHO conditions.

RECOMMENDED BOOKS:

1. Remington's pharmaceutical sciences. 21 st Edition, Lippincott Williams and Willkins- Vol. I & II
2. Novel drug delivery system – Marcel Dekker N.Y. Second Edition, Revised and Expanded by Yie W. Chien. Vol- 50.
3. J. R. Robinson and Vincent H. L. Lee Controlled drug delivery system. Marcel Dekker Second Edition, Revised and Expanded. Vol- 29.
4. N.K. Jain .Novel and controlled drug delivery systems, C.B.S. publishers and Distributors, New Delhi.
5. N.K. Jain. Advances in Novel and Controlled Drug Delivery, C.B.S. publishers and Distributors, New Delhi.
6. Robinson, J.R. & Lee, V.H.I.,: Controlled and Novel Drug Delivery Marcel Dekker, New York. Second Edition, Revised and Expanded Vol- 29.
7. Kim. C., Controlled Release Dosage form Design, Technomic Publishing Co, Basel.
8. J. Swarbrick, 2007. Encyclopedia of Pharmaceutical Technology, Third Edition, Volume 1-6, Informa Healthcare.
9. R. Williams, D. Taft and J. McConville, "Advanced formulation design to optimize therapeutic outcomes" Marcel Dekker, Inc.
10. L. Xiaoling, B.R. Jasti, "Design of Controlled Release Drug Delivery Systems" McGraw-Hill.
11. B. O. Mashkevich, "Drug delivery research advances" Nova Science Publishers, Inc.
12. W.M. Saltzman, 2001 "Drug delivery_Engineering Principles for Drug Thera". Oxford University Press.
13. E. Touitou, W.B. Boca "Enhancement in Drug Delivery" CRC Press Brian.
14. M.J. Rathbone, J. Hadgraft, M.S. Roberts, "Modified-Release Drug Delivery Technology" Marcel Dekker Inc.

Subject code: MC-P8
Subject: BIOLOGICAL EVALUATION
PRACTICAL:

1. Demonstrations will be based on the topics mentioned in Biological Evaluation theory

Subject code: MPH-P9
Subject: PRODUCT DEVELOPMENT AND FORMULATION
PRACTICAL:

8 hrs. /week

1. Determination of molecular weight of the given polymer.
2. Enhancement of solubility of the given drug by solid dispersion technique.
3. Performance of water attack on treated soda lime glass container.
4. Formulation and characterization of topical gels of some anti-inflammatory drugs.
5. Comparison of release rate profile of conventional and sustained release tablets.
6. Preparation of microcapsules by different techniques and their evaluation
7. Formulation and evaluation of ophthalmic dosage forms.
8. Performance of physical stability and dissolution studies of the suspension of given drug.
9. Formulation and evaluation of suppositories of given drug.
10. Determination of the effect process variable on physicochemical characteristics and in-vitro release profile of microcapsule.

Subject code: MPH-P10
Subject: NOVEL DRUG DELIVERY SYSTEMS
PRACTICAL:

8 hrs. /week

1. Formulation and evaluation of sustained release matrix tablet (of any two drugs).
2. Formulation and evaluation of floating microspheres.
3. Formulation and evaluation of floating tablet.
4. Formulation and in vitro evaluation of transdermal patches.
5. Development and evaluation of ocular inserts of a given drug.
6. Preparation and evaluation of buccal film of any two cardiovascular drugs.
7. Taste masking of some bitter drugs by ion-exchange resins.
8. Formulation and evaluation of nasal in situ gel.
9. Preparation and characterization of liposomes.
10. Preparation characterization of wax embedded microcapsules of a given drug.

Semester-III

Subject code: MPH-S13

Subject: BIOPHARMACEUTICS AND PHARMACOKINETICS

THEORY:

60 Hours (4 hrs. /week)

1. Introduction to biopharmaceutics and clinical pharmacokinetics

Definition of Biopharmaceutics, Pharmacokinetic, clinical Pharmacokinetic and its importance.

2. Absorption of drugs

GI absorption of drugs, Cell membrane structure and physiology. Mechanism of drug absorption. Factors influencing drug absorption and bioavailability. Non-oral absorption of drugs. Concepts and kinetics of physiological parameters of absorption.

3. Distribution of drugs

Factors affecting distribution of drugs. Tissue permeability of drugs. Physiological barriers to diffusion of drugs. Organ / Tissue size and perfusion rate. Binding of drugs to blood components and tissue. Factors affecting it. Miscellaneous factors (Age, Pregnancy, Obesity etc) Volume of distribution.

4. Elimination of drug

Concept of clearance. Hepatic metabolism: chemical pathways and factors affecting it. Renal excretion: principle processes and factors affecting It. Non renal excretion: Concepts and kinetics of physiological parameters of elimination

5. Bioavailability and bioequivalence

a) Objective of bioavailability studies, determination bioavailability parameters of bioavailability rate of absorption extent of absorption, relative bioavailability, determination of AUC (using planimeter, counting squares trapezoidal rule and cutting and weighing studies). Study designs of bioavailability and bioequivalence testing. Statistical concept in determination of bioavailability and bioequivalence testing.

b) Drug dissolution rate and bioavailability

Theories of dissolution in-vitro drug dissolution testing models

In-vitro – in-vivo correlation

c) In-vitro and in-situ absorption studies

Various In-vitro & in-situ models – selection of animals

6. Pharmacokinetics

Basic consideration, Pharmacokinetic models, Compartment modeling: One compartment model–IV bolus, IV infusion, Extra-vascular; Multi Compartment models; Two compartment model–IV bolus, IV infusion, Extra-vascular. Application of pharmacokinetics in new drug development and designing of dosage forms and novel drug delivery systems.

7. Non linear pharmacokinetics

Saturable enzymatic elimination process, drug elimination by capacity limited pharmacokinetics, mixed drug elimination, time dependent pharmacokinetics, bioavailability of drug that follow non linear pharmacokinetics, non linear pharmacokinetics due to protein binding (e.g. phenytoin)

RECOMMENDED BOOKS

1. M. Rowland, T.N. Tozer, 2011. "Clinical Pharmacokinetics and Pharmacodynamics: Concept and Applications", 4th Ed. Lippincott, Williams and Wilkins.
2. L. Shargel, S. Wu-Pong, B. C Andrew, 2005. "Applied Biopharmaceutics and pharmacokinetics", Fifth Ed. McGraw-Hill Medical Pub. Division.
3. M. Gibaldi and D. Perrier, Second Edition. 1982. "Pharmacokinetics". M. Dekker.
4. B.N. La Du, H. G. Mandel & E. L. Way, 1972. "Fundamental of drug metabolism and disposition". Williams & Wilkins, Baltimore.
5. T.Z. Csaky, 1975. "Intestinal absorption and malabsorption". Raven Press.
6. S. Niazi, 2007. "Handbook of Bioequivalence testing". Informa Health Care.
7. D.J. Cutler, "Pharmaceutical Product Development: In vitro-In vivo Correlation". Informa Health Care.

Syllabus Prescribed for Degree of Master of Pharmacy in Pharmaceutical Chemistry

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MPC-S4

Subject: ADVANCED PHARMACEUTICAL CHEMISTRY-I

THEORY:

60 Hours (4 hrs. /week)

1. Various Reaction Mechanisms:

a. Substitution Reaction: Nucleophilic substitution reaction in aliphatic systems, SN1, SN2 reactions, Hydride transfer reaction, Cram's rule, Participation of neighbouring group in nucleophilic substitution reaction and rearrangements. Aromaticity, electrophilic and nucleophilic substitution in aromatic systems, Reactivity, orientation in electrophilic substitution.

b. Elimination Reaction: Beta Elimination reactions, E1, E2 and E1cb mechanisms, Hoffman and saytzeff's rule for elimination, stereochemistry of E2 reaction, Elimination from alicyclic compounds.

c. Addition Reaction: Electrophilic and Nucleophilic additions, Stereochemistry involved, Markonikov's rule.

d. Free Radical Reaction: Formation, Detection, Reactions, Homolysis and free radical displacements, addition and rearrangements of free radicals.

2. Esterification reactions and ester hydrolysis.

3. Heterocyclic chemistry:

Nomenclature, synthesis, physical, chemical and spectroscopic properties of pyrrole, furan, thiophen, pyridine, pyridazine, pyrimidine, pyrazine, quinoline, isoquinoline, indole, oxazole, imidazole and benzimidazole.

4. Oxidation and reduction reactions:

Oxidation reaction involving use of potassium permanganate, potassium dichromate, chromic acid, selenium dioxide, periodic acid, N-bromo succinimide and oppenaure oxidation. Reduction reactions using metal and acid, metal amine reduction, catalytic reduction, hydrogenation of double bond, triple bond and aromatic rings, birch reduction, Meerwein-Pondroff-Verley reduction.

5. Modern synthetic methods:

a) Green Synthesis: Introduction; Green reagents; green catalysts; ionic solvents; phase transfer catalysis in green synthesis; application of phase transfer catalysts in green synthesis of heterocyclic compounds: Williamson's synthesis, Wittig reaction.

b) Microwave assisted synthesis: Introduction; microwave reactions in water (Hofmann elimination, hydrolysis and oxidation); microwave reactions in organic solvents; solid state reactions; advantages of microwave technique.

RECOMMENDED BOOKS:

1. Morrison RT and Boyd RN, Organic Chemistry, 11th edition, Prentice-Hall of India Pvt. Ltd, New Delhi,
2. Thomas L. Gilchrist, 2008, Heterocyclic Chemistry, 3rd edition, Pearson Education.
3. Raj K. Bansal, 2010, Heterocyclic Chemistry, 5th edition, New Age International Publishers.
4. J. March, 2005, Advanced Organic Chemistry – Reaction, Mechanism and Structure, 4th edition, A Wiley-Interscience Publication, John Wiley & Sons, New York.
5. Peter Sykes, 1985, A Guidebook to Mechanism in Organic Chemistry, 6th edition, Longmann Scientific and Technical, Copublished with John Wiley & Sons, Inc, New York.
6. James Clark & Duncan Macquarrie, 2002, Handbook of Green Chemistry and Technology, Blackwell Science Ltd
7. William M. Nelson, Green solvents for Chemistry: Perspectives and Practice, Oxford University Press
8. VK Ahluwalia & M Kidwai, 2004, New Trends in Green Chemistry, Kluwer Academic Publishers.
9. VK Ahluwalia & Renu Agarwal, 2006, Organic Synthesis-Special Techniques, Alpha Science International.
10. M. Lancaster, 2002, Green Chemistry: An Introductory Text, Royal Society of Chemistry.

Subject code: MPC-P4

Subject: ADVANCED PHARMACEUTICAL CHEMISTRY-I

Practical:

8 hrs. /week

1. Separation and identification of organic compounds from binary mixtures: Solid-solid.
2. Synthesis, physico-chemical and spectral analysis of some of the following heterocyclic compounds:
 - a) Quinoline
 - b) benzimidazole/derivative
 - c) flavone/chromone
 - d) indole/derivative
 - e) phenothiazine
 - f) oxazole/oxazolone
 - g) benzoxazole
 - h) 3,5 dimethylisoxazole
3. Synthesis and characterization of at least two organic compounds based on green chemistry approach.
4. Synthesis and characterization of at least two heterocyclic/ organic compounds using microwave.

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MPC-S9

Subject: ADVANCED PHARMACEUTICAL CHEMISTRY-II

THEORY:

60 Hours (4 hrs. /week)

I Stereochemistry:

1. Stereochemical nomenclature & terminology.

2. General concepts on: Chirality, Molecular dissymmetry, Elements of symmetry (plane, centre and axis with relevant examples), optical activity and specific rotation, enantiomers distereomers, Sequence rule - Relative and absolute configuration (D, L and R, S nomenclature), Projection formulae (Fischer, Howarth, Newman and Sawhorse).

3. Stereochemistry of compounds with one stereogenic centre, stereochemistry of compounds with two similar and dissimilar stereogenic centres, properties of stereoisomers. Stereochemistry of alkenes. Stereochemistry of allenes, alkylidene cycloalkane, spirans, biphenyls and fused ring.

4. Racemic modification – properties, methods and resolution.

5. Conformational analysis

Conformation and reactivity in acyclic molecules, Conformation of cyclohexane, monosubstituted cyclohexane, disubstituted cyclohexane, cyclohexene and their relative stabilities. Reactivity of alicyclic, cyclic, fused and bridge ring systems. Curtin Hammett principle in determining the course of reaction in different compounds.

6. Stereospecific and stereoselective synthesis

II Reaction Mechanism (Including stereochemistry):

7. Carbonium ions, carbanions, their generation, stability and fate.

8. Wagner-Meerwein rearrangement and related reactions, pinacol-pinacolone rearrangement, Benzil-benzilic acid rearrangement, Hofmann rearrangement, Curtius rearrangement, Schmidt reaction, Beckmann rearrangement, Lossen rearrangement, Claisen rearrangement, Cumin-hydroperoxide rearrangement, Fries rearrangement, Wittig reaction.

RECOMMENDED BOOKS:

1. J. March, 2005, Advanced Organic Chemistry – Reaction, Mechanism and Structure, 4th edition, A Wiley-Interscience Publication, John Wiley & Sons, New York.
2. E.L. Eliel- Stereochemistry of Carbon Compounds, Tata McGraw-Hill Publishing Company Ltd, New Delhi
3. E.L. Eliel and S.H. Wilen, Stereochemistry of Organic Compounds, A Wiley-Interscience Publication, John Wiley & Sons, New York.
4. Thomas Laue and Andreas Plagens(Eds), 2005, Named Organic Reaction, 2nd Ed, John Wiley & Sons Ltd, England.

5. P.S. Kalsi, 2006, Stereochemistry, Conformation and Mechanism, 6th edition, New Age International (P) Limited, Publishers, New Delhi.
6. D. Nasipuri, 2003, Stereochemistry of Organic Compounds – Principles and Applications, 2nd edition, New Age International (P) Limited, Publishers, New Delhi.
7. Laszlo Kurti & Barbara Czako, Strategic application of named reaction in organic synthesis, Elsevier Academic Press.
8. Peter Sykes, 1985, A Guidebook to Mechanism in Organic Chemistry, 6th edition, Longmann Scientific and Technical, Copublished with John Wiley & Sons, Inc, New York.
9. G.R. Stephenson, 1996, Advanced Asymmetric Synthesis, 1st edition, Blackie Academic and Professional, London

Subject code: MPC-S10

Subject: ADVANCED PHARMACEUTICAL CHEMISTRY-III

THEORY:

60 Hours (4 hrs. /week)

1. GENESIS OF NEW DRUGS:

- i) A brief review of the following topics: sources of new drugs; leads from natural products; molecular modifications; random screening; high thought put screening; insilico screening; structural features and pharmacological activity; prodrugs; soft drugs; isosterism. selective optimization of side activities (SOSA) approach, , new use for old drugs – An illustrative study with suitable examples
- ii) A brief account of drug discovery by recombinant DNA technology.

2. PRINCIPLE OF DRUG DESIGN:

Analogue synthesis versus rational design; discovery of lead compounds, Pharmacophoric identification, Prodrugs and soft drug. Physicochemical properties in relation to drug action; metabolic transformation of drugs and its role in development of new drug molecules.

QSAR in drug design.

- a) Physical properties related to potency.
- b) Calculation, measurements and significance of various parameter used in QSAR – (Lipophilicity, steric, Electronic effects).
- c) applications of Hansch Analysis.

Computers in drug design:

Introduction; computer graphics and molecular visualization; computational chemistry overview, force field methods; geometry optimization; conformational searching; molecular dynamics simulations; quantum mechanics; structure based drug design and Pharmacophore perception, predictive ADME.

3. MEDICINAL CHEMISTRY OF

- a. Antiviral Agents and agents under development of HIV infection.
- b. Immunosuppressant and Immunostimulants.
- c. Agents used in Neurodegenerative disease Like Alzheimer's and Parkinsonism.
- d. GABAnergic Agonists.
- e. Antidiabetic agents like Peroxisome Proliferator Activated Receptors inhibitors, Dipeptidyl Peptidase 4 (DPP 4) Inhibitors like Sitagliptin, Vildagliptin, Protein Tyrosine Phosphatase 1 B (PTP 1 B).
- f. Antihypertensives like Direct Renin Inhibitors e.g. Aliskiren

NOTE: "A study of" includes an account of their origin and development, classification, structures, mechanism of action, SAR, uses and toxicity.

4. RECENT ADVANCES IN FOLLOWING CATEGORY:

- a. Cephalosporin
- b. Anticancer agents.
- c. Non-steroidal anti-inflammatory agents
- d. Antihypertensive agents

Synthesis of Following Drugs:

- a. Cefaclor, Cefotaxim, Cefadroxil, Cephalexin
- b. chlorambucil, methotrexate, Trimetrexate, Tamoxifen
- c. paracetamol, ibuprofen, aceclofenac, Allopurinol
- d. Propranolol, Nifedipine, Fosinopril, Candesartan

5. A STUDY OF:

- a) Penicillin
- b) Anthihyperlipidemic agents
- b) Phosphodiesterase inhibitors
- c) Quinolone antibacterial agents

RECOMMENDED BOOKS:

1. E.J. Ariens, 1975, Drug Design, Academic Press New York.
2. S.H. Salkovisky, A.A. Sinkula and S.C. Valvani, Physical Chemical Properties of Drug, Marcel Dekker Inc. New York.
3. M.E. Wolff, Burger's Medical Chemistry, Vol. III, 5th Edition, John Willey and Sons. New York.
4. R.F. Doerge, Wilson and Gisvold's Text Book of Organic Medicinal and Pharmaceutical Chemistry, 9th edition, J. Lippincott Co., Philadelphia.
5. Wilson & Gisvold's Text book of Medicinal Chemistry, 9th edition, J. B. Lippincott.
6. Hansch, Sammes, Taylor, Comprehensive Medicinal Chemistry series I-IV, Academic Press.
7. Ed. Stevenson & Wi, Latest, 1990, Recent advances in chiral separations, Plenum Press.
8. Ed. Fennirl Hicham, 2000, Combinatorial Chemistry, Oxford University
9. D. Sriram, Medicinal Chemistry, 2nd edition, Pearson.

Subject code: MPC-P9

Subject: ADVANCED PHARMACEUTICAL CHEMISTRY-II

Practical:

8 hrs. /week

1. Synthesis from some of the following reactions and their characterization:
 - 1) Beckmann rearrangement
 - 2) Fries rearrangement
 - 3) Benzil benzilic acid rearrangement
 - 4) Hofmann rearrangement
 - 5) Pinacol pinacolone rearrangement
 - 6) Methylation
 - 7) Metal/acid reductions
 - 8) Friedel-Crafts alkylation & Acylation
 - 9) Nitration using different reagents
2. Asymmetric synthesis of some organic/medicinal compounds.
3. Resolution of racemic mixture/modification.
4. Microwave assisted synthesis of any two compounds and their characterization

Subject code: MPC-P10

Subject: ADVANCED PHARMACEUTICAL CHEMISTRY-III

Practical:

8 hrs. /week

1. Practical based on some topics covered in the theory part including synthesis of medicinal compounds basic operations like Molecular distillation, fractional crystallization, and purification by column chromatography and preparative TLC
2. Synthetic studies of following drugs with characterization by chemical test, UV and IR method
 - Acetyl Salicylic acid using acetyl chloride (2 Steps)
 - Chloramin –T (3 Steps)
 - Sulphanilamide (3 Steps)
 - 5,5-Diphenyl Hydantoin
 - Dimethyl–p-phenylenediamine (3 steps)
 - Sulfanilic acid
 - Chalcones
3. Microwave assisted synthesis of organic/medicinal compounds and their characterization

Semester-III

Subject code: MPC-S13

Subject: ADVANCED PHARMACEUTICAL CHEMISTRY-IV

THEORY:

60 Hours (4 hrs. /week)

The following topics will be discussed keeping in view the recent advances:

- 1. Psychopharmacological agents:** Biochemical basis of mental disorders; abnormal protein factors; endogenous amines and related substances; faulty energy metabolism; genetic disorders and nutritional disorders; phenothiazines – chemistry; synthesis. Screening methods; pharmacological actions; SAR; mechanism of action; uses; toxicity; ring analogues of phenothiazines; fluorobutyrophenones; Development of atypical antipsychotics clozapine synthesis of chlorpromazine, prochlorperazine, fluphenazine, haloperidol.
- 2. Anxiolytics, sedatives and hypnotics:** Benzodiazepines and related compounds; barbiturates; other classes; mechanism of action, SAR; uses and toxicity Synthesis of Chlordiazepoxide, diazepam, alprazolam, Phenobarbital, meprobamate.
- 3. Antidepressants:** MAO inhibitors; tricyclic antidepressants; SAR; mechanism of action; uses; toxicity other classes like: selective serotonin reuptake inhibitors, selective 5-HT and NE reuptake inhibitors; selective serotonergic reuptake inhibitors and 5-HT_{2A} antagonists; 5-HT_{1A} agonists and partial agonists and α ₂-antagonists. Synthesis of tranycypromine, amitriptyline, fluoxetine, buspirone.
- 4. Antiepileptics & CNS stimulants:**
 - a) Antiepileptics:** Screening methods; classification of epilepsies; symptoms; drugs used; classification; structural features common to drugs; SAR; mechanism of action; toxicity and uses; synthesis of diphenylhydantoin, carbamazepine, sodium valproate.
 - b) CNS stimulants:** an account of the drugs with CNS stimulant activity; structures and uses.
- 5. Diuretics:** anatomy and physiology of nephron; classification of diuretics based on site of action; carbonic anhydrase inhibitors; thiazide and thiazide like diuretics; loop and potassium sparing diuretics; miscellaneous diuretics emerging developments in the use of diuretics to treat hypertension and congestive heart failure.
- 6. Microorganism in drug development:** Microbial conversions of drugs like steroids, prostaglandins and antibiotics. These should include some biotechnology-oriented chapters like enzymes immobilization techniques.
- 7. Classification of colors, preservatives and artificial sweetening agents** in food, food product, drugs and cosmetics. detection and determination of colors, preservatives and artificial sweetening agents.
- 8. Radiopharmaceuticals,** Detection of radioactivity, instrumentation and measurement, methods of radiolabeling, preparation and quality control of radiopharmaceuticals, isotope dilution methods. Radioimmunoassay of selected drugs and hormones. Application of radiopharmaceuticals.

9. Radioprotective drugs

10. Synthon approach

- a. Definition of terms - disconnection, synthon, functional group interconversion (FGI).
- b. Basic rules in Disconnection.
- c. Use of synthon approach in synthesis of some medicinal/organic compounds

11. Principal of toxicology and treatment of intoxication.

RECOMMENDED BOOKS:

1. Burger's Medicinal Chemistry, Vol. III, 5th, Edition, John Wiley Sons, New York.
2. Wilson and Gisvold's Text Book of Medicinal Chemistry, Lippincott Williams and Wilkins.
3. T.L. Lemke, D.A. Williams, V.F. Roche and S.W. Zfto, Foye's Principles of Medicinal Chemistry, 6th edition, Lippincott Williams and Wilkins.
4. Lednicer, Organic chemistry of synthetic drugs. Vogel's Textbook of practical organic chemistry by Arthur I Vogel, 5th edition, ELBS and Lognman
5. The Organic Chemistry of Drug Synthesis (3 volumes) by Daniel Lednicer & Laster A. Mitscher (John Wiley & Sons).
6. Ashutosh Kar, 2004, Advanced Practical Medicinal Chemistry, 1st edition, New Age International Publication.
7. Abraham Statman (Ed), Progress in chemical toxicology, Vol. I-V, Academic press.

Syllabus prescribed for Degree of Master of Pharmacy in Pharmacology

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MPL-S4

Subject: ADVANCED PHYSIOLOGY AND PATHOPHYSIOLOGY

THEORY:

60 Hours (4 hrs. /week)

1. Membrane Physiology, Nerve and Muscle

Physicochemical properties of cell membrane, permeability & transport. Genesis of resting membrane potential. Action potential. Contraction of skeletal and smooth muscles.

2. Blood

Principles of hemopoiesis. Erythropoiesis. Fate of RBC's. Regulation of WBC production. Functions of WBC. Immune system. Blood groups. Hemostasis and blood coagulation. Pathophysiology of Jaundice and Anemia.

3. Cardiovascular System

Properties of cardiac muscle. Action potential and spread of impulse in the heart. ECG. Cardiac cycle. Neural regulation of cardiac activity. Cardiac output: measurement and regulation. Neural control of circulation. Pathophysiology of Hypertension, Arrhythmia, Angina pectoris and Cardiac failure.

4. Respiratory System

Lung volumes and capacities. Mechanics of respiration. Exchange of gases in the lungs. O₂ CO₂ carriage, dissociation curve. Neural regulation of respiration. Chemical regulation of respiration. Pathophysiology of Pneumonia, Asthma, Hypoxia, Cyanosis and Dyspnoea.

5. Gastrointestinal System

General organization of G.I. tract. Motility, Nervous Control and Blood Circulation. Gastric secretion, Biliary and pancreatic secretions. Digestion and Absorption. Pathophysiology of Peptic Ulcer, Constipation and Diarrhea.

6. Endocrine System

Various endocrine glands and their related disorders.

7. Reproduction

Male reproductive physiology. Female reproductive physiology. Hypothalamic – pituitary – gonadal axis. Puberty. Pregnancy. Parturition and lactation.

8. Renal System

Renal hemodynamics and glomerular filtration. Renal tubular function. Regulation of renal function. Micturition. Regulation of Acid-Base balance. Alkalosis and Acidosis.

9. Neurophysiology

i) General

Introduction to neurophysiology. Properties of synaptic transmission. Neurotransmitters

ii) Sensory system

Coding of sensory information. Functional organization of ascending sensory pathways. Thalamus Sensory cortex. Perception of sensory stimuli. Physiology of pain and analgesia system. Pathophysiology of Hyperalgesia, Herpes Zoster and Headache.

iii) Motor system

Characteristics and properties of reflexes. Functional organization of motor system. Brain stem reflexes, stretch reflexes and tendon reflexes. Basal ganglia. Cerebellum. Vestibular neck reflexes: maintenance of equilibrium. Pathophysiology of Parkinsonism and Huntington's Chorea.

iv) Visceral and motivational system

Autonomic nervous system. Hypothalamus. Limbic system and emotions

v) EEG, sleep and higher nervous functions

Electroencephalography. Sleep and wakefulness. Learning and memory. Speech. Pathophysiology of Epilepsy, Dementia, Psychosis Schizophrenia and Alzheimer's disease.

vi) Special Senses

Structure and functions of skin. Central mechanisms of vision and visual perception. Central auditory mechanism and auditory perception. Olfaction. Physiology of taste.

RECOMMENDED BOOKS:

1. Textbook of Medical Physiology by A.C. Guyton, Saundersco. London (2011) 12th edition.
2. Review of Medical Physiology by W.F. Ganong Mc Graw Hill Medical Publishing (2005) 22nd edition.
3. The Physiological Basis of Medical Practice by C.H.Best and N.B.Taylor. The Williams and Wilkins Co. Batlimore (1991) 12th edition .
4. Understanding Medical Physiology by R. L. Bijlani, Jaypee Brothers, New Delhi (2011) 4th edition.
5. Principles of Anatomy and Physiology by G.J.Tortora and B.Derricson. John Wiley & Sons Inc N.J.
6. Robbins Pathologic Basis of Disease by R.S.Cotran, V.Kumar and T.Collins WB Saunders Co (1999) 6th edition.
7. Textbook of Pathology by Harsh Mohan. Jaypee Brothers New Delhi (2005) 5th edition.
8. Textbook of Pathology by B.N.Datta. Jaypee Brothers New Delhi (2004) 2nd edition.

Subject code: MPL-P4

Subject: ADVANCED PHYSIOLOGY AND PATHOPHYSIOLOGY

Practical:

8 hrs. /week

1. Introduction to use of Physiographs in experimental Pharmacology, Demonstration of invasive / non invasive rat blood pressure experiment, ECG, EEG etc
2. Use of anesthetics and cannulation of veins, arteries and trachea of rat. Demonstrations of methods of collection of blood from experimental animals, various methods of euthanasia.
3. Identification of phases of estrous cycle in rats.
4. Study of different tissue section of animals.
5. Use and interpretation of biochemical data viz: (Significance of screening the parameter)
Diagnostic prognostic screening tests like (rationale behind performing following tests)
 - a) Blood sugar : by O-toluidine, glucose oxidase
 - b) Blood protein by Biuret, Lowery's method
 - c) Blood urea
 - d) Serum uric acid
 - e) Urine calcium
 - f) Serum cholesterol
 - g) Serum bilirubin
 - h) Blood creatinine
 - i) Blood chlorides
 - j) SGPT
 - k) SGOT
 - l) Urine amylase
 - m) LDH
6. Pregnancy test in rats
7. Measurement of Glucose by glucometer
8. Qualitative tests for identification of given protein sample
9. Preparation of plasma (using diff.anti-coagulants), serum
10. Widal test
11. Rheumatoid Arthritis factor test

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MPL-S9

Subject: ADVANCED SYSTEMIC PHARMACOLOGY

THEORY:

60 Hours (4 hrs. /week)

1. Basic Principles of Pharmacology: Mechanisms of drug action, membrane transporters and drug response, adverse drug reactions, and pharmacogenetics.

2. Pharmacology of the Autonomic Nervous System:

Physiology of autonomic nervous system, Muscarinic receptor agonists and antagonists, Anticholinesterase agents, Agents acting at neuromuscular junction and autonomic ganglia, Adrenergic agonists and antagonists, 5-Hydroxytryptamine receptor agonists and antagonists.

3. Pharmacology of Autocoids:

Histamine, bradykinin, and their antagonists, Lipid derived autocoids: Eicosanoids and platelet activating factor.

4. Drugs Acting on the Central Nervous System:

Neurotransmission in central nervous system, General anesthetics, Local anesthetics, Hypnotics and sedatives, Opioid analgesics, Pharmacology of ethanol, Drug addiction and drug abuse.

5. Analgesic, Antipyretic, and Anti-inflammatory Agents

6. Drugs Affecting Renal and Cardiovascular Function:

Diuretics, Vasopressin and other agents affecting the renal conservation of water, Renin, angiotensin, and their modulators, Calcium channel blockers.

7. Immunosuppressants and Immunostimulants

8. Hormones and Their Antagonists:

Pituitary hormones and their hypothalamic releasing factors, Thyroid and antithyroid drugs, Estrogens and progestins, Androgens, Adrenocortical steroids and their synthetic analogs, inhibitors of synthesis and actions of adrenocortical hormones, Agents affecting mineral ion homeostasis and bone turnover.

9. Drugs Acting on the Blood and Blood-Forming Organs:

Hematopoietic agents: Growth factors, minerals, and vitamins, Blood coagulation and anticoagulant, thrombolytic, and antiplatelet drugs.

10. Pharmacology of Dermatological Agents

11. Ocular Pharmacology

RECOMMENDED BOOKS:

1. Goodman and Gilman, Pharmacological Basis of Therapeutics, Mc Graw Hill (2006) 11th edition.
2. Craig C R and Stitzel B E, Modern Pharmacology with Clinical Application, Lippincott Williams & Wilkins (2004) 6th edition.
3. Katzung B G, Basic and Clinical Pharmacology, Lange Medical Publisher, USA (2009) 11th edition.
4. Melmon K L and Morelli, Clinical Pharmacology: Basic Principles of Therapeutics, Mc Millan, New York (2000) 4th edition.
5. Harrisons Principles of Internal Medicine, McGraw Hill 18th edition.
6. Davidson's Principles and Practice of Medicine, Vol I and II, Churchill Livingstone 14th edition.
7. Rang H P, Dale M N, Pharmacology, Churchill Livingstone, UK (2011) 7th edition.
8. Roger and Walkar, Clinical Pharmacy and Therapeutics, Churchill Livingstone, London (2007) 4th edition.
9. Patten J, Neurological Differential Diagnosis, Springer-Verlag London (2005) 2nd edition.
10. Koda-Kimble, Hand book of Applied Therapeutics Lippincott Williams & Wilkins (2007) 8th edition
11. Herfidal E T and Hirschman J L, Clinical Pharmacy and Therapeutics Williams and Wilkins (1984) 3rd edition.
12. Review articles and Research articles from Medical and Pharmacological Journals

Subject code: MPL-S10

Subject: ADVANCED PHARMACOLOGY AND PHARMACOTHERAPEUTICS

THEORY:

60 Hours (4 hrs. /week)

1. Basic Principles of Clinical Pharmacology:

Monitoring of drug therapy, patient compliance, principles of pediatric and geriatric pharmacology, drug therapy in pregnant and lactating mothers.

2. Drug Therapy of Cardiovascular Disorders:

Pathophysiology and drug therapy of congestive cardiac failure, hypertension, cardiac arrhythmias, ischemic heart disease, hyperlipidemia, and atherosclerosis.

3. Drug Therapy of Neurological Disorders:

Pathophysiology and drug therapy of epilepsy, Parkinson's disease, migraine, and myasthenia gravis.

4. Drug Therapy of Psychiatric Disorders:

Pathophysiology and drug therapy of anxiety, schizophrenia, Alzheimer's disease, mood and sleep disorders, and memory.

5. Drug Therapy of Endocrine Disorders:

Pathophysiology and drug therapy of diabetes mellitus, contraception, and infertility.

6. Drug Therapy of Inflammatory Disorders:

Biology of inflammation, pathophysiology and drug therapy of osteoarthritis, rheumatoid arthritis, and gout.

7. Drug Therapy of Respiratory Diseases:

Pathophysiology and drug therapy of asthma.

8. Drug Therapy of Gastrointestinal Diseases:

Pathophysiology and drug therapy of peptic ulcers, emesis, irritable bowel syndrome, and inflammatory bowel disease.

9. Drug Therapy of Metabolic and Sexual Disorders:

Pathophysiology and drug therapy of obesity and erectile dysfunction.

10. Pharmacology of Chemotherapeutic and Antimicrobial Agents:

General considerations of antimicrobial therapy, Sulfonamides, trimethoprim, quinolones, other related agents, Penicillins, cephalosporins, and other beta-lactam antibiotics, Aminoglycosides, Protein synthesis inhibitors and miscellaneous antibacterial agents, Antifungal agents, Antiviral agents (Non-retroviral).

11. Pathophysiology of cancer and Antineoplastic Agents

12. Drug Therapy of Infectious Diseases:

Pathophysiology and drug therapy of tuberculosis, leprosy, HIV and related opportunistic infections, malaria, amoebiasis, and helminth infections.

RECOMMENDED BOOKS:

1. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London (2007) 4th edition.
2. Dipiro, Joseph L.; Pharmacotherapy: A Pathophysiological Approach, McGraw Hill Companies (2011) 8th edition.
3. Russell J. Greene and Norman D. Harris, Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Pharmaceutical Press (2008) 3rd edition.
4. Herfindal, E.T. and Hirschman, J L.; Clinical Pharmacy and Therapeutics, Williams & Wilkins (1984) 3rd edition.

5. Koda and Kimble, Hand book of Applied Therapeutics: The Clinical Uses of Drugs, Lippincott Williams & Wilkins (2007) 8th edition.
6. Relevant Reviews Articles from Medical and Pharmaceutical Literature
7. Davidson's Principles of Internal Medicine, Vol-I And II, 14th Edition, Mc GrawHill
8. Harrison's Principle And Practice Of Medicine, 18th Edition, Churchill, Livingston, London
9. Chaudhari, Quintessence of Medical Pharmacology; Central Publishers, New Delhi
10. Kundu, A.K.; Bedside Clinics in Medicine, Academic Publishers, Part-I and II
11. Oxford Textbook of Medicine, Oxford University Press (2005), 4th edition.
12. Panda, U.N., Textbook of Medicine, CBS publisher, New Delhi (2000).
13. Patten, J; Neurological Differential Diagnosis, 2nd Edition

Subject code: MPL-P9

Subject: ADVANCED SYSTEMIC PHARMACOLOGY

Practical:

8 hrs. /week

1. Bioassays:

- a) Estimation of potency of test substance by three point and four point bioassay method using different isolated tissues.
- b) To determine the PA2 value using different isolated tissues.

2. In-vivo experiments:

- a) To study antisecretory and ulcer protective effect of Cimetidine in pylorus ligated rats.
- b) To study Diuretic effect of any one marketed preparation in rats.

3. Clinical:

In this module, it is expected a student should collect data from field targeted as disease oriented, drug use oriented, adverse events oriented, biochemical oriented etc and compile it with conclusive output.

4. Statistical:

- a) Statistical evaluation of data and finding level of significance.
- b) Hand on experience on online, offline, open source statistical software's.

5. Demonstration:

To demonstrate different experiments using simulated computer softwares.

Subject code: MPL-P10

Subject: ADVANCED PHARMACOLOGY AND PHARMACOTHERAPEUTICS

Practical:

8 hrs. /week

1. Prerequisite for Pharmacology Practicals:

In this module it is expected student should know general principles, techniques and strategies for pharmacological screening of drugs, animal care, handling, ethical requirements and regulations therein.

2. Basic Experimental Techniques:

1. Standard techniques collection of blood samples and feeding of animals
2. Administration of drugs by different routes in mice
3. Use of anaesthetics and cannulation of veins, arteries, trachea

3. Experiments on intact animals:

1. To study locomotor activity by using Actophotometer.
2. To evaluate analgesic activity of drug using tail flick latency test.
3. To determine the effect of carrageen induced edema in rats by using digital Plethysmometer.
4. To study the anticonvulsant effect of Phenobarbitone against MES induced convulsions in rats.
5. To determine the analgesic effect by using Eddy's hot plate.
6. To study effect of pentobarbitone sodium on righting reflex (hypnosis) in mice.
7. To study Anti-anxiety effect of diazepam in mice using elevated plus maze apparatus.
8. To study the Apomorphine induced compulsive behaviour (Stereotype) in mice.
9. To study the muscle relaxant property of Diazepam in mice using rotarod.
10. To study amnesic (loss of memory) effect of drug using passive avoidance step-down task paradigm in mice.
11. To study the antidepressant effect of drug using forced swimming test apparatus.

4. Toxicity Studies:

1. Regulations and guidelines of toxicity studies
2. Method of calculation of ED50 and LD50
3. Observation of behavioral changes in animals during acute and sub acute toxicity study of test drug.

5. Practicals using computer software's :

In this module it is expected student should know working of software and setting of physiologic and animal experimentation and perform at least four experiments from following or others-

1. To record temperature using thermal transducer

2. To measure blood pressure using Blood pressure transducer
3. To measure drug response curve using isotonic transducer
4. Measurement of isometric contraction using force displacement transducer.
5. To measure a change in volume using volume transducer
6. To measure a respiration using a respiratory transducer
7. To study various transducers and couplers
8. To study ECG using ECG coupler with BioPac
9. To measure vital capacity, forced expiratory volume etc., using isotonic transducer and Spirometer.

Semester-III

Subject code: MPL-S13

Subject: MOLECULAR PHARMACOLOGY AND TOXICOLOGY

THEORY:

60 Hours (4 hrs. /week)

1. Molecular mechanism of drug action: Receptor occupancy and cellular signaling systems such as G-proteins, cyclic nucleotides, calcium and phosphatidyl inositol. Ionic channels and their modulators.

2. Endogenous bioactive molecules such as cytokines, neuropeptides and their modulators, neurosteroids, nitric oxide, phosphodiesterase enzyme and protein kinase C, arachidonic acid metabolites.

3. Recent trends on different classes of receptors and drugs acting on them

Angiotensin receptors, Excitatory amino acid receptors, Kinin receptors, Adrenoceptors, Low molecular weight heparins, Imidazole receptors, Cholinergic receptors, Dopamine receptors, Serotonin receptors, Hormone receptors, GABA receptors, Purinergic receptors, Glutamate receptors.

4. Ion channel and their modulators: calcium, potassium, sodium and chloride channels

5. Basic Concepts of Chronopharmacology and their implications to Drug Therapy.

6. Concept of gene therapy and recent development in the treatment of various hereditary diseases. Transgenic mouse and its applications. Human genome mapping and its potential in drug research.

7. Toxicology: Principles of toxicology, elementary knowledge of systemic toxicology, manifestation of toxicology, Management and treatment of poisoning, immunotoxicity, toxic effect on genetic material and cell proliferation, non therapeutic toxicants, air pollutants, solvents, vapour and pesticides toxicity, food additives and contaminant toxicity, heavy metal toxicity, toxins of animal origin, radiations and radioactive material toxicity, adverse drug reactions, toxicity of drug overdosing and its management.

RECOMMENDED BOOKS:

1. Katzung, B.G; Basic and Clinical Pharmacology, Lange Medical Publisher, USA (2009) 11th edition.
2. Paul W. E. ed. Fundamental immunology, Lippincott-raven, Philadelphia 1999, 4th edition.
3. Bowman, W.C. and Rand, M.J.; Textbook of Pharmacology, Blackwell, Oxford 2nd edition.

4. Craig, C.R. and Stitzel, B.E.; Modern Pharmacology, Lippincott Williams & Wilkins (2004) 6th edition.
5. Bacq Z.M., Cepek, Fundamentals of Biochemical Pharmacology Pergamon Press.
6. Goodman and Gilman; Pharmacological Basis of Therapeutics, Mc Graw Hill (2006) 11th edition.
7. Rang, H.P., Dale, M.N., Pharmacology, Churchill Livingstone, UK (2011) 7th edition.
8. Casarett and Doull's Toxicology: The basic science of poisons 6th edition McGraw Hill, Newyork, 2001
9. Ellenhorn's Medical toxicology 2nd Edition Williams and Wilkins, Baltimore, 1997.
10. Haddad, L. M. and Winchester, J. F. eds Saunders, Philadelphia, 1983
11. Frank A. Barile, Clinical toxicology principle and mechanism. CRC press, London
12. Recent review articles in different international journals of repute.

Syllabus Prescribed for Degree of Master of Pharmacy in Pharmacognosy

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MPG-S4

Subject: ADVANCED PHARMACOGNOSY AND PHYTOCHEMISTRY

THEORY:

60 Hours (4 hrs. /week)

- 1. Nutraceuticals:** Introduction, probiotics & Prebiotics, Study of some plant constituents and their products in international market, study of lycopene, proanthocyanidin and grape products, ornithine, flax seed and flax oil, melatonin and ornithine.
- 2. Study of herbal extracts:** General methods for the extraction of herbal drugs, processing and analytical profile, stability, preservation and evaluation of extracts. Effect of solvent, solvent mixtures and solution on extraction.
- 3. Extraction, isolation, purification and estimation of following phytoconstituents:**
 - Alkaloids : Caffeine, Atropine, Berberine, Piperine
 - Glycosides : Sennosides, Digoxin
 - Flavonoids : Rutin, Hesperidin
 - Terpenoids : Taxol, Andrographolide
 - Saponins : Diosgenin, Glycyrrhizin
- 5. General aspects of cultivation and collection:** Good agricultural practices in cultivation and collection. Plant growth regulators. Weeds and pest control techniques.
- 6. Drug discovery from Natural Products.**
- 7. Ethnobotany in Herbal Drug Evaluation.**
- 8. Adverse reactions and safety in herbal medicine**

RECOMMENDED BOOKS:

1. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons Limited, New Delhi.
2. Advances in Natural Product Chemistry, extraction and isolation of biologically active compounds. S. Natori et al., Wiley, New York.
3. Phytochemical methods by J.B. Harborne, Chapman and Hall, International Ed., London.
4. Modern methods of plant analysis by Peach and Tracey, Vol. II, IV, Springer Verlag.
5. G.E. Trease and W.C. Evans., Pharmacognosy, W.B. Saunders Co. Ltd., Harcourt Publishers Ltd. UK.

6. Chaudhari R.D., Herbal Drug Industry, Eastern Publication.
7. Quality Control Methods for medicinal plant material, WHO Geneva.
8. Wagner H, Bladt S, 1996. Plant Drug Analysis- A Thin Layer Chromatography Atlas, 2nd Ed., Springer-Verlag, Berlin.
9. Stahl Egon, Thin layer chromatography, 2nd Edition, Springer Publication.
10. Mukherjee PK, 2003. GMP for Indian system of medicine. In GMP for Botanicals. Verpoorte R, Mukherjee PK (Edn.), Business Horizons Limited, New Delhi.
11. Herbal Drug technology by SS Agrawal and M Paridhavi, Orient Longman
12. Indian Herbal Pharmacopoeia, Vol. I- II, SS Handa, RRL Jammu Tawi, and IDMA Mumbai.
13. The Aurvedic Pharmacopoeia of India, 1999. Government of India, Ministry of Health and Family Welfare, Department of Indian Systems of Medicine and Homeopathy, New Delhi.
14. Standardization of Botanicals by V. Rajpal, Vol. I and Vol II, Eastern Publishers, New Delhi.
15. Practical Evaluation of Phytopharmaceuticals by K.R. Brain and T.D. Turner, Wright-Scientifica, Bristol.
16. Houghton P, Mukherjee PK. Evaluation of Herbal Medicinal Product, Pharmaceutical Press, London, 2009.
17. British pharmacopoeia, 2008. The department of Health, Vol I- IV, British Pharmacopoeia Commission, London.
18. Neutraceuticals by Lisa Rapport and Brain Lockwood.

Subject code: MPG-P4

Subject: ADVANCED PHARMACOGNOSY AND PHYTOCHEMISTRY

Practical:

8 hrs. /week

1. Extraction of active principles i.e. alkaloids, glycosides, resins, essential oils, terpenoids, fixed oils, carbohydrates, fats, tannins, steroids, pectins, etc. from natural drugs.
2. Preliminary phytochemical screening of the plant extracts.
3. Extraction, isolation, purification and identification of important phytoconstituents as follows:
 - a. Sennosides from Senna leaves
 - b. Curcumin from Turmeric
 - c. Glycyrrhizin from Liquorice
 - d. Hesperidin from Orange peels
 - e. Caffeine from Tea
 - f. Rutin from *Ruta graveolens*
 - g. Aloin from Aloes
 - h. Piperine from Pepper
 - i. Quinine from cinchona bark
 - j. Berberine from *Berberis aristata*
 - k. Diosgenin from *Dioscorea*
4. Evaluation of crude drugs by different WHO Standards.

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MPG-S9

Subject: STANDARDIZATION OF NATURAL PRODUCTS

THEORY:

60 Hours (4 hrs. /week)

1. Introduction: Need of standardization, limitations of herbal medicines, current regulation of standardization of natural products, their quality, safety and efficacy assessment.
2. Application of various chromatographic techniques i.e. Paper chromatography, TLC, HPTLC, HPLC, GLC, GC-MS for the standardization of plant extracts.
3. Application of UV, FTIR, NMR (¹H- and ¹³C-NMR) and Mass spectroscopy for structural elucidation of flavonoids (Rutin, Hesperidin, Kaempferol), Terpenoids (Camphor, Menthol, Eugenol, Citral) and phytosterols (B-sitosterol, stigmasterol).
4. WHO guidelines for the quality control of herbal plant materials.

RECOMMENDED BOOKS:

1. Quality Standards of Indian Medicinal Plants Vol. I- V, Indian Council of Medical Research, New Delhi.
2. WHO guide lines for the quality control of Herbal plant materials.
3. Phytochemical methods by J.B. Harborne, Chapman and Hall, International Ed., London.
4. The essential oils by E. Guenther, Vol. I- IV, Van Nostrand Co.
5. Modern methods of plant analysis by Peach and Tracey, Vol. II, IV, Springer Verlag.
6. Biological Standardization by JN Barn, DJ Finley and LG Goodwin.
7. Standardization of Botanicals by V. Rajpal, Vol. I and Vol II, Eastern Publishers, New Delhi.
8. Practical Evaluation of Phytopharmaceuticals by K.R. Brain and T.D. Turner, Wright-Scientifica, Bristol.
9. PDR for Herbal Medicines, Second Ed., Medicinal Economics Company, New Jersey.
10. Textbook of Industrial Pharmacognosy by AN Kalia, CBS publishers and Distributors, New Delhi.
11. Mohd. Ali (2001). Techniques in Terpenoid Identification. Birla Publications, Shahdara, Delhi.
12. Advances in Natural Product Chemistry, extraction and isolation of biologically active compounds. S. Natori et al., Wiley, New York.
13. Official Methods of Analysis, Association of Official Analytical Chemists Publication, Washington, New York.

Subject code: MPG-S10

Subject: HERBAL DRUG FORMULATION AND DEVELOPMENT

THEORY:

60 Hours (4 hrs./ week)

1. Herbal based Industry: Scope, study of infrastructure, staff requirement, project profiles, plant and equipment, processing, research and development, regulatory requirement. Pilot plant scale up techniques.
2. Principles of Ayurvedic systems of medicine. Introduction to different dosage forms, Preparation and evaluation methods of Ayurvedic medicines i.e. Asavas and Aristas, Arkas, Avalehas, Churnas, Ghritas and Tailas, Guggulu preparations, Ksara, Lauha kalpas, Lepas, Vatika and Bhasmas.
3. Standardization of polyherbal formulations: syrups, powders, ointments and other semisolid preparations, tablets and capsules.
4. Evaluation aspects of Herbal products containing Ashwagandha, Kalmegh, Shatavari, Phyllanthus, Guduchi and Shilajeet by study of HPTLC and HPLC fingerprints.
5. WHO and Indian regulatory requirements of Clinical trials for herbal formulations.
6. Determination of shelf life of raw drugs, powdered drugs, extracts, fractions and finished products. Factors affecting stability of herbal formulations, ICH and other guidelines, methods of stabilization and stability testing.

RECOMMENDED BOOKS:

1. Kalia AN, Textbook of Industrial Pharmacognosy, CBS publishers and Distributors.
2. Pharmacopoeial Standards for Ayurvedic formulations – CCRAS, Delhi.
3. Good manufacturing practices for pharmaceuticals, SH Willing, Vol. 78, Marcel Dekker, NY. New drug approval process, RA Guarino, Vol 100, Marcel Dekker, NY.
4. Standardization of Botanicals by V. Rajpal, Vol. I and Vol II, Eastern Publishers, New Delhi.
5. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons Limited, New Delhi.
6. Ayurvedic formulary of India, Government of India, Ministry of Health and Family Welfare.
7. The Aurvedic Pharmacopoeia of India, 1999. Government of India, Ministry of Health and Family Welfare, Department of Indian Systems of Medicine and Homeopathy, New Delhi.
8. Indian Pharmacopoeia, 2010. Government of India, Ministry of Health and Family Welfare, Vol. I III, The Indian Pharmacopoeia Commission, Ghaziabad.
9. United States Pharmacopoeia, 2009. The Official Compendia of Standards, Vol. 1-3, the United States Pharmacopoeial Convention, Rockville.
10. Indian Herbal Pharmacopoeia, 1999. Vol I- II, Council of Scientific and Industrial Research, Jammu-Tawi, New Delhi.

Subject code: MPG-P9

Subject: STANDARDIZATION OF NATURAL PRODUCTS

Practical:

8 hrs. /week

1. Determination of Anthracene derivatives in senna by spectrophotometric method, Reserpine in Rauwolfia, Carvone content of Caraway fruits, Citral content in Lemon oil.
2. Determination of ascorbic acid by UV spectroscopic method in some crude drugs.
3. Paper chromatography and TLC of active principles of natural products.
4. Study of UV and FTIR spectral data of some marker compounds.
5. Separation of Solanaceous alkaloids from Belladonna leaves by TLC using hyoscyne and hyoscyamine as reference compounds.
6. Quantitative estimation of Ephedrine in Ephedra extracts by HPTLC method (demonstration only).
7. Quantitative estimation of Reserpine in Rauwolfia extracts by HPLC method (demonstration only).
8. Study of HPTLC and HPLC fingerprinting of some important phytoconstituents (demonstration only).

Subject code: MPG-P10

Subject: HERBAL DRUG FORMULATION AND DEVELOPMENT

Practical:

8 Hours / week

1. Formulation and evaluation of different polyherbal formulations.
2. Stress induced stability evaluation of different polyherbal formulations.
3. Quantitation of some therapeutically important phytoconstituents from herbal drug formulations by HPTLC.
4. Identification of some phytoconstituents from herbal drug formulations by TLC.
5. Evaluation of some marketed Ayurvedic formulations like Asavas and Aristas, Avalehas, Churnas, Ghritas and Vatika.
6. Evaluation of Antimicrobial activity of some important polyherbal formulations.

Semester-III

Subject code: MPG-S13

Subject: Selected Topics in Pharmacognosy

THEORY:

60 Hours (4 hrs. /week)

1. Problems and Prospects of discovering new drugs from higher plants. Natural products: its impact on industry and medicine.
2. Phytosomes
3. Anticancer and Psychosomatic drugs of plant origin
4. Marine drugs of medicinal importance.
5. Antimicrobials from higher plants.
6. Pharmacological screening methods of natural products for their a. Hepatoprotective; b. antidiabetics; c. antioxidants; d. analgesic and anti-inflammatory; e. Antihyperlipidemic; f. antimicrobials; antiepileptics activities.
7. Bioassay Guided Isolation, Separation and Structural Characterization
8. Recent advances in alkaloids: Chemistry, isolation, purification, identification and estimation by physical and chemical methods of following alkaloids: Atropine, Ephedrine, Reserpine, Ergometrine, Vinblastine, Quinine.
9. Recent advances in glycosides: Chemistry, isolation, purification, identification and estimation by physical and chemical methods of following glycosides: Rutin, Glycyrrhizin, Picosides, Kutkosides, Diosgenin, Hesperidin.
10. Recent advances in terpenoids: Chemistry, isolation, purification, identification and estimation by physical and chemical methods of following terpenoids: Menthol, Carvone, Citral, Eugenol and Cineol.

RECOMMENDED BOOKS:

1. New natural Products and Plant Drugs with Pharmacological, Biological and Therapeutic Activity, Proceeding of the First International Congress on Medicinal Plant Research, Ed. Wagner and Wolff, Springer – Verlag, 1977.
2. Miller- Reinhold, Phytochemistry, Vol. I – III, Van Nostrand Reinhold Co., New York
3. Recent advances in Phytochemistry, Vol. 9 by V.C. Runeckles, Plenum Press.
4. Plants used against cancer by S.L. Hartwell Lioydia, 1967, 1968 and 1970.
5. Marine Pharmacognosy by DF Martin and GM Padilla, Academic Press.
6. The technology and chemistry of alkaloids by Frank E. Hamersiaq, 1950, D. Van Nostrand Co.
7. Modern methods of plant analysis by Peach and Tracey, Vol. II, IV, Springer Verlag.
8. Agrawal OP, Chemistry of Organic Natural Product, Goel Publication House, UP.
9. Pridham JB, Swain T, Biosynthetic pathway in higher plants, Academic Press, New York.
10. G.E. Trease and W.C. Evans., Pharmacognosy, W.B. Saunders Co. Ltd., Harcourt Publishers Ltd. UK.
11. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons Limited, New Delhi.
12. Phytochemical methods by J.B. Harborne, Chapman and Hall, International Ed., London.
13. Modern methods of plant analysis by Peach and Tracey, Vol. II, IV, Springer Verlag.
14. Herbal Drug technology by SS Agrawal and M Paridhavi, Orient Longman.

Syllabus Prescribed for Degree of Master of Pharmacy in Biotechnology

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MBT-S4

Subject: FUNDAMENTALS OF BIOTECHNOLOGY

THEORY:

60 Hours (4 hrs /week)

- 1. Microbial biotechnology:** Bacteria, actinomycetes, fungi, algae and viruses: structure, chemistry, morphology, nomenclature, general classification, molecular & genotypic taxonomy, cultural, physiological and reproductive features, methods of isolation, cultivation, and maintenance of pure cultures. Industrially important microorganisms: examples and applications.
- 2. Microbial pathology:** identifying 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.
- 3. Cellular Biology:** Cell structure & function: cell organelles, cytoskeleton & cell movements, basic aspects of cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics, secondary metabolism & its applications. Intracellular vesicular traffic, 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.
- 4. Cell Cycle and Cytoskeleton:** Cell Division and its Regulation, G-Protein Coupled Receptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, Intermediate Filaments. Microtubules, Functional Role and Therapeutic Potential of Cytoskeleton.
- 5. Apoptosis and Oncogenes:** Programmed Cell Death, Tumor cells, Proto-oncogenes, oncogenic mutations, cell cycle & controls, carcinogens & repair.
- 6. Differentiation and Developmental Biology:** Fertilization, Events of Fertilization, In Vitro Fertilization, Embryonic Germ Cells, Stem Cells and its Application.

RECOMMENDED BOOKS:

1. MJ Pelczar, Jr. ECS Chain, NK Kreig, 2008. Microbiology, McGraw Hill Edition, New York.
2. Modern Biotechnology by SB Primrose, 1987. Blackwell Science Inc.
3. Eukaryotic Gene Regulation by David Lachman, 2005. Taylor & Francis; 1st edition.
4. Microbial genetics by David Friefelder by David Freifelder, John E Cronan, Stanley R Maloy. 2nd edition.

5. Joe Sambrooke, 2001. Molecular cloning: A laboratory Manual. 3rd Edition, Vol. I, Cold Spring Harbor Laboratory Press.
6. LE Casida, 1968. Industrial Microbiology. The University of Michigan, Wiley.
7. Hugo and Russel, Pharmaceutical Microbiology, Blackwell Scientific Publication, Oxford.
8. Biotechnology the biological principles by M. D. Trevan, S. Bofley.

Subject code: MBT-S4

Subject: FUNDAMENTALS OF BIOTECHNOLOGY

Practical:

(8 hrs /week)

1. Basic Laboratory Procedure – Instrument Introduction and Handling, Maintenance, Aseptic condition maintenance, Sterilization, Microscopy, etc.
2. Basic Microbiology Practicals: Preparations of various important media, Culturing and harvesting of microbes. Staining and identification. Maintenance.
3. To study several kinds of bacteria, yeast, moulds, actinomycets, fungi etc. by morphological and cultural techniques. Counting of micro-organisms. Total and Hable count (air, water, soil etc.).
4. Isolation of a pure culture from different samples and its identification in the Laboratory.
5. Effects of temperature on the growth of micro-organisms. To find out the normal death rate of different micro-organisms.
6. To find out the drug resistance in bacteria by testing the sensitivity of bacteria to antimicrobial agents, using filter paper discs.
7. Evaluation of potency of antibiotics by different methods.

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MBT-S9

Subject: MOLECULAR BIOLOGY

THEORY:

60 Hours (4 hrs/ week)

- 1. Recombinant DNA Technology:** DNA structure and functions, restriction endonucleases, plasmid cloning, methods of creating and screening gene library, cloning DNA sequences that encode eukaryotic proteins, vectors for cloning large pieces of DNA, genetic transformation, and selection of prokaryotes.
- 2. Molecular Diagnostics:** DNA diagnostic systems, hybridization probes, diagnosis of malaria, fluorescent in situ hybridization procedure, molecular diagnosis of genetic diseases – PCR/OLA procedures, ligase chain reaction (LCR),
- 3. Monoclonal Antibodies:** Scope and limitation of monoclonal antibodies, formation and selection of hybrid cells, identification of specific antibody producing hybrid cell lines. Applications of monoclonal antibodies in clinical, treatment, and biomedical research. Monoclonal antibodies as therapeutic agents, preventing rejection of transplanted organs, treatment of bacterial blood infections. Chemically linked monoclonal antibodies, human monoclonal antibodies, and hybrid human-mouse monoclonal antibodies.
- 4. Biopharmaceuticals:** Basic principles of development of protein pharmaceuticals with special reference to human insulin, human interferons, human growth hormone, erythropoietin, variants of t-PA, immunoadhesions, and chimeric proteins.

RECOMMENDED BOOKS:

1. PI Good, A Managers Guide to Design and Conduct of Clinical trials, Wiley-Liss, Hoboken, USA, 2002.
2. BR Glick and JJ Paternak, Molecular Biotechnology: Principles and Applications of DNA Recombinant Technology. ASM Press, Washington, USA, 1994.
3. MJ Pelczar, Jr. ECS Chain, NK Kreig, 2008. Microbiology, McGraw Hill Edition, New York.
4. LE Casida, 1968. Industrial Microbiology. The University of Michigan, Wiley.
5. Prescott and Dunn's Industrial Microbiology, 1981. Gerald reed 9Ed), Chapman & Hall; 4 Sub edition.
6. Hugo and Russel, Pharmaceutical Microbiology, Blackwell Scientific Publication, Oxford.

Subject code: MBT-S10

Subject: FERMENTATION TECHNOLOGY

THEORY:

60 Hours (4 hrs. /week)

- 1. Production and Analysis of different products from microorganisms by fermentation technology:** Production of culture. Production and mechanisms of ethanol fermentation. Production of alcoholic beverages, wines, alcohols, beers, brandies, rum etc.
- 2. Glycerol fermentation:** Organic acids-citric, lactic, gallic, fumaric, gibberilic etc. Antibiotics-chloramphenicol, novobiocin, griseofulvin, erythromycin and other commonly used therapeutic agents.
An outline of production of solvents and amino acids like alanine, methionine as well as fermented Ayurvedic preparations, Biofertilizers, Biogas.
- 3. Isolation and Purification of Fermentation Products:** Theory, Equipment, Design, operation and application of filtration, Solvent extraction, counter-current-distribution, Adsorption and crystallization. Turbidity and cell yield determination.
- 4. Production of Vaccine and Sera:** Study of Enzymes-chemistry, structure, function, requirements, mechanism of action, regulation, synthetic and artificial enzymes, Use of enzymes in biotechnology and engineered alteration of enzyme activity, specificity and stability. Mechanisms based in activation of enzymes, active site directed reagents and transition state analogues in relation to enzyme and drug development, selected aspects of immobilization of enzymes and cells, kinetics of free enzyme and immobilized enzyme and cells. Site directed mutagenesis, protein engineering and synthetic enzymes.

RECOMMENDED BOOKS:

1. Prescott and Dunn's Industrial Microbiology, 1981. Gerald reed 9Ed), Chapman & Hall; 4 Sub edition.
2. Peppier and Perlman, Microbial Technology, Vols. I - II, Academic Press.
3. EA Rawlins Bentley's Text Book of Pharmaceutics. Bailliere, Tindall & Cox, All India Travellers Booksellers Publishers & Distributors.
4. SJ Carter, Cooper Gunn's Dispensing for Pharmaceutical Students, CBS Publishers, Delhi.
5. Scragg, Biotechnology for Engineers: Biological System in Technological Processes, Ellis Horwood Ltd.
6. Trevan and Others, Biotechnology, The Biological Principles, Tata McGraw Hill Publishing Co.
7. Wang, Coonney, Domain, Fermentation and Enzyme Technology, John Wiley & Sons.
8. Angold & Others, Food Microbiology, Cambridge.
9. Juan A Asenjo, 1990. Separation Processes in Biotechnology, Marcel Dekker Inc.

Subject code: MBT-P9
Subject: MOLECULAR BIOLOGY
Practical:

(8 hrs. /week)

1. Isolation of human DNA.
2. Quality assessment DNA by spectrophotometer and gel electrophoresis
3. Restriction digestion of DNA
4. Separation of DNA fragments by gel electrophoresis
5. Staining of DNA bands with ETH-Br, DNA visualization.
6. Isolation of RNA from microbial sources and estimation.

Subject code: MBT-P10
Subject: FERMENTATION TECHNOLOGY
Practical:

(8 hrs /week)

1. Preparation of some biochemical products in laboratory using fermentation technology:
(a) Preparation of bacterial yeast, (b) Preparation of citric acid, (c) Preparation of alcohol, (d) Preparation of antibiotics.
2. Biological assays of various fermented products.
3. Chemical analysis of various fermented products.
4. Tests for sterility of various products.
5. Standardisation of vaccine and sera.
6. Standardisation of antisera using animals.
7. Demonstration of Ab by (1) Precipitation test, (2) Immuno diffusion test, (3) Immunelectrophoresis.
8. Phagocytosis staining after engulfment of Ab coated SRBC.

Semester-III

Subject code: MBT-S13

Subject: ADVANCED TISSUE AND CELL CULTURE TECHNIQUES

THEORY:

60 Hours (4 hrs. /week)

- 1. Principles of tissue and cell culture for both animal and plant:** Tissue culture techniques, isolation of tissues, nutrient media culture techniques, histological, histochemical and biochemical techniques. Cell suspensions, Culture media plating of cell suspension. Cytology of culture cells. Single cell clones, organogenesis, embryogenesis and cyto differentiation. Tumor cells. Protoplast culture.
- 2. A review with useful recent advances of plant growth:** Tropism, photomorphogenesis, photoperiodism and plant growth regulations, Biosynthesis, chemical properties, distributions, classification and function (s) of : Glycosides, alkaloids, terpenoids, steroids, production of secondary metabolites, culture systems, selection of nutritional factors and other physical parameters for optimal products on applications of plant cell tissue culture : Agriculture crops, forest trees, ornamental plants, medicinal plants.
- 3. Short outline of special techniques in animal cell tissue culture:** Aminocentesis, Enucleation, in-vitro mutagenesis, carcinogenesis, cryotoxicity, cell fusion of hybridoma technique, actions of hormone on cell and organ cultures etc.
- 4. Gene Transfer in Plants:** a. (i) Using vectors of *Agrobacterium*, (ii) DNA Mediated gene transfer–Electroporation, Microprojectile, Macro & Microinjection, Liposomes, Ultrasonication & Chemical mediated gene transfer. b. Localization of transferred gene in genetically modified plants: i. Nucleic acid Hybridization, ii. Use of Radioisotopes & Molecular Markers (Auto Radiography and Electrophoresis).
- 5. Applications of Transgenic Plants:** a. Resistance of herbicide, b. Resistance to insect, fungus & virus, c. Resistance to Physiological stress, d. Production of Phytopharmaceuticals, e. Edible vaccine.

RECOMMENDED BOOKS:

1. Trevan and Others, Biotechnology, The Biological Principles, Tata McGraw Hill Publishing Co.
2. Wilman, Cells and Tissues in Cultures, Vol. 3, Academic Press.
3. Evans WC (2002) Trease & Evans' Pharmacognosy, W.B. Saunders & Co., London.
4. Pharmaceutical biotechnology S.P. Vyas and V.K. Dixit, CBS Publishers and Distributors, 2001.
5. Advanced methods in plant breeding & biotechnology by David R. Murray. CAB International Panima book distributors.1991.
6. Plant tissue culture by Dixon IRL Press Oxford Washington DC, 1985.
7. Plant Chromosome analysis, manipulation and engineering by Arun And Archana Sharma 1st Edition Harwood Academic Publishers 1999.
8. Comprehensive Biotechnology by Murray Moo-Young Vol I- IV Pergamon Press LTD, 1985.
9. Transgenic Plants by R Ranjan Agrobotanica.1999.

Syllabus Prescribed for Degree of Master of Pharmacy in Quality Assurance

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MQA-S4

Subject: PHARMACEUTICAL VALIDATION

THEORY:

60 Hours (4 hrs. /week)

- 1. Introduction:** Introduction to Pharmaceutical validation, the validation committee, validation protocol and report, pre- approval inspection, pilot plant scale up and technical transfer, stages of validation.
- 2. Equipment validation:** Installation and validation of typical equipments such as dry powder mixers, fluid bed and tray dryers, tablet compression machine, capsule filling machine, autoclaves.
- 3. Analytical method validation:** General principles of analytical method validation, sampling and sample handling, validation of analytical instruments i.e. UV / VIS spectrophotometers, HPLC, dissolution test apparatus.
- 4. Process validation:** Regulatory basis for process validation, prospective process validation and retrospective validation. Manufacturing and process validation of sterile and non-sterile products i.e. coated tablets, capsules, ampoules and vials, ointments and creams, liquid orals and parenterals. Validation of processes like mixing, granulation, drying, compression, filtration, filling etc.
- 5. Validation of solid dosage forms:** Introduction, validation of raw materials, definition and control of process variables, in-process tests, finished products tests, guidelines for process validation of solid dosage forms, tablets, tablet composition, process evaluation and selection, equipment evaluation, capsules, capsule composition, process evaluation and selection, encapsulation equipment evaluation.
- 6. Validation of Stability studies:** ICH guidelines and stability protocols for different Pharmaceutical dosage forms.

RECOMMENDED BOOKS:

1. Pharmaceutical Process Validation, Edited by Robert A. Nash, Alfred H. Wachter, Vol. 129, Marcel Decker Inc.
2. Validation of Pharmaceutical Process (Sterile Products), 2nd Ed., FJ Carleton and JP Agalloco, Marcel Decker Inc.
3. Automation and validation of information in pharmaceutical processing by Despautz JF, Marcel Decker Inc.

4. Current Good Manufacturing Practices by Potdar MA, Pharma-Med Press, Hyderabad.
5. Pharmaceutical Quality Assurance by Potdar MA, Nirali Prakashan, Pune.
6. Good Manufacturing Practices for Pharmaceuticals by Sidney H. Willing and Murray M. Tuckerman, Vol. 16, Marcel Dekker Inc.
7. Microbiology in Pharmaceutical Manufacturing by Richard Prince, Davis Harwood, International Publishing.
8. Introduction to the environmental monitoring of Pharmaceutical Areas by Michel Jahnke, Davis Harwood International Publishing.

Subject code: MQA-P4

Subject : PHARMACEUTICAL VALIDATION

Practical:

8 hrs. /week

1. Validation of analytical method (minimum four experiments)
2. Validation of following equipments;
 - a. Autoclave
 - b. Hot air oven
 - c. Powder Mixer (Dry)
 - d. Tablet compression machine
 - e. Dryers
3. Validation of at least two analytical instruments.
4. Cleaning validation of one equipment.
5. Stability study of active pharmaceutical ingredients and finished products (minimum two).
6. Validation of granulation process.
7. In-process testing of solid dosage forms.

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MQA-S9

Subject: QUALITY ASSURANCE OF COSMECEUTICALS

THEORY:

60 Hours (4 hrs./week)

1. Factors to be considered in designing of cosmetic products: Regulatory requirements of cosmetic products, consumer safety consideration with microbiological preservation of cosmetic, intellectual property issue: patents of trade secrets.
2. Quality Management of cosmetics:
 - i) Manufacturing techniques and evaluation of the cosmetic finished products,
 - a) The skin
Irritation and sensitization of the skin
Nutrition and hormonal control of the skin
Preparation for the facial skin: Vanishing cream, cold and moisturizing cream, makeup preparations and face powder.
 - ii) Preparation for oral hygiene: Dentifrices, mouthwashes.
Preparation for hands and feet
 - iii) Body cosmetics: Antiperspirant and deodorant, talcum powder, sun-screen, sun tan, and anti sun burn preparation.
 - iv) Preparation for hair: Shampoos, anti-dandruff preparations, hair dyes and conditioners, hair oil, depilatories, and hair grooming aids.
 - v) Preparation for nails
 - vi) Cosmetics for Men: shaving preparation, pre shave and after shave lotion
 - vii) Baby cosmetics
 - viii) Perfumes used in cosmetics
3. Toxicity testing methods, special toxicity testing like teratogenicity, and skin sensitivity testing.
4. General principle of quality control of cosmetic product
5. Stability evaluation of cosmetics

RECOMMENDED BOOKS:

1. Perfumes, Cosmetics and Soap by W.A.Poucher (Volume I,II,III) Chapman and Hall, London.
2. Cosmetic Science and Technology, Volume I,II,III by M.S. Balsam, Wiley Interscience.
3. Cosmetic and the Skin, F.V. Wells, Reinhold Book Corporation.
4. Biological Standardization by H.H.Buru, D.J.Finney and L.B.Goodnin, Geoffery Cumberlege, Oxford University Press, London.
5. Peter E. Siegler, Animal and clinical Pharmacological Technique in drug evaluation, Volume I, II, III, Meacoal Publisher Inc, Chicago.
6. J.A. Kolmer, E.H. Spaulding and H.W.Robinson. Approved Laboratory Techniques, Appleton Century-Crofts, New York.

7. P. P. Sharma. Cosmetics- Formulation, manufacturing and Quality Control. 2nd Edition, Vandana Publications Pvt. Ltd., Delhi.
8. Harry's Cosmeticology. 7th Ed., JB Wilkinson and RJ Moore (Ed.), Longman Scientific and Technical.

Subject code: MQA-S10

Subject: NOVEL DRUG DELIVERY SYSTEMS

THEORY:

60 Hours (4 hrs. /week)

1. Fundamentals of controlled release drug delivery systems :

Fundamentals and Rationale of Sustained / controlled drug delivery, factors influencing the design & performance of sustained/ Controlled release products, Drug Targeting, Use of polymers in controlled release of active agents, Pharmacokinetic / Pharmacodynamic basis of controlled drug delivery systems, regulatory requirements.

2. Oral drug delivery : Formulation, fabrication and evaluation of various oral controlled drug delivery systems including dissolution and diffusion controlled delivery systems, gastro retentive, colon targeted and pulsatile drug delivery. TIMER_x, MASSR_x & COSR_x, Procise technology, RingCap technology, Theriform Technology, Accudep Technology, THREEFORM Technology, DissoCube IDD Technology, Zydis Technology for poorly soluble drugs, Orasolv & Durasolv technology, Egalet Technology, Buccal Mucoadhesives, Periochips.

3. Parenteral controlled release system: Scope, terminology & techniques used, injectable controlled release, formulation. Implantable drug delivery, microspheres, liposomes & their quality control.

4. Mucosal drug delivery models: Buccal, rectal, nasal & vaginal drug delivery. Mechanisms of transports of drugs through mucosal routes, penetration enhancers, formulation development, in-vitro, ex-vivo and in-vivo methods of evaluation (for each route).

5. Transdermal drug delivery system: Permeation through skin including mechanism, permeation enhances, In-vitro skin permeation, technologies for developing transdermal drug delivery system, mechanism of release kinetics, evaluation of transdermal drug delivery systems.

6. Ocular Drug Delivery: Transport of drugs through ocular tissues, approaches to improve ocular drug delivery.

7. Site specific drug delivery system: Active & passive targeting, resealed erythrocyte, monoclonal antibodies, drug targeting by particulate carrier system, drug targeting to brain, lung & colon.

8. Protein & peptide drug delivery system: Physical aspects, biochemistry of protein drug (structure, properties & stability- Mechanisms of destabilization. Techniques of stabilization of Proteins and Peptides.) General methods of analysis of protein & peptide drugs, barrier to transport & Pharmacokinetics, different route of delivery, practical considerations. Importance of pre-formulation & formulation considerations, toxicity immunogenicity, stability & regulatory perspective.

9. Regulatory consideration in controlled release: Demonstration of safety, efficiency & controlled release nature. WHO & Indian conditions.

RECOMMENDED BOOKS:

1. Remington's pharmaceutical sciences. 21 st Edition, Lippincott Williams and Wilkins- Vol. I & II
2. Novel drug delivery system – Marcel Dekker N.Y. Second Edition, Revised and Expanded by Yie W. Chien. Vol- 50.
3. J. R. Robinson and Vincent H. L. Lee Controlled drug delivery system. Marcel Dekker Second Edition, Revised and Expanded .. Vol- 29.
4. N.K. Jain .Novel and controlled drug delivery systems.
5. N.K. Jain. Advances in Novel and Controlled Drug Delivery.
6. Robinson, J.R. & Lee, V.H.I.,: Controlled and Novel Drug Delivery Marcel Dekker, New York. Second Edition, Revised and Expanded Vol- 29.
7. Kim. C., Controlled Release Dosage form Design, Technomic Publishing Co, Basel.
8. J. Swarbrick, 2007. Encyclopedia of Pharmaceutical Technology, Third Edition, Volume 1-6, Informa Healthcare.
9. R. Williams, D. Taft and J. McConville, "Advanced formualtion design to optimize therapeutic outcomes" Marcel Dekker, Inc.
10. L. Xiaoling, B.R. Jasti, "Design of Controlled Release Drug Delivery Systems" McGraw-Hill.
11. B. O. Mashkevich, "Drug delivery research advances" Nova Science Publishers, Inc.
12. W.M. Saltzman, 2001 "Drug delivery_Engineering Principles for Drug Thera". Oxford University Press.
13. E. Touitou, W.B. Boca "Enhancement in Drug Delivery" CRC PressBrian.
14. M.J. Rathbone, J. Hadgraft, M.S. Roberts, "Modified-Release Drug Delivery Technology" Marcel Dekker Inc.

Subject code: MQA-P9

Subject: QUALITY ASSURANCE OF COSMECEUTICALS

Practical:

8 hrs. /week

1. Evaluation of cosmetic raw materials (Minimum of 5 experiments).
2. Formulation and evaluation of various types of cosmetic preparations (Minimum of 5 experiments).
3. Evaluation of some marketed brands of cosmetic preparations (Minimum of 5 experiments).
4. Evaluation of stability of cosmetic preparation (Minimum of 5 experiments).
5. Determination of microbial load of cosmetic preparation (Minimum of 2 experiments).

Subject code: MQA-P10

Subject: NOVEL DRUG DELIVERY SYSTEMS

Practical:

8 hrs. /week

1. Formulation and evaluation of sustained release matrix tablet (of any two drugs).
2. Formulation and evaluation of floating microspheres.
3. Formulation and evaluation of floating tablet.
4. Formulation and in vitro evaluation of transdermal patches.
5. Development and evaluation of ocular inserts of a given drug.
6. Preparation and evaluation of buccal film of any two cardiovascular drugs.
7. Taste masking of some bitter drugs by ion-exchange resins.
8. Formulation and evaluation of nasal in situ gel.
9. Preparation and characterization of liposomes.
10. Preparation characterization of wax embedded microcapsules of a given drug.

Semester-III

Subject code: MQA-S13

Subject: QUALITY MANAGEMENT

THEORY:

60 Hours (4 hrs. /week)

1. Concept of Total Quality Management, Different quality management systems, ISO 9001:2000, ISO 14000, and their Philosophy, Introduction to ICH processes.
2. Documentation requirements in pharmaceutical industry for GMP compliance:
 - a. Equipment, selection, purchase specifications, maintenance clean in place and sterilize in place.
 - b. Manufacture and controls on various dosage forms. Manufacturing documents i.e. Master Formula, Batch formula, production record review, drug product inspection, Standard Operating Procedures, Quality audits of manufacturing processes and facilities.
 - c. In process quality control on sterile and non-sterile dosage forms. Standard Operating Procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, fumigation, sterilization, membrane filtration etc.
 - d. Packaging and labeling controls, line clearance and other packaging material.
3. Quality Audits: Raw materials, Finished Products and analytical procedures, manufacturing processes.
4. Quality control laboratory responsibilities and good laboratory practices.
5. Finished product release, quality audits, batch release documents.
6. Good warehousing practices and materials management.
7. Distribution records, handling of returned goods, recovered materials and processing.
8. Complaints and recalls, evaluation of complaints and recall procedures, related records and documents, drug product salvaging.
9. Waste and scrap disposal procedures and records.
10. Good Manufacturing Practices according to Schedule M of D & C Act
11. Environmental protection act and Factory act .

RECOMMENDED BOOKS:

1. Good Manufacturing Practices for Pharmaceuticals by Sidney H. Willing and Murray M. Tuckerman, Vol. 16, Marcel Dekker Inc.
2. Encyclopedia by pharmaceutical technology edited by James Swarbrick, James C. Boylan, Marcel Dekker Inc.
3. How to practice GMPs by Sharma PP, 3rd Ed., Vandana Publication.
4. Drug and Cosmetic Act and Rules (Government of India)
5. Current Good Manufacturing Practices by Potdar MA, Pharma-Med Press, Hyderabad.
6. Pharmaceutical Quality Assurance by Potdar MA, Nirali Prakashan, Pune.
7. Girmaldi, Monica and Gough, Janet, The internal quality audit, Davis Harwood International Publishing.
8. Singer, Guidelines for laboratory quality auditing, Marcel Dekker
9. Lewis, Pharmaceutical experimental design, Marcel Dekker.
10. Guarino, New Drug approval process, 2nd ed., Vol 56, Marcel Dekker, New York.
11. Gough, Janet, Hosting a compliance audit. Davis Harwood International Publishing. ISO 14000 and ISO 9000 by Rothary B.

Syllabus Prescribed for Degree of Master of Pharmacy in Industrial Pharmacy

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MIP-S4

Subject: ADVANCED INDUSTRIAL PHARMACY-I THEORY:

60 Hours (4 hrs. /week)

- 1. Principles of improved Tablet Production system design :** introduction, Benefits of improved Tablet production system, Material Handling, processing step combination or elimination, Unit operation improvements, Role of Computer process Control.
- 2. Compression:** Process of Compression, The Properties of Tablets influenced by Compression, Measurement of Compressional force. Energy expenditure, Transmission of force, Nature of material. Manufacture and Formulation Techniques of Chewable tablets, Medicated Lozenges and Specialized Tablets
Compression coating-formulation, Layered Tablets and its formulation, Inlay tablets.
- 3. Pelletization technology:** Introduction, Pelletization process and formulation, Requirements for pelletization.
- 4. Sterile Dosage forms:** Formulation and Processing of large volume parenterals, Small volume Parenterals and Related parenteral products, Parenteral devices.
- 5. Drying and Dryers:** Introduction, Mode of heat Transfer, Internal Mechanism of Moisture flow, Psychrometry, Drying Mechanisms, Drying methods for Pharmaceutical Granulation.
- 6. Evaporation and Evaporators:** Introduction, Types of Evaporators, Design of Evaporators, operation of Evaporators.
- 7. Pilot plant Scale Up Techniques:** General Consideration, Purpose and functions concepts of pilot plant for Development and control, Planning for pilot plant, Size of pilot plant. Organisation and Personnel, Basic Consideration in Developing the process for Production of dosage forms, GMP consideration. Transfer of Analytical methods to Quality assurance, Product consideration, Pilot plant study design for solid dosage forms, Liquid orals and semi-solids.

REFERENCE BOOKS:

1. B.S. Banker. Modern Pharmaceutics, Marcel Dekker.
2. Gennaro, Remington Pharmaceutical Sciences, Mack Publishing Company.
3. Lachman, Theory and Practice of Industrial Pharmacy, Lea and Febiger.
4. Liberman, Lachman and Schwartz. Pharmaceutical Dosage forms Tablets, Vole, II and 111, Marcel Dekker.
5. Lieverman, Lachman and Avis, Pharmaceutical dosage Forms. Parenteral Medication, Vols I and II Marcel Dekker.

6. King and Turco, Sterile Dosage Forms, Lea and Febiger.
7. Ghebre, sellasie, Pharmaceutical Polletization technology, Marcel Dekker.
8. Swarbrick and Boylan, Encyclopedia of Pharmaceutical Technology, Vole 4 and 5, Marcel Dekker.

Subject code: MIP-P4

Subject : ADVANCED INDUSTRIAL PHARMACY-I

Practical:

8 hrs. /week

1. To study the effect of particle size, moisture content and lubricant on flowability and
2. compressibility of powders.
3. To prepare and evaluate antibiotic dispersible tablet.
4. To prepare and evaluate chewable tablet.
5. To prepare and evaluate medicated logenzes.
6. Development and evaluation of compression coated tablet of some drugs.
7. Design and characterization of drug loaded pellets by different techniques.
8. To prepare and evaluate parenteral suspension
9. To prepare and evaluate parenteral solution
10. To prepare and evaluate parenteral emulsion
11. To prepare and evaluate sterile reconstituted powder.
12. To prepare and evaluate microsphere prepared by spray drying technique

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MIP-S9

Subject: ADVANCED INDUSTRIAL PHARMACY-II

THEORY:

60 Hours (4 hrs. /week)

- 1. Optimization techniques in pharmaceutical formulation and processing**
Concept of optimization, Optimization parameters, Classical optimization, Statistical design, and Optimization methods.
- 2. Stability testing**
Physicochemical and biological factors affecting stability of drugs, Methods to find out degradation pathways, Determination of shelf life by accelerated stability testing, Overages.
- 3. Bioavailability and bioequivalence studies**
Definition, Objective of bioavailability, Parameters of bioavailability, Determination of AUC. Estimating absorption rate of drugs; Measurement of bioavailability- Pharmacokinetic methods and Pharmacodynamic methods. Drug dissolution rate & bioavailability. *In vitro* drug dissolution testing models. In-vitro in-vivo correlation. Definitions: Bio equivalence, Chemical equivalence, Therapeutic equivalence, Pharmaceutical equivalence; Testing of bioequivalence of dosage forms.
- 4. Methods of enhancing bioavailability**
Solubilization, Prodrugs, and enhancement of dissolution characteristics, cyclodextrin, permeation enhancer, solid dispersion, surfactant, bioavailability enhancers.
- 5. Biochemical and molecular biology approaches to controlled drug delivery:**
Microparticulate drug carriers : liposome, microspheres and cells, selective endocytosis of micromolecular drug carriers, antibodies for drug delivery, released erythrocytes, neosomes.
- 6. Engineering :** Adequate knowledge of mechanical, electrical and electronic *parts* of pharmaceutical machinery and equipment, preventive maintenance, assessing plant and machinery efficiency and life. Material handling, transfer, transport and conveyance of bulk material.
- 7. Packaging Material Science:** Packing design and specification, packaging validation trials, materials of construction. Component product validation, regulatory requirements, quality control testing and standards, GMP requirements and its deficiencies. In processes control during component manufacture, documentation sterilization of packing component, packaging and filling equipment, pharmaceutical packaging including sterile area.

RECOMMENDED BOOKS:

1. Lachmann and Libermann , Theory and Practice of Industrial Pharmacy. Third edition, Varghese Publishing House.
2. Leon Lachmann, Pharmaceutical dosage forms: Tablets Vol. 1-3. Third Edition.

3. Leon Lachmann. Pharmaceutical Dosage forms: Disperse systems, Vol, 1, 2, 3. Second edition.
4. Gillbert and S. Banker. Modern Pharmaceutics.. Fourth Edition. Volume 121.
5. Remington's Pharmaceutical Sciences. Vol.I-II, 21 st Edition.
6. Rawlins. Bentley's Textbook of Pharmaceutics. Eight Edition
7. Sidney H. Willig. Good manufacturing practices for Pharmaceuticals: A plan for total quality control. Second Ed.
8. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
9. D.P.S. Kohli and D.H. Shah. Drug formulation manual. Third Edition, Eastern publishers, New Delhi.
10. P. P. Sharma. How to practice GMPs. Fifth Edition, Vandana Publications, Agra.
11. M. Rowland, T.N. Tozer, 2011. "Clinical Pharmacokinetics and Pharmacodynamics: Concept and Applications", 4th Ed. Lippincott, Williams and Wilkins.
12. L. Shargel, S. Wu-Pong, B. C Andrew, 2005. "Applied Biopharmaceutics and pharmacokinetics", Fifth Ed. McGraw-Hill Medical Pub. Division.
13. M. Gibaldi and D. Perrier, Second Edition. 1982. "Pharmacokinetics". M. Dekker.

Subject code: MIP-S10

Subject: ADVANCES IN DRUG DELIVERY SYSTEMS

THEORY:

60 Hours (4 hrs. /week)

1. **Polymer science:** Introduction, synthesis of polymers, polymer classification, biodegradation of polymers, properties of polymers, pharmaceutical application of polymers.
2. **Sustained release formulations:** Introduction, concept, advantages and disadvantages. Physicochemical and biological properties of drugs relevant to sustained release formulations, evaluation of SRDFs.
3. **Concept and system design for rate-controlled drug delivery:** Classification of controlled drug delivery systems, rate-programmed release, activation modulated and feedback-regulated drug delivery systems, effect of system parameters on controlled release drug delivery.
4. **Controlled release oral drug delivery systems:** Dissolution, Diffusion, Combination of dissolution and diffusion controlled systems, osmotic pressure controlled release systems, floating drug delivery systems, pH dependent systems, ion exchange controlled systems.
5. **Mucoadhesive drug delivery systems:** Concepts, advantages and disadvantages, structure of oral mucosa, transmucosal permeability, mucosal membrane models, mucoadhesive polymers, permeability enhancers, *in vitro* and *in vivo* methods for buccal absorption. Nasal and pulmonary drug delivery systems and its applications.
6. **Ocular drug delivery systems:** Drawback of conventional ophthalmic dosage forms, types, formulation and evaluation of ophthalmic inserts, *in situ* ophthalmic gels.
7. **Transdermal drug delivery systems:** Anatomy and physiology of skin, permeation through skin, factors affecting permeation, basic components of TDDS, formulation approaches used in development of TDDS and their evaluation, permeation enhancers, penetration enhancement techniques, iontophoresis, sonophoresis, transferosomes, ethosomes
8. **Parenteral controlled release drug delivery systems:** Approaches for injectable controlled release formulations and development of implantable drug delivery systems.

9. **Intrauterine drug delivery systems:** Anatomy & physiology of vagina, development of intra uterine devices (IUDs), copper IUDs, hormone-releasing IUDs, and vaginal rings.
10. **Targeted drug delivery systems:** Principles of targeting, classification, advantages and disadvantages, biological processes and event involved in drug targeting, microspheres, magnetic microspheres, nanoparticles, liposomes, niosomes, dendrimers, resealed erythrocytes, and monoclonal antibodies.
11. **Protein and peptide drug delivery:** Introduction, classification and structure of protein, drug delivery systems for proteins and peptides, manifestation of protein instability and stability.
12. **Vaccine delivery:** Novel vaccination strategies, microparticles as vaccine adjuvants and delivery systems, liposomes and ISCOMs in vaccine delivery, virosomal technology, vaccines for specific targets, nanotechnology for vaccine delivery

RECOMMENDED BOOKS

1. Fried J.R. Polymer Science & Technology, 2nd edition. Prentice-Hall India Pvt. Ltd.
2. Coleman M.M., Painter P.C. Fundamentals of Polymer Science: An Introductory Text. CRC Press.
3. Lliun Lisbeth, Davis Stanley S. Polymers in Controlled Drug Delivery. Wright Bristol.
4. Robinson J.R., Lee V.H.L. Controlled Drug Delivery. Marcel Dekker, Inc.
5. Juliano R.L., Drug Delivery Systems: Characteristics and Biomedical Applications. Oxford University Press.
6. Chien Y.W. Novel Drug Delivery Systems. Marcel Dekker, Inc.
7. Vyas S.P., Khar R.K. Controlled Drug Delivery-Concepts and Advances. Vallabh Prakashan.
8. Mathiowitz E. Encyclopedia of Controlled Delivery. John Wiley & Sons, Inc.
9. Jain N.K. Controlled and Novel Drug Delivery. CBS Publishers & Distributors.
10. Carstensen J. T. Drugs and Pharm.Sci. Series, vol. 43, Marcel Dekker Inc.
11. Johnson P., Lloyd-Jones, J.G. Drug Delivery Systems: Fundamentals and Techniques. VCH.
12. Audus K.L., Juliano R.L. Targeted Drug Delivery. Springer-Verlag.
13. Lee V.H.L. Peptide and Protein Drug Delivery. Marcel Dekker, Inc.
14. Guy R.H., Hadgraft G. Transdermal Drug Delivery. Marcel Dekker, Inc.
15. Edith Mathiowitz, Donald E. Chickering, Claus-Michael Lehr. Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches and Development. Marcel Dekker, Inc.
16. Kasliwal N. Liposomes/Niosomes As a Drug Delivery System. Lambert Academic Publishing.
17. Dietrich G., Goebel W. Vaccine Delivery Strategies. Horizon Scientific Press.
18. Kaufmann S.H.E. Novel Vaccination Strategies. Wiley-VCH.

Subject code: MIP-P9

Subject: ADVANCED INDUSTRIAL PHARMACY II

Practical:

8 hrs. /week

1. Optimization of formulations by factorial design.
2. Preformulation studies on tablets.
3. To study the decomposition kinetics of any three drugs.
4. To study the effect of copper ions on the ascorbic acid stability in solution
5. To determine the aqueous solubility of given drug sample at various temperature and report its thermodynamic parameters.
6. To study the dissolution kinetics of given drug.
7. To study the effect of pH (2, 4, 6 and 8.0) on the apparent partition coefficient of a drug in n-octanol- water buffer system.
8. To perform powdered glass test and whole container test as per USP on given glass containers.
9. Preparation and comparative evaluation with marketed products for antacid efficiency of neutralizing property of suspensions.
10. To determine water absorption capacity of different packaging materials.

Subject code: MIP-P10

Subject: ADVANCES IN DRUG DELIVERY SYSTEMS

Practical:

8 hrs. /week

1. Formulation and evaluation of sustained release matrix tablet (of any two drugs).
2. Formulation and evaluation of floating microspheres.
3. Formulation and evaluation of floating tablet.
4. Formulation and in vitro evaluation of transdermal patches.
5. Development and evaluation of ocular inserts of a given drug.
6. Preparation and evaluation of buccal film of any two cardiovascular drugs.
7. Taste masking of some bitter drugs by ion-exchange resins.
8. Formulation and evaluation of nasal in situ gel.
9. Preparation and characterization of liposomes.
10. Preparation characterization of wax embedded microcapsules of a given drug.

Semester-III

Subject code: MIP-S13

**Subject: INDUSTRIAL PROCESS VALIDATION AND PRODUCTION
MANAGEMENT**

THEORY:

60 Hours (4 hrs. /week)

- 1) **Definition.** regulatory history of process validation, regulatory basis of process validation.
- 2) **Organisation :** Structure, corresponding departments, scope of validation work, protocol and documentation.
- 3) **Validation of Sterile dosage form :** Theoretical approaches, validation of steam, dry heat and ethylene oxide. Sterilization cycle. Validation of radiation and sterilising filters.
- 4) **Validation of solid dosage form :** Definition and control of process variables, guidelines for process validation of solid dosage form, validation of raw material and analytical methods.
- 5) **Prospective process validation :** Introduction, Organisation and documentation. Formulation development and development of manufacturing capability Scale up studies, qualification trials master product documents. Experimental design and analysis.
- 6) **Retrospective process validation :** Process, validation strategies. Selection and evaluation of historical data.
- 7) **Process of raw material :** Cost verses risk analysis. Establishment of specifications, test procedure for sampling. Establishment of optimum storage conditions.
- 8) **Analytical methods validation :** Assay validation during development phase. Retrospective and prospective analytical methods validation.
- 9) **Production and planning management :** Space allocation, environmental factors, manufacturing, materials management. Forecasting cost control. Industrial relation. Entrepreneurship development.
- 10) **Safety management:** Industrial hazards due to fire, accident, mechanical and electrical equipment, chemicals and pharmaceutical safety measures.
- 11) **Drug regulatory methods :** Definition. Federal food, drug and cosmetic Act. Review of Indian Laws relating to drugs. Drugs efficacy studies, implementation review, OTC review, drug listing, drug amendments, patents copy rights, trade marks, drug recalls, product liabilities, customer complaint.

RECOMMENDED BOOKS :

1. Nash R.A., Berry I. R. Pharmaceutical Process Validation. Marcel Dekker, Inc.
2. Willing S.H., Stoker J.R. Good Manufacturing Practices in Pharmaceuticals- A Plan for Total Quality Control. Marcel Dekker, Inc.
3. Balchandra and Nambudri. Production Management-Text and cases. Prentice Hall of India-
4. Lachman. Lieberman, and Kenig. The Theory and Practice of Industrial Pharmacy. VargHese publishers.
5. Agalloco J.P., Carleton F.J. Validation of Pharmaceutical Processes: Sterile Products. Marcel Dekker, Inc.
6. Wilin S.H. Tuckerman M.M., Hitching S. Good Manufacturing Practices for Pharmaceuticals-A Plan for Total quality Control. Marcel Dekker, Inc.
7. Sharma D.D. Total Quality Management-Principles, Implementation and Cases. Sultan Chand & Sons.
8. Kenneth L. A. The Managers Guide to ISO 9000. Free Press.
9. Pothdar M.A. Current Good Manufacturing Practices. BS Publications.

Syllabus Prescribed for Degree of Master of Pharmacy in Pharmacoinformatics

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MPI-S4

Subject: INFORMATION TECHNOLOGY

THEORY:

60 Hours (4 hrs. /week)

1. Chemoinformatics: Introduction, molecular structures, representation and manipulation of 2D and 3D structures, generation of 3D structures visualization techniques, molecular databases, virtual screening, chemical libraries, molecular descriptors, calculation of descriptors reflecting physical and chemical properties of molecules, molecular similarities and complementarities, selection of structurally diverse and representative sets, molecular properties, solubility partition coefficient, drug like properties, data analysis, quantitative and qualitative structure activity relationship, prediction of ADME properties, application of chemoinformatics in drug research.
2. Programming in C, C⁺⁺, character manipulation, programming techniques for data base management and developing database oracle.
3. Programming in database environment, development of databases, relational databases, information retrieval systems, general search methods, Means-ends analysis, depth first search, breath first search, optimal search, branch and bound etc. Oracle database environment.
4. Web based search engines and the details of their search algorithms especially pertaining to bio-computing.
5. Molecular modeling : Energy minimization, geometry optimization, conformational analysis, global conformational minima determination, approaches and problems, bioactive vs. global minimum conformations, automated methods of conformational search, advantages and limitations of available software, molecular graphics, computer methodologies behind molecular modeling including artificial intelligence methods.
6. Structure activity relationships in drug design: qualitative vs. quantitative approaches, advantages and disadvantages, random screening, nonrandom screening, drug metabolism studies, clinical observations, rational approaches to lead discovery, homologation, chain

branching, ring chain transformations, bio-isosterism, insights into molecular recognition phenomenon, structure based drug design, ligand based drug design.

7. QSAR: Electronic effects, Hammett equations, lipophilicity effects, Hansch equation, steric effects, Taft equation, experimental and theoretical approaches for determination of physicochemical parameters, parameter inter-dependence, case studies, regression analysis, extrapolation vs. interpolation, linearity vs. non linearity, importance of biological data in the correct form, 3D-QSAR –example CoMFA and CoMSIA.

RECOMMENDED BOOKS:

1. Westhead, D.R, Parish, J.H. and Twyman, R.M., Instant notes in bio informatics, BIOS scientific publishers, 2002. (ISBN. 1859962726)
2. Attwood, T.K. and parry-smith, D.J., Introduction to bioinformatics, Addison-Wesney-Longman Ltd. 1999. (ISBN 0582327881)
3. Baxevanis, A.D. and Ouellette, B.F.F., Bioinformatics; A practical guide to the analysis of genes and proteins, John wiley, 1998 (ISBN 047119196)
4. Mount, D.W, Bioinformatics: Sequence and genome analysis, cold spring harbor laboratory press. (ISBN 0879695978)
5. Lesk, A.M., Introduction to bioinformatics, Oxford university press (ISBN 0199251967)
6. Durbin,R., Eddy, S.,Krogh and Mitchison, G., Biological sequenceanalysis: Probabilistic models of proteins and nucleic acid, Cambridge university press, 1998. (ISBN 0521629713)
7. Baldi, P. and Brunak, S., Bioinformatics: The machine learning approach, MIT, 1998 (ISBN 026202442X.)
8. Brandon, C.I. and Tooze J., Introduction to protein structure, Garland pub., 1991. (ISBN 0815302703)
9. Lesk, A.M., Introduction to protein architecture: The structural biology of proteins, Oxford university press 2001. (ISBN 0198504748)
10. Creighton, T.E., Protein Structure: A practical approach. Irl. Pr., 1997. (ISBN 0199636184)
11. Schultz, G.E., Principles of protein structure, springer verlag,1978.(ISBN: 0387903348)
12. Sternberg, M (ed)., Protein structure prediction- A practical approach, Oxford university press, London 1996.

Subject code: MPI-P4

Subject: INFORMATION TECHNOLOGY

Practical:

8 hrs. /week

1. Windows Operating system basic commands and utility software exposures
2. Basic operations on MS-office and Foxpro software.
3. Statistical operations using SPSS packages
4. C- language fundamentals and programming
5. Sequence data retrieval using SRS and Entrez
6. Sequence similarity search using BLAST and FASTA tools
7. Sequence and Structure Analysis using EMBOSS Package.
8. Molecular visualization using visualizing tools- Rasmol, Pymol, Cn3D, Swiss PDB viewer.
9. Protein Target Identification.
10. Selection of Template structures.

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MPI-S9

Subject: BIOINFORMATICS

THEORY:

60 Hours (4 hrs. /week)

1. Bioinformatics basic: Computers, biology and medicine, importance of Unix and Linux systems and its basic commands, data base concepts, protein and nucleic acid database concepts, protein bases, Biological XML DTD's; pattern matching algorithm basics.
2. Computational tools for DNA sequence analysis: GCG: The Wisconsin package of analysis program, web bases interfaces for GCG sequence analysis program.
3. Database and search tools: biological background for sequence analysis. Identification of protein sequence from DNA sequence, searching of database similar sequence. The NCBI; Publicly available tool resources at EBI, resources on the web data base mining tools.
4. DNA sequence analysis: The gene bank sequence data base; submitting DNA sequence to the data base and data base searching, sequence alignment, pairwise alignment, techniques, multiple sequence analysis, multiple sequence alignment, flexible sequence similarity searching with the FAST3 program package, the use of CLUSTALX for the multiple sequence alignment.
5. Submitting DNA protein sequence database: Where and how to submit SEQUIN, genomcentres; submitting aligned set of sequence updates and internet resources.
6. Protein modeling: Introduction; forcefield methods; energy, buried and exposed residue, side chain and neighbours; fix region, hydrogen bonds, mapping properties onto surfaces; fitting monomers, rms fits of confirms, assigning secondary structures: sequence alignment methods, evaluation, scoring, protein completion, backbone construction and side chain addition, small peptide, methodology, software accessibility, building peptides, protein displayed; substructure manipulation, aneling,
7. Peptidomimetics: Introduction, classification; conformationally restricted peptides, design pseudopeptides, peptidomimetics and transition state analogs; biologically active template; amino acid replacement; peptidomimetics and rational drug design; CADD techniques in peptidomimetics; development of nonpeptide peptidomimetics,
8. Protein structure prediction: Protein folding and model generation; secondary structure; protein loop searching, loop generating methods, loop analysis; homology modeling,

concept of homology modeling potential application, description methodology, homologous sequence identification; align structure, align model sequence; construction of variables and conserved region, threading technique, topology fingerprint approach for prediction, evaluation of alternate models; structure prediction on a mystery sequence, structure aided sequence technique of structure prediction, structure profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; significant ability; flexy dock, creatine analysis, scoring technique, sequence-sequence scoring.

9. Protein-ligand docking: Introduction; docking problems, methods for protein ligand docking, validation studies and application; screening small molecule database, docking of combinatorial libraries input data, input data, analysis docking results, software accessibility; flexy dock, creating input structures, ligand prepositioning, binding pockets, flexible bonds, torsional space, genetic algorithm, scoring.
10. The virtual library: searching MEDLINE, PubMed, current content, science citation index and current awareness services, electronic journals, grant and finding information.

REFERENCE BOOKS:

1. John, S. and Haywell, W., A guide to chemical basis of drug design, Introduction to the principles of drug design, Wright PSG.
2. Wolff, M.E., Burgers medicinal chemistry and bases of medicinal chemistry, vol. III, 5th ed., A Wiley interscience publishers, 1996.
3. Delgado, J.H. and William, A.R (eds), Wilson and Giswold's, Text book of organic, medicinal and pharmaceutical chemistry, computer assisted drug design, 11th ed. Lippincott publisher, 2004
4. Gudman and Gillmans, The pharmacological basis of therapeutics, 10 ed. Pergamon press, 2001.
5. Robert, S.M and Price, D.J., Medicinal chemistry- The role of organic chemistry in drug research, Mc-Grawhill, medical publishers.
6. William D.A and Lemke, T.L. Foye's Principles of medicinal chemistry, 5th ed., Lippincott publisher, 2002
7. Furniss, B.S., Hannaford, A.J. Smith, B.W.G and Tatchall, A.R. Vogel practical organic chemistry, 5th ed, Addison-Wesley publishers, 1998.
8. Frberick M.A., Current protocol in molecular biology.
9. Tomstrachan and Andrew, P.R, Human molecular genetics.
10. Chrietine orengo, Bioinformatics genes, protein and computer.
11. Geffrey, M. Cooper, The cell- A molecular approach.
12. Nancy S, Templaton D and Lasio, Gene therapy- therapeutic mechanism and strategies.
13. Rajan, S. S. And Balaji, R., Introduction to Bioinformatics, Himalaya Publishing house, Mumbai. 2003.
14. Murthy, C.S.N., Bioinformatics, Himalaya Publishing House, Mumbai, 2004.

Subject code: MPI-S10

Subject: MOLECULAR BIOLOGY

THEORY:

60 Hours (4 hrs. /week)

1. System and methods of molecular biology: Introduction to genetics engineering and biotechnology, genes and gene expression, bacteria, bacteriophage, yeasts, animal cells; use of mutants, genetics analysis of mutants, genetics of recombination, complementation.
2. DNA replication, transcription and translation: Enzymology of replication, initiation of replication, reverse transcriptase, bidirectional replication; transcription signals, promoter sites, rho and sigma factor, RNA processing; the genetic code, the wobble hypothesis, polycistronic mRNA, overlapping genes, polypeptide synthesis.
3. Mutation: types of mutation, biochemical basis of mutation, mutagenesis, mutator genes, reversion.
4. Plasmids and transposable elements: plasmid DNA and its transfer, plasmid replication, structure of transposable elements and its transcription, genetic phenomenon mediated by transposons.
5. Gene cloning: nucleic acid isolation, cloning vectors, salient features and types, biology of bacteriophage lambda, cosmid vectors and their use, cloning methods.
6. Regulation of gene activity in prokaryotes and eukaryotes: principles of regulation, E. coli. Lactose system, tryptophan operon, autoregulation, feedback inhibition, gene family, gene dosage, gene amplification, regulation of transcription and processing, transcriptional control, gene rearrangement.
7. DNA-protein interaction: single protein binding to a regulatory DNA site, levels of specificity, single stranded DNA binding protein in E. coli., protein-DNA binding in tobacco mosaic virus, structural and functional studies of ribonuclease T1, Tet repressor, Tet operator, condensation of chromatin.
8. Genomics: Technology vs. philosophy, DNA, RNA, proteins, the central dogma in molecular biology, splicing, gene structure. Bioinformatics as an essential part of genomics.

RECOMMENDED BOOKS :

1. Baltimore, D.H. and Berk, A., et. al., Molecular Cell Biology-Scientific American Book, Lodish, New York, 1995.
2. Lewin, B., Gene VII, Oxford University Press, New York, 1999.
3. DeVita Jr., Hellman, S., Rosenberg, S.A (eds.), Cancer: Principle and practice of oncology 6th ed., Lippincott, Williams and Wilkins publication 2001

4. Alberts, B., Bray ,D., Lewis J., Raff, M., Roberts, K. and Watsons, J.D., molecular biology of the cell, 3rd ed., Garland publishing Inc
5. Murthy ,C.S.N., bioinformartics , Himalaya publishing house ,Mumbai,2004.
6. Vedpal, S. M., Padma, S., Mohan and Premlani,R., industrial biotechnology, Oxford and IBH Publishing Co. Pvt. Ltd., New Delhi ,1992.

Subject code: MPI-P9

Subject: BIOINFORMATICS

Practical:

8 hrs. /week

1. Validation and active site prediction of the modeled target structure using SAVS,CAS Tp and PASS.
2. Identification and generation of ligand molecule from Chemical structure database.
3. Docking the ligand molecule with the protein target using AUTODOCK
4. Creating Databases like SARS PROTEIN , Amino acid and querying using MYSQL
5. Usage of String , Mathematical & Date Functions on MYSQL
6. Understanding the KEYS and references in MYSQL

Subject code: MPI-P10

Subject: MOLECULAR BIOLOGY

Practical:

8 hrs. /week

1. Applications of Analytical techniques –
Ultra-violet and Visible spectroscopy, infra-red spectroscopy.
2. Applications of Chromatographic techniques –
3. Column chromatography, TLC, - HPTLC, HPLC and GC-MS.
4. Identification of chemical compounds by Nuclear Magnetic Resonance (NMR) - spectroscopy.
5. Determination of metals by Flame photometry and Absorption spectrometry.
6. Seperation of proteins by Gel –Electrophoresis.

Semester-III

Subject code: MPI-S13

Subject: SELECTED TOPICS IN PHARMACOINFORMATICS

THEORY:

60 Hours (4 hrs. /week)

1. Drug metabolism and toxicity and metabolic disorder:

Introduction to metabolic errors and metabolic diseases, metabolism in health and diseases, regulatory enzymes for metabolic pathways, metabolic problems as diagnostic criteria, advanced concept in the organization and control of carbohydrates, lipid and nitrogen metabolism in eukaryotes, regulation at cellular levels via metabolite trafficking and control of enzyme activity, integration of metabolism at the whole body level by hormonal signaling, the molecular basis of inherited metabolic diseases, use of anti metabolites in the chemotherapy molecular graphics and modeling of metabolites and biomolecules, resource for macromolecular modeling and pharmacoinformatics, pharmacogenetic variations influencing metabolism and its clinical relevance, toxicogenomics, toxicogenetics, microarray expression profiles, gene expression and databases of microarray expression profiles, gene expression biomarkers, toxicology informatics.

2. Pharmacoinformatics – The tools

Patterns recognition techniques with examples from spectral patterns and biological sequence patterns, artificial intelligence, logical programming, experts systems, artificial neural network(ANN), genetic algorithms.

Pharmaco informatics- The methodology

a) Pharmacoinformatics: Integration of bioinformatics, chemoinformatics, genomics and proteomics; in silico identification and validation of novel therapeutic targets, 3D database search method, artificial neural network methods, genetic algorithm methods in chemoinformatics, evaluation of diverse compounds subsets from chemical structures databases, recognition of hypothesis, validation of hypothesis using pharmacophore pattern searching methods in chemoinformatics, spectral and crystallographic databases, abinitio gene prediction technique to predict novel gene targets, case studies.

b) In silico combinatorial and high throughput methods: computational methods of library design.

c) Virtual screenings, Lead compounds selection and lead optimization using virtual screening, filtering methods, rapid QSAR methods for virtual screening rapid molecular docking methods for virtual screening; receptor selectivity mapping; testing the lead drug candidates (from chemoinformatics method) for their selectivity across a broad panel of

targets (from bioinformatics methods) ,scoring function and their importance in virtual screening, case studies internet computing in drug discovery.

Pharmacy informatics

Introduction to pharmacy informatics, role of informatics to enhance the services provided by pharmaceutical care gives health information system architecture, health data management, medical coding and classification, medical databases, clinical data collection and aquisition and evaluation methods; privacy and security of clinical data, clinically relevant drug-drug interaction and databases, telemedicine and telehealth, ethics in medical informatics, pharmacy system and automation, drug information systems, electronic records, informatics application in pharmacy, survey and evaluation of online resources.

RECOMMENDED BOOKS :

1. Murthy,C.S.N., bioinformatics, Himalaya Publishing House, Mumbai, 2004.
2. Jogdond, S.N.,medical biotechnology, Himalaya Publishing House, Mumbai,2000.
3. Balasubramnian,D.,Boys,C.F.A.,Dharmalingam, K. J., Green and Kunthala Jayaraman, Concepts in biotechnology, Universities Press Hyderabad, 1996.

Syllabus Prescribed for Degree of Master of Pharmacy in Clinical Pharmacy

Semester-I

Advanced Analytical Techniques (MC-S1 & PC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MCP-S4

Subject: ADVANCED CLINICAL PHARMACY AND PHARMACOTHERAPEUTICS–I

THEORY:

60 Hours (4 hrs. /week)

Pathophysiology and clinical pharmacotherapy of diseases associated with following system;

1. Cardiovascular system

Hypertension, congestive cardiac failure, ischemic heart disease, myocardial infarction, arrhythmias, hyperlipidemias.

2. Respiratory system

Asthma, chronic obstructive airways diseases, drug acting on pulmonary diseases.

3. Hematological diseases

Anemia's deep vein thrombosis, drug induced hematological diseases.

4. Arthritic diseases

Rheumatoid arthritis, osteoarthritis, gout, systemic lupus erythematosus.

5. Gastrointestinal system

Peptic ulcer diseases, reflux esophagitis, inflammatory bowel diseases, Hepatitis, jaundice, cirrhosis, diarrhea and constipation, drug induced liver diseases.

6. Pain management

Pain pathways, Analgesics and NSAID'S, neuralgias including herpetic, trigeminal and glossopharyngeal neuralgia.

7. Immunology

Autoimmunity – Definition, classification, mechanism of autoimmune disease, pathogenesis of autoimmunity, immunoglobulin.

8. Prescribing guidelines for

Pediatric patients, geriatric patients, pregnancy and breast feeding.

RECOMMENDED BOOKS :

1. Roger and Walker, Clinical Pharmacy and Therapeutics, Churchill Livingstone Publications.
2. Joseph T. Dipiro, Pharmacotherapy: A Path Physiologic Approach.
3. Robinson S. L., Pathologic Basis of Disease, sounders Publication.
4. Green & Harris, Pathology & Therapeutics for Pharmacist: A Basis for Clinical Pharmacy Practice, Chapman & Hall Publication.
5. Hefindal E.T., Clinical Pharmacy & Therapeutics, Williams & Wilkins Publication.
6. Young L. & Kimble K., Applied Therapeutics: The Clinical Use of Drugs, MA (ISBN-033-65881-7).

7. Avery's Drug Treatment, 4th Edition, Adis International Ltd. 1997.
8. Scott L. T., Basic Skills In Interpreting Laboratory Data, American Society of Health System Pharmacist.
9. Practice Standards & Definitions- The Society Of Hospital Pharmacist Australia 1997.
10. Rowland & Tozer, Clinical Pharmacokinetics, Williams & Wilkins Publications.
11. Shargel L., Biopharmaceutics & Applied Pharmacokinetics, Printice & Hall Publications.
12. Relevent Review Article from Recent Medical & pharmaceutical Journals.

Subject code: MCP-P4

Subject: ADVANCED CLINICAL PHARMACY AND PHARMACOTHERAPEUTICS-1

Practical:

8 hrs. /week

Following aspect should be studied in detail in each ward round. Patient medication history in the review, answering drug information questions, patient medication counseling, in ward round. Case presentation should be done in the department. The cases being studied and the follow up studies should be recorded in the practical record books

1. Answering drug information related questions (Queries related to dosage, administration, contraindication, adverse drug reactions, drug interaction, drug used in pregnancy & lactation, drug profile, efficacy & safety)
2. Patient Medication counseling (common diseases like diabetes, asthma, Hypertension, TB, COPD)
3. Case studies related to laboratory investigation (Hematology, thyroid, renal, cardiac enzymes) Patient medication interview, medication review, detection & assessment of adverse reactions & their documentation.
4. The case presentation in the department should include cases of the following diseases.

Diabetes Type I	Schizophrenia
Diabetes Type II	Depression
Hyperthyroidism	Anxiety
Hypothyroidism	Epilepsy
Acute Renal Failure	Parkinsonism
Chronic Renal Failure	

The students should be trained in the following aspects of services provided at the hospitals and should be assessed for their performance on the same. The students are required to submit a record of activities performed which includes the strategies used.

- Patient medication interviews
- Answering drug information queries
- Patient medication counseling
- Literature evaluation
- Therapeutic drug monitoring
- Problem solving in clinical pharmacokinetics
- Ward round participation
- Medication order review
- Detection & Assessment of adverse reactions & their documentation

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MCP-S9

**Subject: ADVANCED CLINICAL PHARMACY AND
PHARMACOTHERAPEUTICS – II**

THEORY:

60 Hours (4 hrs. /week)

Pathophysiology and clinical pharmacotherapy of diseases associated with following system;

1. Renal System: Acute/ chronic renal failure, renal dialysis & transplantation, drug induced renal diseases
2. Central Nervous System: Ischemia, Headache, Epilepsy, Parkinsonism.
3. Endocrine System: Thyroid disease, oral contraceptives, hormone replacement therapy, osteoporosis.
4. Psychiatric diseases: Schizophrenia, depression ,anxiety, sleep disorder, drug induced psychosis
5. Infectious diseases: General guidelines for the rational use of antibiotics, meningitis, respiratory tract infections ,gastroenteritis, bacterial endocarditis septicemia, otitis media, urinary tract infection, tuberculosis, leprosy, malaria, helmentiasis, HIV and opportunistic infections, fungal infection ,rheumatic fever
6. Neoplasia: General principles of cancer chemotherapy of lung cancer, cytological malignancy, management of nausea and vomiting.
7. Drug and poison information

Introduction to information resources available

1. Systematic approach in answering drug information queries.
2. Critical evaluation of drug information and literature
3. Preparation of written and verbal reports.
4. Establishing a drug information center.
5. Poison information organization and information resources.
6. Poison management in drug dependence and drug abuse(opiates,cocaine,amphetamines,alcohol,benzodiazepines,barbiturates,tobacco) Role of emetics, anti-emetics and respiratory stimulants
8. Clinical Pharmacokinetics: Clinical pharmacokinetics models, physiological determination of drug clearance and volume of distribution, renal and non-renal clearance, organ extraction and models of hepatic clearance ,estimation and determination of bioavailability, multiple dosing, calculation of loading and maintenance dose, dose adjustment in renal failure, hepatic dysfunction, gastric and pediatric patient, therapeutic drug monitoring (general aspects).
9. Research design and conduct of clinical trials: research support including planning and execution of clinical trials, guidelines for good clinical research practice and ethical requirement, various phases of clinical trials, categories of phase IV studies, monitoring and auditing of clinical trials.

RECOMMENDED BOOKS :

1. Roger and Walker, Clinical Pharmacy and Therapeutics, Churchill Livingstone Publications.
2. Joseph T. Dipiro, Pharmacotherapy: A Path Physiologic Approach.
3. Robinson S. L., Pathologic Basis of Disease, sounders Publication.
4. Green & Harris, Pathology & Therapeutics for Pharmacist: A Basis for Clinical Pharmacy Practice, Chapman & Hall Publication.
5. Hefindal E.T., Clinical Pharmacy & Therapeutics, Williams & Wilkins Publication.
6. Young L. & Kimble K., Applied Therapeutics: The Clinical Use of Drugs, MA (ISBN-033-65881-7).
7. Avery's Drug Treatment, 4th Edition, Adis International Ltd. 1997.
8. Scott L. T., Basic Skills In Interpreting Laboratory Data, American Society of Health System Pharmacist.
9. Practice Standards & Definitions- The Society Of Hospital Pharmacist Australia 1997.
10. Rowland & Tozer, Clinical Pharmacokinetics, Williams & Wilkins Publications.
11. Shargel L., Biopharmaceutics & Applied Pharmacokinetics, Printice & Hall Publications.
12. Relevent Review Article from Recent Medical & pharmaceutical Journals.

Subject code: MCP-S10

Subject: CLINICAL RESEARCH

THEORY:

60 Hours (4 hrs. /week)

1. **Overview of clinical research**

Clinical research, the drug development process, phases of clinical research, elements of clinical research and the role of clinical research coordinator in clinical research, the study work area and resources.

2. **FDA regulations and good clinical practice guidelines**

Code of federal regulations (CFR), ICH GCP guideline, responsibilities of investigators, responsibilities of sponsor, financial disclosure by clinical investigators, electronic signature, the institutional review board, subjects informed consent, regulatory references.

3. **The study: Planning stages and commencement**

Protocol development, the planning stages of a study, study commencement, keeping up with the study, study termination.

4. **Interactions with the sponsor**

Sight monitoring visits, resolution of problems identified at site visits, grant – sponsored visits (audits and inspections), telephone monitoring, written correspondence, investigator's meetings, study procedures manual.

5. **Interactions with the institution**

The principle investigator and subinvestigators, the institutional review board, study logistics, preparing hospital staff.

6. **The role of the study subject**

The subject, study subject recruitment, obtaining informed consent, assessing subjects for study participation, keeping the subject on the study/ facilitating compliance ,

determining noncompliance, subject leaving the study, what is an evaluable subject?, subject compensation, subject and medical team relationship.

7. Data management

General issues in developing forms for data collection, recording data and completing case report forms, source documents, analyzing the data, reporting the data.

8. Adverse events

Adverse events, assessment of adverse events, recording adverse event data, medical management of adverse events, unblinding the study because of an adverse event, serious adverse events.

9. Investigational agent management

Investigational drug agents in a clinical trial, code breakers, study drug labels, receiving and storing the investigational agent, dispensing the investigational drug agent, instructions to study subjects, study drug accountability, destruction of the investigational drug agent, final disposition.

10. Inspection of clinical research sites

Preparing for an inspection, the data audit, end of the inspection.

RECOMMENDED BOOKS:

1. Avery's Drug Treatment, 4th Edition, Adis International Ltd. 1997
2. Scott L. T., Basic Skills In Interpreting Laboratory Data, American Society of Health System Pharmacist
3. Practice Standards & Definitions- The Society Of Hospital Pharmacist Australia 1997
4. Rowland & Tozer, Clinical Pharmacokinetics, Williams & Wilkins Publications
5. Shargel L., Biopharmaceutics & Applied Pharmacokinetics, Printice & Hall Publications
6. Relevent Review Article from Recent Medical & pharmaceutical Journals.

Subject code: MCP-P9

Subject: ADVANCED CLINICAL PHARMACY AND PHARMACOTHERAPEUTICS-II

Practical:

8 hrs. /week

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Subject code: MCP-P10
Subject: CLINICAL RESEARCH
Practical:

8 hrs. /week

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Semester-III

Subject code: MCP-S13

Subject: COMMUNITY AND CLINICAL PHARMACY

THEORY:

60 Hours (4 hrs. /week)

Community Pharmacy:

1. The role of community pharmacy and its relationship to other local health care providers
2. Prescribed medication order – Interpretation & legal requirements communication skills-communications with prescriber and patients, over the counter (OTC) sales.
3. Primary health care on Hospital Pharmacy – Family planning, first aid, participation in primary health care programs, smoking cessation, screening programs.
4. Community Pharmacy Management – Financial Materials, Staff infrastructure requirements, drug information, resources & computers.
5. Code of ethics for community pharmacist
6. Pharmacoepidemiology – Definition & scope, methods (Source of Data, study design, drug utilization studies, meta-analysis) social culture, economic factor influencing drug use. System for monitoring drug effects. Advantages & disadvantages of pharmacoepidemiology.
7. Pharmacoeconomics: Definition & scope, types of economic evaluation, cost models & cost effectiveness analysis.
8. Nutrition: Mal nutrition & deficiency states, enteral & parenteral nutrition.
9. Introduction to clinical pharmacy – Definition, development & scope, introduction to pharmaceutical medicine, the drug development process, new drug discovery, clinical development of drugs, essential clinical trial documents.
10. Introduction to daily activities of a clinical Pharmacist – Drug therapy monitoring (medication chart review, clinical review, pharmacist intervention), ward round participation, adverse drug reaction management & pharmacovigilance, drug information & poison information, medication history, patient counseling, pharmaceutical care, drug utilization (DUE) & review (DUR), Quality assurance of clinical pharmacy services.
11. Patient data analysis – Patient case history, its structure and use in evaluation of drug therapy and understanding, common medical abbreviations & terminologies used in clinical pharmacy, communication skills including patient counseling techniques, medication history, interview presentation of cases, teaching skill, clinical laboratory test used in evaluation of disease state & interpretation of test results like: Hematological, liver function, renal function, thyroid function test associated to cardiac disorder, fluid & electrolyte balance, microbial culture sensitivity test, pulmonary function test.

RECOMMENDED BOOKS :

1. Hassen W.E., Hospital pharmacy, Lec & Febiger Publications.
2. Textbook of Hospital Pharmacy, Allwood M C & Blackwell.
3. Avery's Drug Treatment, 4th Edition, Adis International Ltd. 1997.
4. Scott L. T., Basic Skills in Interpreting Laboratory Data, American Society of Health System Pharmacist.

5. Practice Standards & Definitions- The Society Of Hospital Pharmacist Australia 1997.
6. Rowland & Tozer, Clinical Pharmacokinetics, Williams & Wilkins Publications.
7. Shargel L., Biopharmaceutics & Applied Pharmacokinetics, Printice & Hall Publications.
8. Relevent Review Article from Recent Medical & pharmaceutical Journals.

Syllabus Prescribed for Degree of Master of Pharmacy in Natural Product

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MNP-S4

Subject: INDUSTRIAL PHARMACOGNOSY

THEORY:

60 Hours (4 hrs. /week)

1. Factors influencing production of crude drugs. Plant growth regulators, Disease management of medicinal and aromatic plants.
2. Commercial cultivation technology and post-harvest care of following medicinal plants Ashwagandha, Neem, Liquorice, Aloe, Guggul, Medicinal Yams, Ergot, Belladonna, Senna, Opium, Psyllium, Steroid bearing Solanums, Ammi majus, Ipecac, Henbane, Digitalis, Saffron.
Commercial scale cultivation and processing of following aromatic plants-Lemon grass, Geranium, Basil, Palmarosa, Vetiver, Patchouli, Japanese Mint, Rose, Hops, Jasmine, Sandal, Dill, Celery, Anise, Artemisia.
3. Extraction and Utilization of Biomedicinals:
Occurrence, Methodology for extraction and Chemistry of following- Sennosides, Digoxin, Ginsenosides, Solasodine, Berberine, Quinine, Scopolamine, Atropine, Emetine, Ergot alkaloid, Caffeine, Taxol, Withanolides, Podophyllotoxin, Rutin, Hesperidin, Andrographolide, Glycyrrhizin, Cod-liver oil and Shark-liver oil
4. Pharmaceutical aids: Profile for manufacture and commerce of papain, pectin, pharmaceutical gums, starch, absorbent cotton and gelatin.
5. Phytochemical screening of crude drugs: General methods of isolation, purification, identification and estimation of phytoconstituents. Various chromatographic techniques, U.V., TLC, GLC, HPLC and HPTLC, Spectrometry, Fluorimetry and Colorimetry for evaluation.
Preparation of standardized extracts suitable for incorporation in solid dosage forms like tablets, capsules, etc.
6. Herbal formulations: Types of herbal formulations. Recent trends in poly-herbal medicines. Herbal cosmetics and herbal teas. Manufacture, Packaging and approach to quality control of herbal formulations. GMP for herbal drug formulations.

RECOMMENDED BOOKS :

1. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons Limited, New Delhi.
2. Advances in Natural Product Chemistry, extraction and isolation of biologically active compounds. S. Natori et al., Wiley, New York.
3. Phytochemical methods by J.B. Harborne, Chapman and Hall, International Ed., London.
4. Modern methods of plant analysis by Peach and Tracey, Vol. II, IV, Springer Verlag.

5. G.E. Trease and W.C. Evans., Pharmacognosy, W.B. Saunders Co. Ltd., Harcourt Publishers Ltd. UK.
6. Chaudhari R.D., Herbal Drug Industry, Eastern Publication.
7. Quality Control Methods for medicinal plant material, WHO Geneva.
8. Wagner H, Blatt S, 1996. Plant Drug Analysis- A Thin Layer Chromatography Atlas, 2nd Ed., Springer-Verlag, Berlin.
9. Stahl Egon, Thin layer chromatography, 2nd Edition, Springer Publication.
10. Mukherjee PK, 2003. GMP for Indian system of medicine. In GMP for Botanicals. Verpoorte R, Mukherjee PK (Edn.), Business Horizons Limited, New Delhi.
11. Herbal Drug technology by SS Agrawal and M Paridhavi, Orient Longman
12. Indian Herbal Pharmacopoeia, Vol. I- II, SS Handa, RRL Jammu Tawi, and IDMA Mumbai.
13. The Aurvedic Pharmacopoeia of India, 1999. Government of India, Ministry of Health and Family Welfare, Department of Indian Systems of Medicine and Homeopathy, New Delhi.
14. Standardization of Botanicals by V. Rajpal, Vol. I and Vol II, Eastern Publishers, New Delhi.
15. Practical Evaluation of Phytopharmaceuticals by K.R. Brain and T.D. Turner, Wright-Scientific, Bristol.
16. Houghton P, Mukherjee PK. Evaluation of Herbal Medicinal Product, Pharmaceutical Press, London, 2009

Subject code: MNP-P4

Subject: INDUSTRIAL PHARMACOGNOSY

Practical:

8 hrs. /week

1. Preliminary phytochemical screening of the plant constituents.
2. Extraction of active principles such as alkaloids, glycosides, resins, essential oils, terpenoids, fixed oils, carbohydrates, fats, tannins, steroids, pectins, etc. from natural drugs.
3. Extraction, isolation, purification and identification of important phytoconstituents as follows:
 - a. Eugenol from clove oil
 - b. Sennosides from Senna leaves
 - c. Curcumin from Turmeric
 - d. Glycyrrhizin from Liquorice
 - e. Hesperidine from Orange peels
 - f. Caffeine from Tea
 - g. Strychnine and Brucine from Nux-Vomica
 - h. Rutin from Ruta graveolens
 - i. Aloin from Aloes
 - j. Piperine from Pepper
 - k. Quinine from cinchona bark
 - l. Berberine from Berberis aristata
 - m. Diosgenin from Dioscorea
4. Determination of lead, arsenic, copper, mercury, etc. from natural drugs or their preparations.

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MNP-S9

Subject: NATURAL PRODUCTS & BIO-ORGANIC CHEMISTRY

THEORY:

60 Hours (4 hrs. /week)

1. Marine natural product: Chemistry and biology of marine natural products, marine chemical ecology, marine bioactive compounds and marine toxins from bacteria, micro algae, rhodophyta, chlorophyteporifera, ascidians, corals, nudibranchs. Biosynthesis of marine natural product. Recent developments in natural product chemistry of plant and microbial source.
2. Carbohydrates: Mono, di, oligo- and polysaccharides, separation and isolation, purification, structure determination, linkage stereochemistry, biological activity.
3. Glycoproteins, lipoproteins and glycopeptidolipids; Structure and biological activity, isolation, purification, degradation, structure determination.
4. Glycosides and saponins: Classification, separation and isolation, linkages stereochemistry, structure determination, biological activity, study of examples.
5. Alkaloids, steroids and triterpenoids: Classification, methods of isolation, stereochemistry, biological activity, general theory of biogenesis.
6. Coumarins, lignans and flavonoids classification, isolation, stereochemistry, biological activity, biosynthesis.
7. Lipids and terpenoids: Classification, identification, biological activity, study examples.

RECOMMENDED BOOKS :

1. Vardemme, E., Biotechnology of Industrial antibiotics.
2. Vapporte and Swendson, Chromatography of Alkaloids.
3. Lala, P.K., Elements of Chromatography.
4. Srivastava, V.K. and Kishore, K., Introduction to Chromatography Theory & Practicals.
5. Knevell, A. N., Jenkin Quantative Pharmaceutical Chemistry.
6. Moual, A. C., Clerk's Isolation & Identification of-drugs.
7. Finar, H., Organic chemistry, Vol II.
8. Guenther, E., The Essential Oil, Vol.I and IV, Van Nostrand Co.
9. Schwartz, J.C.P., Physical Methods in Organic Chemistry.
10. Creger, W., Techniques in Organic Chemistry.
11. Anderson, L. A., Herbal Medicines-Janne Barnes.
12. Kanfinan, P. B., Natural Products from Plants.
13. World Health Organisation, W.H.O., 2000.

14. Toms, G., Marine Pharmacognosy in Chemotaxonomy of the Leguminous Ed. Harborne, Boulter and Tuner, Academic press.
15. Fransworth, N. It S., Some Hallucinogenic and Related Plants.
16. Iliis, Pergamon, Recent Development in the Chemistry of Natural Phenolic Compounds, 1961.
17. Harborne J.B., Phytochemical methods, Chapman and Hall.
18. Asolkar, Diosgenin and Other Steroidal Drug Precursors.
19. Welnsted, M.I. and Wagman, G.H., Antibiotics, Isolation & Seperation.
20. Butt, W.R., Hormone Chemistry.
21. Gorog, S., Quantitative Analysis of Steroid.
22. Feiry & Feisher, Steroids.
23. Pelletier, S.W., Alkaloids Chemical & Biological.

Subject code: MNP-S10

Subject: STANDARDIZATION OF NATURAL PRODUCTS

THEORY:

60 Hours (4 hrs. /week)

1. Stability testing of natural products, procedures, predictable chemical and galencial changes, technical limitations, testing methods and combination products.
2. Bioavailability and pharmacokinetics aspects for herbal drugs with examples of well known documented clinically used herbal drugs. Phytoequivalence, pharmaceutical equivalence.
3. World Health Organisation guide lines for herbal drugs including standards for pesticide residue/aflatoxins. Current status of regulatory affairs for herbal formulations.
4. Problems encountered in and prospects of discovering new drugs from plants. Natural substances as raw materials in drug synthesis. Biomedicinals of recent discovery.
5. Emerging plant drugs- Anti-hepatotoxic, anti-fertility, antimalarial, anti-hypertensive and antibiotic plants.
6. Current status of anti-cancer, anti-diabetic and immunomodulatory herbal drugs Bio-evaluation of herbal drugs.
7. Saponins and Terpenoids with biological activity of pharmaceutical significance. Recent trends in utilization of vegetable laxatives and vegetable bitters.
8. Natural coloring and sweetening agents.
9. Hallucinogenic, allergic, teratogenic and other toxic plants.
10. Endangered species of medicinal plants.
11. Drug and Pharmaceuticals from marine sources (Marine Pharmacognosy), with special reference to cardiovascular, cytotoxic, antimicrobial and anti-inflammatory compounds. Current status of plants on alternative system of medicines like Chinese, Ayurveda, Homeopathy, Unani and Siddha.

RECOMMENDED BOOKS :

1. Wagner and Black, Plant Drug Analysis.
2. Barn, J. N., Finley, D. J. and Goodwin, R. G., Biological Standardization.
3. Trease and Evans, Pharmacognosy.
4. Tyler, Bready and Robbers, Pharmacognosy.
5. Ramstad, Modern Pharmacognosy.
6. John, Dodds and Lorin, Experiments in Plant Tissue Culture.
7. Handa, S.S. and Kaul, K.I., Supplements to Cultivation and Utilization of Medicinal Plants.
8. Wealth of India. Raw Material, CSIR, Lucknow.
9. Quality Standards of Indian Medicinal Plants, Vol.1, ICMR, New Delhi.
10. WHO Guidelines for Quality Control of Herbal Plant Material.
11. Indian Pharmacopoeia, 2010
12. Ayurvedic Formulary of India,
13. British Herbal Pharmacopoeia, 1993.
14. Harborne, Comparative Biochemistry of Flavonoids.
15. Turner, R., Screening Methods of pharmacology.
16. Choudhary, R. D., Herbal Drug Industry, 1st Ed., Eastern Publisher, New Delhi, 1996.
17. Mukherjee, P. R., GMP for Botanicals-Regulatory and Quality Issues and Phytomedicines , 1st Ed., Business Horizons, 2003.
18. Pande, H., Herbal Cosmetics, Asia Pacific Business Press, New Delhi.
19. Pande, H., Herbal Perfumes and Cosmetics, National Institute of Industrial Research, New Delhi.
20. PDR for Herbal Medicines, 2nd Ed., Medicinal Economic Company, New Jersey, 2000.
21. Indian Herbal Pharmacopoeia, Vol I and II, RRL IDMA, 1998 and 2000.
22. Rangari, V. D., Pharmacognosy and Phytochemistry.

Subject code: MNP-P9

Subject: NATURAL PRODUCTS & BIO-ORGANIC CHEMISTRY

Practical:

8 hrs. /week

1. Determination of leaf surface data such as stomatal number, stomatal index, palisade ratio, vein-islet number and vein-islet termination number.
2. Experiments based on WHO guidelines for quality control of medicinal plants.
3. Preparation of permanent slides of important medicinal plants.
4. Study of spectroscopy and degradative methods for alkaloids, flavonoids, triterpenoids, sterols, coumarin (2-3 examples)

Subject code: MNP-P10

Subject: STANDARDIZATION OF NATURAL PRODUCTS

Practical:

8 hrs. /week

1. Determination of Anthracene derivatives in senna by spectrophotometric method, Reserpine in Rauwolfia by Photometric method, Carvone content of Umbeliferous fruits, Citral content in Lemongrass oil.
2. Determination of ascorbic acid by UV spectroscopic method in some crude drugs.
3. Paper chromatography and TLC of active principles of natural products.
4. Study of UV and FTIR spectral data of some phytoconstituents.
5. Separation of Solanaceous alkaloids from Belladonna leaf by TLC using hyoscyne and hyoscyamine as reference compounds.
6. Quantitative estimation of Ephedrine in Ephedra extracts by HPTLC method (only demonstration).
7. Quantitative estimation of Reserpine in Rauwolfia extracts by HPLC method (only demonstration).
8. Study of HPTLC and HPLC fingerprinting of some important phytoconstituents (only demonstration).

Semester-III

Subject code: MNP-S13

Subject: SELECTED TOPICS IN NATURAL PRODUCTS

THEORY:

60 Hours (4 hrs. /week)

1. Herbal formulations (general considerations); Single and composite drug formulation of various types; Ayurvedic formulations (Churn, Avaleh, Satwa, Asawa, Aristha etc); Formulations using herbal extracts/pure phytopharmaceuticals. Study of herbal extracts, Processing, Plant and equipment, Project profile, Standardization of herbal formulations.
2. Study of following pharmacognostic parameters -
Lycopodium spore analysis involving quantitation of discrete structures (starch, stone-cells), linear structures (fibers) and spread out tissues (epidermal area) and fluorescence analysis.
3. Study of following analytical methods (with the sole objective of quantitative analysis of active constituents and if needed, comparison with reference compounds)
 - i) Chromatographic methods of analysis (PC, TLC, HPTLC, HPLC & GLC)
 - ii) Colorimetric and fluorimetric methods
 - iii) Spectral methods (UV, Visible, IR, H-NMR and Mass)
4. Pesticide residues, heavy metal content and microbial contamination in the formulations. Preparation and standardization of herbal cosmetics. Shampoo, Hair conditioners, Hair dye, Skin care products.

RECOMMENDED BOOKS :

1. Choudhary, R. D., Herbal Drug Industry, 1st Ed., Eastern Publisher, New Delhi, 1996.
2. Verpoorte R. and Mukharjee, P. K., GMP for Botanicals-Regulatory and Quality Issues on Phytomedicine., 1st Ed., Business Horizons, New Delhi, 2003.
3. Pande, H., Herbal Cosmetics, Asia Pacific Business Press, New Delhi.
4. Pande, H., "The Complete Technology Book on Herbal Perfumes and Cosmetics", National Institute of Industrial Research, Delhi.
5. Mukhrjee, P. K., Quality Control of Herbal Drugs, 1st Ed., Business Horizons Pharmaceutical Publisher, New Delhi, 2002.
6. PDR for Herbal Medicines, 2nd Ed., Medicinal Economic Company, New Jersey.
7. Indian Herbal Pharmacopoeia, Vol I & II, RRI, IDMA.
8. Kokate, Purohit, Gokhale, Textbook of Pharmacognosy, 4th Ed., Nirali Pralcashan, 1996.
9. Rangari, V. D., Text book of Pharmacognosy and Phytochemistry.
10. Wanger and Bladt, Plant Drug Analysis, 2nd Ed.
11. Barn, J.N., Finley D.J. and Goodwin, L.G., Biological Standardization.
12. Ayurvedic Pharmacopoeia, Vol. I, II and III, 1999.
13. Herbal Pharmacopoeia, Vol I & II, RRI, IDMA.
14. Silverstein, R.M. and Webster, F.X., Spectrometric Identification of Organic Compounds, John Wiley and Sons Inc.

Syllabus prescribed for Degree of Master of Pharmacy in Pharmaceutical Management

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MPM-S4

Subject : PHARMACEUTICAL MANAGEMENT-I (GENERAL AND PERSONNEL) THEORY: 60 Hours (4 hrs. /week)

- 1. Pharmaceutical Management:** Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling—a preliminary idea of concepts, processes and techniques.
- 2. Fundamental concepts** of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, accounting, auditing and budgetary control. Entrepreneurship development.
- 3. Understanding organizations:** Meaning, process, types of organization structures & departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labs.
- 4. Professional Managers:** Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.
- 5. Personnel Management:** Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.
- 6. Management of Industrial Relations:** Industrial disputes, settlement of disputes through various routes such as bargaining, etc.
- 7. Motivational aspects:** theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

RECOMMENDED BOOKS:

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo.
3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.
4. David R, Modern Management by Hempran.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.
7. Paul and Blanchard Kenneth, Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Prentice Hall of India, New Delhi
8. Richard. H. Hall, Organization Structure, Process and out comes Vth Edition
9. Harry A. Smith. ,Principles and Methods of Pharmacy Management IIIrd Edition
10. Harold Koontz, Heinz Weihrich, Management “Global Perspective” , Tata Mcgraw Hill.
11. P. C. Tripathi., Personnel Management and Industrial Relations.

Subject code: MPM-P4

Subject: PHARMACEUTICAL MANAGEMENT-I (GENERAL AND PERSONNEL)

Practical: 8 hrs.
/week

1. Case studies based on the topics mention in theory

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MPM-S9

Subject: PHARMACEUTICAL MANAGEMENT-II (PRODUCTION)

THEORY:

60 Hours (4 hrs. /week)

1. Production Management: Fundamentals of production, organization, economic policy, manufacturing economics, production capacities, production lines and job balancing, visible and invisible inputs, methodology of activities. Development of efficient work methods, quality control and management of R&D.

2. Production planning and control, production processes - mass, job and project; plant location and layout; work study (preliminary idea only), materials management- purchase, inventory control and store keeping.

3. Productivity management: Concepts, problems, tools and techniques for improvement. Operation research techniques by PERT and CPM.

Considerations for design of large scale manufacturing units including intricate design criteria for units to manufacture sterile and non-sterile products with special reference to tablets, capsules, and injections.

Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non-sterile dosage forms.

Warehousing design, construction, maintenance and sanitation; good warehousing practice, materials management.

4. Product Planning: Selection of product, new product development and product differentiation, pricing, promotion – personal selling; salesmanship, qualities of salesman, management of sales force, advertising, publicity and window display, channels of distribution.

5. Plant Maintenance Management: Importance of maintenance, objective, classification-corrective, scheduled, preventive, and predictive. Replacement analysis.

6. Documentation and Records: Material identification system codes, Master formula records, Master and Batch production and control records. Equipment cleaning and use of Log book, Record relating to container, closure and labeling, production record review, distribution records, Complaints files.

RECOMMENDED BOOKS:

1. Management by Tripathi P. C. and Reddy P. N.; Tata Mc Graw Hill.
2. Business Organization and Management by Shukla M. C.; S. Chand and Company.
3. Business Organization and Management by Sherlakar S. A.; Himalaya.
4. Personnel Management by Filippo E. B.; McGraw Hill.
5. Organizational Behavior by Rao and Narayan; Konark Publishers.
6. Personnel Management by Tripathi P. C.; S. Chand and Company.
7. Pharmaceutical Production and Management by C.V.S. Subrahmanyam, Vallabh Prakashan.
8. Production and Operations Management by S.N.Chary

Subject code: MPM-S10

Subject: PHARMACEUTICAL MARKETING MANAGEMENT

THEORY:

60 Hours (4 hrs. /week)

- 1. Marketing:** Meaning, concepts, importance and emerging trends; Marketing environment; Industry and competitive analysis, Indian Pharmaceutical Industry; Analysing consumer buying behaviour; industrial buying behaviour, Pharmaceutical market segmentation & targeting. Mix Role of 7 P's (Product, Price, Promotion, Place, Physical Evidence, Process, People) in Pharmaceutical Marketing Management,
- 2. Product Decision:** Meaning, Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.
- 3. Pricing:** Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).
- 4. Pharmaceutical marketing channels:** Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.
- 5. Promotion:** meaning ,methods, determinants of promotional mix, promotional budget; overview-personal selling, advertising, sales promotion and public relations.
- 6. Strategic marketing planning:** Marketing implementation and evaluation.
- 7. E-Pharma Marketing.**
- 8. Marketing Research:** Definition and importance, Pharmaceutical Marketing Research techniques, marketing information system, pharmaceutical marketing research area.
- 9. Market Demands and Sales Forecasting:** Major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales, forecasting.

RECOMMENDED BOOKS:

- 1) Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
- 2) Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC Graw Hill, New Delhi.
- 3) Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
- 4) Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
- 5) Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
- 6) Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, Indian Context,Macmilan India, New Delhi.
- 7) Shanker, Ravi: Service Marketing, Excell Books, New Delhi
- 8) Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.
9. Principle and Practice of Marketing in India by Memoria C. B.
10. Principles of Pharmaceutical Marketing By Mickey Smith C.B.S. Publications.
11. Marketing Hand Book Vol. II , Marketing Management by Edwin – E Bobrow, Mark – D. Bobrow.

Subject code: MPM-P9

Subject: PHARMACEUTICAL MANAGEMENT II (PRODUCTION)

Practical: 8 hrs. /week

1. Case studies based on the topics mention in theory

Subject code: MPM-P10

Subject: PHARMACEUTICAL MARKETING MANAGEMENT

Practical: 8 hrs. /week

1. Case studies based on the topics mention in theory

Semester-III

Subject code: MPM-S13

Subject: PHARMA PRODUCT MANAGEMENT

THEORY:

60 Hours (4 hrs. /week)

- 1. Introduction to product management:** Definition, role of management and scope of product management.
- 2. Product planning and development:** Meaning of product, classification of pharma products, strategic planning for segmenting, targeting and positioning pharma product, product research and need gap analysis and health services. Operational pharma product planning including pharma sales program and budgeting, organizing and controlling for pharma product management.
- 3. New product development process and methods:** types of new pharma products, complete product development process, product innovation, new product adoption and diffusion process, opinion leadership.
- 4. Pharma product mix strategies:** product portfolio management strategies, product mix, and product line strategies, decision regarding buying and making new product. Product life cycle, strategies: Domestic pharma product life cycle and international pharma product life cycle; stages and strategies for each stage. R and D management for new product development.
- 5. Brand, packaging, and other pharma product feature:** pharma branding process and strategy, OTC generic and prescription product branding. Packaging and labeling, legal and social consumer reports for different kind of packaging and labeling design control of spurious products.
- 6. Pharma product pricing issues:** Social, economic, legal, ethical issues for pharma product pricing in India. Pricing methods and techniques. Other factors influencing pharma product pricing.
- 7. Pharma product distribution management:** pharma product channel design, single channel v/s multiple channel strategies, roles, and responsibilities of chemist for product promotion and distribution.
- 8. Pharma product promotion:** issues in pharma product promotion, approaches for pharma product promotion, DTC, E-detailing, physician related promotion programmes for increasing acceptance and sales of pharma products.
- 9. Pharmaceutical Brand Management:** Branding and its potential within pharmaceutical industry: history, meaning, need, importance, branding in pharmaceutical industry, building brand values and brand strategy, timing, patient power, strategic brand management process. The role of advertising in branding pharmaceuticals.

RECOMMENDED BOOKS:

1. Aswathappa, k., Organizational Behavior, Himalaya Publishing House, Revised and Enlarge edition, 1994.
2. Luthans, F., Organizational Behavior, Mc-Graw Hill, International Edition.
3. Rao, S.S.V., Human Resource Management and Industrial Relation, Himalaya Publishing House, I edition 1997.
4. Kumar, K., Human Resource management, I edition, 2001.
5. Harrison, T., The Product Manager's Hand book , Published kogan Page London, paperback Edition 1997.
6. Ahiya, K.,K., Material Management, CBS Publishers and Distributors, 1992.
7. Udupa, N., Selected Topic in Industrial Pharmacy, Verghese Publishing House, II edition 1992.
8. Mickey C. Smith, Principles of Pharmaceutical Marketing, Second Edition, Published by Lea Febiger. 1975,
9. Smarta, R, B., Revitalizing the Pharmnaceutical Business, Innovative Marketing Approaches 1st Edition, 1999, Response Books (Sage Publications)

Elective Subjects:

Group A: Pharmaceutics, Industrial Pharmacy, Biotechnology

1. Advanced biotechnology
2. Advances in Fermentation Technology
3. Hospital and Clinical pharmacy
4. Nanotechnology and Biotechnology
5. Pharmaceutical Plant Design and Operations
6. Sterile Product Formulation and Technology

Group B: Pharmaceutical Chemistry

1. Chemistry of Natural Products
2. Chemoinformatics
3. Combinatorial Chemistry
4. Green Chemistry
5. Organic Drug Synthesis
6. Rational Drug Design

Group C: Pharmacology, Clinical Pharmacy

1. Advance Molecular Biology
2. Clinical Research and Development
3. Immunopharmacology
4. Neurobiology
5. Pharmacoepidemiology
6. Safety Pharmacology

Group D: Pharmacognosy, Natural Products

1. Advances in Phytochemistry
2. Herbal Cosmetics
3. Herbal Drug Technology
4. Medicinal Plant Biotechnology
5. Natural Product Management
6. Plant Tissue Culture Techniques

Group E: Quality Assurance, Pharmaceutical Management, Pharmacoinformatics

1. Active Pharmaceutical Ingredients (APIs) Management Technology
2. Human Behaviour in Organization
3. Material Management and Inventory Control
4. Packaging Technology
5. Pharmaceutical Marketing and Market Research
6. Quality Planning and Analysis

Draft Syllabus Prescribed for M. Pharm. (Credit System) - Elective Subjects

GROUP A: PHARMACEUTICS, INDUSTRIAL PHARMACY, BIOTECHNOLOGY

Subject code: MPHE1

Subject: ADVANCED BIOTECHNOLOGY

Theory:

30 Hours (2 hrs./week)

1. **Biomembrane and Bioenergetics:** Introduction to Biological Membranes: Historical development of the concept of unit membrane. Diversity of membrane composition. Membranes in different organelles. Unified concept of membrane in terms of biological functions.
2. **Molecular Organisation in Biomembranes:** Role of lipids and proteins. Artificial membrane like structures. Liposomes, Stability of bilayer, Semifluidity and temperature transition. Singer-Nicholson model. Asymmetry in membrane constituents. Molecular motion in biomembrane. Hydrophobicity of membranes. Physico chemical probes in membrane studies.
3. **Membrane Functions:** Barrier to prediffusion, specific transport mechanism, passive carrier mediated, active, translocation. Transport of proteins. Molecular mechanism of active transport. REC membrane and glucose transport, lactose transport in bacteria. Membrane proteins and recognition. Insulin and other hormone receptors. Receptors for neurotransmitters, Adenyl cyclase.
4. **Energetics:** Classical thermodynamics, Irreversible thermodynamics, on sagar matrix, coupling open systems, equilibrium and other equilibrium conditions. Central role of ATP. High energy compounds. Oxidation-reduction enzymes and electron transport chain. Oxidative phosphorylation. Structure of mitochondria- Mitochondrial vesicles. Mitochondria ATPase. Theories of oxidative phosphorylation. Chemiosmotic theory of Mitchell. Uncouplers. Innophores Protein gradient and energy generation. Transmembrane potential. Energy trapping in closed vesicle-natural or artificial.

RECOMMENDED BOOKS:

1. Reddish, Antiseptics, Disinfectants, Fungicides and Chemical and Physical Sterilisation, Lea and Febiger.
2. Rainbow and Rose, Biochemistry of Industrial Microorganisms, Academic Press.
3. MW Miller, 1961. The Pfizer Handbook of Microbial Metabolites. McGraw-Hill, Blakiston Division, New York.
4. Trevan and Others, Biotechnology, The Biological Principles, Tata McGraw Hill Co.
5. Wilman, Cells and Tissues in Cultures, Vol. 3, Academic Press.
6. MJ Pelczar, Jr. ECS Chain, NK Kreig, 2008. Microbiology, McGraw Hill Edition, New York.
7. H W DOELLE, 1975. Bacterial Metabolism (2nd Edition). New York-San Francisco-London 1975, Academic Press.

Subject code: MPHE2

Subject: FERMENTATION TECHNOLOGY

Theory:

30 Hours (2 hrs./week)

- 1. Introduction:** General review of microbial products and processes. Bacterial starter cultures, different types of microorganisms used in the industries for the production of various microbial products e.g. bacteria, actinomycetes, fungi, yeast etc.
- 2. Screening of Cultures:** Isolation, identification and preservation of culture, Development of strain: introduction, cell division (mitosis/meiosis), Mendelian genetics metabolic controls, mutational selection and classes of mutants, protoplast fusion, Recombination DNA technology.
- 3. Theory and design of aerobic fermentation:** Operations involved, importance of each process, value of the products, degree of asepsis required, nature of organism used, choice of equipment and its design, biochemical engineering problems in fermentation technology.
- 4. Bioreactors:** Introduction, oxygen transfer, gas liquid mass transfer in microbial growth and effect of mixing and non-mixing on O₂ uptake rate, effect of substance concentration, accumulation of product and temperature on growth and respiration rate, effect of temperature on specific death rate and its determination, various types of bioreactors-stirred tank, airlift, fluidized, microcarrier, membrane bioreactor, fluid bed and film bed bioreactor, mono chemostat model and effect of recycle concept of nonideal bioreactor. Design of steriliser, batch sterilisation of media, temperature-time profile and design calculation continuous, sterilisation of media, residence time concept. Types of cultures of micro-organism-batch continuous, semibatch, recycle reactor. Enzyme reactors-theory and limitation, film and floes, immobilised enzymes and cell reactors.
- 5. Downstream processing:** physical separation processes-solid-liquid systems, flocculation, coagulations, centrifugation, Equilibrium processes-distillation, drying and crystallisation. Rate processes-chromatography, membrane separation, reverse osmosis.

RECOMMENDED BOOKS:

1. Prescott and Dunn's Industrial Microbiology, 1981. Gerald reed 9Ed), Chapman & Hall; 4 Sub edition.
2. Stanbury and Whitaker, Principles of Fermentation Technology, Pergamon Press.
3. Peppier, Perlman, Microbial Technology, Vol. I and II, Academic Press.
4. Scragg, Biotechnology for Engineers, Biological System in Technological Processes, Ellis Horwood Limited.
5. Dechow, Separation and Purification Techniques in Biotechnology, Noyes Publications.
6. Asenjo, Separation Processes in Biotechnology, Marcel Dekker. Inc.
7. Fermentation Technology in Industries, B. V. Patel Education Trust.

Subject code: MPHE3

Subject: HOSPITAL AND CLINICAL PHARMACY

Theory:

30 Hours (2 hrs. /week)

1. Pharmacoepidemiology

Definition, Origin and evaluation of pharmacoepidemiology, aims and applications, need for pharmacoepidemiology. Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement.

Drug utilization review, surveys of drug use, case reports, case series, cross-sectional studies, cohort studies, case control studies, meta-analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

2. Clinical Pharmacokinetics and therapeutic drug monitoring

i) Clinical Pharmacokinetics

Introduction to clinical pharmacokinetics Nomograms and tabulations in designing dosage regimen, conversion from intravenous to oral dosing, determination of dose and dosing interval, drug dosing in the elderly and pediatrics and obese patients.

Pharmacokinetic drug interactions, Inhibition and induction of drug metabolism, Inhibition of biliary excretion.

ii) Therapeutic drug monitoring

Introduction

Individualization of drug dosage regimen (variability – genetic, age and weight, disease, interacting drugs). Indications for TDM, Protocol for TDM

Pharmacokinetic/Pharmacodynamic correlation in drug therapy TDM of drugs use in the following disease conditions: cardiovascular disease, CNS conditions.

iii) Dosage adjustment in renal and hepatic disease

Renal impairment. Pharmacokinetic considerations. General approach for dosage adjustment in renal disease. Measurement of glomerular filtration rate and creatinine clearance. Effect of hepatic disease of pharmacokinetics

3. Clinical Toxicology

General principles involved in the management of poisoning

Antidotes and their clinical applications. Supportive care in clinical toxicology

Gut decontamination. Elimination enhancement. Toxicokinetics

4. Clinical symptoms and management of acute poisoning with the following agents:

Pesticide poisoning: organophosphorus compounds, carbamates, organochlorines, pyrethroids Opiate overdose, Antidepressants, Barbiturates and benzodiazepines, Alcohol: ethanol, methanol, Paracetamol and salicylates, Non-steroidal anti-inflammatory drugs, Radiation poisoning

5. Clinical symptoms and management of chronic poisoning with the following agents:

Heavy metals: Arsenic, lead, mercury, iron, copper. Food poisoning

6. Hospital pharmacy – organization and management

Organisational structure – staff, infrastructure & work load statistics. Management of materials and finance. Roles & responsibilities of hospital pharmacist

The budget – Preparation and implementation

7. Hospital drug policy

Pharmacy and therapeutic committee (PTC); Hospital formulary; Hospital committees: Infection committee, Research and Ethical committee

8. Hospital pharmacy services

Procurement & warehousing of drugs and pharmaceuticals

Inventory control: definition, methods of inventory control, ABC, VED, EOQ, lead time, safety stock.

9. Drug distribution in the hospital

Individual prescription method. Floor stock method. Unit dose drug distribution method.

Distribution of Narcotic and other controlled substances. Central sterile supply services – role of pharmacist. Radio pharmaceuticals – handling and packaging.

RECOMMENDED BOOKS:

1. Malcolm Rowland & Thomas Tozer. Clinical Pharmacokinetics & Concepts and Applications Lippincott Williams & Wilkins 1995
2. Ellenhorn's Medical Toxicology – Diagnosis and treatment of poisoning. Mathew J. Ellenhorn. Williams and Wilkins publication, London. Second Edition
3. Hospital Pharmacy by William E. Hassan
4. Brian L. Strom, Stephen E. Kimmel. Textbook of Pharmaco-epidemiology. Wiley Drug Interactions. Stockley I.H. (1996). The Pharmaceutical Press
5. Toxicology - The basic science of poisons, international edition, Curtis D.Klaassen, 6th edition
6. Toxicology – Principles and Applications, Raymond J.M.Niesink, John de.Vries, Manfred A. Hollinger
7. Drug Interaction Facts, 2003. David S. Tatro.
8. Toxicology - The basic science of poisons, international edition, Curtis D.Klaassen, 6th edition.

Subject code: MPHE4

Subject: NANOTECHNOLOGY AND BIOTECHNOLOGY

Theory:

30 Hours (2 hrs. /week)

1. **Bionanotechnology:** History, opportunities and challenges of bionanotechnology, growth potential of bionanotechnology, significance of nanosize in biotechnology and medicine.
2. **New Drug Delivery:** Conventional delivery of biotechnologicals and its limitations, Biological barriers in delivery of therapeutics, importance of nano-size in site-selective delivery, Targeted delivery of biotechnological using nanoconstructs, Application of nanocarriers in delivery of biotechnologicals, Nano-drug delivery chip.
3. **Bionanocarriers:** Design and fabrications of nanocapsules, nanoliposomes, nanoparticles, nanoemulsion, Nanopore technology, Nano-self assembling systems, Bionanoarrays, Dendrimers, Carbon nanotubes, Nanosomes and Polymersomes, Inorganic nanoparticles (Gold-gold colloids, gold nanofilm, gold nanorods, Titanium and Zinc oxide), structured DNA nanotechnology.
4. **Nanomedicine Nanobiology and Nanobiotechnology:** Synthesis and assembling of nanoparticles/nanostructures using bio-derived templates, Proteins and nanoparticles,

covalent and non-covalent conjugates, Cantilevers array sensors for bioanalysis and diagnostics, Nanowire and nanotube biomolecular sensors for in-vitro diagnosis of cancer and other diseases. Biologically inspired hybrid nanodevices, Nanotube Membranes for Biotechnology, Shelf-assembling of short peptides for nanotechnological applications.

- 5. Bionanoimaging:** Quantum dots-luminescent semiconductor QD in cell and tissue imaging, Fluoroimmunoassay using QD. Ultrasound contrast agents, Magnetic nanoparticles, Nanoparticles in molecular imaging, Nanoforce and imaging-AFM, Molecules, cells, materials and systems design based on nanobiotechnology for use in bioanalytical technology.
- 6. Instrumentation and Principles:** Electrophoresis techniques, Laser confocal microscopy, Digital image analysis, Biosensors in diagnostics, Enzyme purification and assay techniques, techniques in cytogenetics: DNA sequencing, DNA microarray, Spectral analysis techniques: Introduction, estimation of proteins, DNA and RNA.
- 7. Safety Concern of Bionanotechnologicals:** Inhalation, Contact/dermal delivery, Environmental impact, Explosion hazards.

RECOMMENDED BOOKS:

1. E.S. Papazoglou and A. Parthasarathy, "Bionanotechnology". 1st Ed. Morgan & Claypool.
2. N.H. Malsch. 2005. "Biomedical nanotechnology" CRC Press.
3. D.S. Goodsell, 2004. "Bionanotechnology: lessons from nature" Wiley-Liss Publication.
4. T. Vo-Dinh, "Nanotechnology in biology and medicine: methods, devices, and applications" CRC Press.
5. V. Labhasetwar, D.L. Leslie-Pelecky, 2007. "Biomedical applications of nanotechnology". Wiley-Interscience: Hoboken.
6. S.P. Vyas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and controlled drug delivery" CBS Publishers and Distributors.

Subject code: MPHE5

Subject: PHARMACEUTICAL PLANT DESIGN AND OPERATIONS

Theory:

30 Hours (2 hrs. /week)

- 1. Regulatory Aspects:** Introduction, Key stages in drug Approval Process, Example of Requirement, Post-Marketing Evaluation, Procedures for Authorizing Medicinal Products.
- 2. Good Manufacturing Practice:** Introduction, GMP Design Requirement, GMP Reviews of Design.
- 3. Validation:** Introduction, Preliminary Activities, Validation Master Planning (VMP), Development of Qualification Protocols and Reports, Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), Handover and Process Optimization, Performance Qualification, (PQ), Process Validation (PV), Cleaning

Validation, Computer System Validation, Analytical Method Validation, Change Control and Revalidation.

4. **Primary Production:** Reaction, Key Unit Operation, Production Methods and Considerations, Principles for layout of Bulk Production Facilities, GMP.
5. **Secondary Pharmaceutical Production:** Products and Processes, Principles of layout and Building Design, The Operating Environment, Containment Issues, Packaging Operations, Warehousing and Material Handling, Automated Production Systems, Advanced Packaging Technologies.
6. **Safety, Health and Environment (SHE):** Introduction, SHE Management, System Approach to SHE, Risk Assessment, Pharmaceutical Industry SHE Hazards, Safety, Health and Environment Legislation.
7. **Design of Utilities and Services:** Introduction, Objective, cGMP, Design, Utility and Service System Design, Sizing of System for Batch Production, Solids Transfer, Cleaning System, Effluent Treatment and Waste Minimization, General Engineering Practice Requirements, Installation, In-House Versus Contractors, Planned and Preventive Maintenance.
8. **Laboratory Design:** Introduction, Planning a Laboratory, Furniture Design, Fume Cupboards, Extraction Hoods, Utility Services, Fume Extraction, Air Flow System, Safety and Containment.
9. **Process Development Facilities and Pilot Plant:** Introduction, Primary and secondary Processing, Process Development, Small Scale Pilot Facilities, Chemical Synthesis pilot plants, Physical Manipulation Pilot plant, Final formulation, Filling and packing pilot plants, Safety, Health and Environmental Reviews, Optimization.
10. **Pilot Manufacturing Facilities for the Development and manufacturing of Biopharmaceutical Product:** Introduction, Regulatory, Design and Operating Considerations, Primary Production, Secondary Production, Design of Facilities and Equipment, Process Utilities and Services.

RECOMMENDED BOOKS:

1. Pharmaceutical Manufacturing handbook: Production and processes, Edited by Shayne Cox Gad, John Wiley and Sons, Inc., New Jersey.
2. Pharmaceutical production: An Engineering Guide, Edited by Bill Bennett and Graham Cole, 2003, Published by Institute of Chemical Engineers, Warwickshire, UK.
3. Pharmaceutical production Facilities: Design and Applications, Edited by Graham Cole, second edition, Taylor and Francis, 2003.
4. Good pharmaceutical manufacturing practice: rationale and compliance, John Sharp CRC Press.
5. Modern pharmaceutical industry, Thomas Jacobson, Albert Wertheimer, Jones and Barlett publishers, LONDON, UK.
6. Ethics and Pharmaceutical industry, Michael Santoro, Thomas Gorrie, Cambridge university press, 2005, new York, USA.

Subject code: MPHE6

Subject: STERILE PRODUCTS FORMULATION AND TECHNOLOGY

Theory:

30 Hours (2 hrs. /week)

- 1. Biopharmaceutical Factors Influencing Bioavailability:** Physicochemical influences on bioavailability, Physiologic factors influencing drug absorption, Dosage form considerations, Drug absorption and bioavailability from intramuscular injection. Drug absorption from subcutaneous injection, Biopharmaceutics of intrathecal injections, Parenteral administration of peptides and proteins, Parenteral drug delivery systems.
- 2. Preformulation Research:** Introduction, Drug substance physicochemical properties, General modes of drug degradation, Preformulation studies for proteins and peptides, Preformulation screening of parenteral packaging components.
- 3. SVP and LVP:** Introduction to SVP, Formulation principle, Special types of parenterals (Suspension, Emulsion, Dried Forms), Container effect on formulation, Stability evaluation. Introduction to LVP, Concept of formulation, Formulation development, Solution Quality.
- 4. Sustained/Controlled Release Parenterals Drug products:** Biopharmaceutics, Biocompatibility of polymeric materials, Sustained/controlled release dosage forms: - Aqueous solutions, Aqueous suspensions, Oil solutions, Oil suspensions, Biocompatible carrier, Liposomes, Nanoparticles, Infusion devices, Prodrug.
- 5. Design Consideration For Parenteral Production Facility:** Introduction, Site selection, Facility area use planning, Design concepts.
- 6. Environmental control:** Introduction, Control of contamination, Environmental contamination control system design, Clean rooms, Personnel contamination control.
- 7. Quality Control:** Sterility testing, FDA guidelines on sterility testing, Pyrogen testing, Particulate matter testing, Package integrity testing.

RECOMMENDED BOOKS:

1. K. E. Avis, H. A. Liebermann and Lachman; Pharmaceutical dosage forms: Parenteral Medications: Vol.1, 2, 3, Marcel Dekker.
2. S. J. Turco Sterile Dosage Forms: their preparation and clinical application; 4th Edition. Lee and Febiger.
3. N. K. Jain; Controlled and Novel drug delivery: CBS Publication.
4. J. R. Robinson and H. L. Lee; Controlled drugs delivery: Fundamentals and Applications; Marcel Dekker.
5. S.P. Vyas and R. K. Khar, Controlled drug delivery: concepts and advances; Vallabh Prakashan.
6. M. J. Akers, Parenteral Quality Control. Third Edition. Marcel Dekkers.

GROUP B: PHARMACEUTICAL CHEMISTRY

Subject code: MPCE7

Subject: CHEMISTRY OF NATURAL PRODUCTS

Theory:

30 Hours (2 hrs. /week)

- 1. Alkaloids:** General introduction, classification, isolation and purification methods, general methods employed for determining the structure of alkaloids, constitution of morphine, reserpine, atropine and quinine.
- 2. Steroids:** Introduction, stereochemistry, nomenclature and structure elucidation of cholesterol, sapogenin and cardiac glycosides.
- 3. Amino acids and peptides:** Introduction, synthesis of peptides and amino acids. End group analysis, structural features of Insulin, vasopressin and oxytocin.
- 4. Carbohydrates:** Brief introduction, Configuration of monosaccharides, ring structure of monosaccharides, disaccharides – determination of structures of sucrose, maltose and lactose, Polysaccharides – cellulose and starch.
- 5. Flavonoids:** Detailed chemical account of rutin and quercetin.
- 6. Coumarins:** General methods of isolation and purification and structural determination of Xanthotoxin and psoralene.
- 7. Structure elucidation:** Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (^1H , ^{13}C).
 - i) Carvone, citral; menthol
 - ii) Luteolin; kaempferol
 - iii) Luteolin-7-O-glucoside
 - iv) Nicotine; papaverine
 - v) Estrone; progesterone

Note: In teaching unit – 7 the exact shift values need not be given. It is sufficient if the student is taught how many peaks appear for the compound in the NMR and approximately, in which region.

RECOMMENDED BOOKS:

1. I.L. Finar, Organic Chemistry, Vol.2, Stereochemistry and Chemistry of Natural Products 5th edition, Pearson - Pearson Education.
2. L.F. Fieser and M. Fieser, Steroids, Reinhold Publishing Co., New York.
3. K.B.G. Torsell, Natural Products Chemistry, John Wiley and Sons, New York.
4. J.B. Harborne, Phytochemical Methods, Chapman and Hall, London.
5. Burger's Medicinal Chemistry and Drug Discovery, Vol. I. Principle and Practice, 5th, Edition, John Wiley Sons, New York.
6. Wilson and Gisvold's Text Book of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Williams and Wilkins.
7. T.L. Lemke, D.A. Williams, V.F. Roche and S.W. Zfto, Foye's Principles of Medicinal Chemistry, 6th edition, Lippincott Williams and Wilkins.
8. M.L. Wickery and B. Wickery, Secondary Plant Metabolism McMillan Press Ltd. London.
9. G.A. Cordell, 1999, The Alkaloids, Vol. 52, Academic Press.

Subject code: MPCE2

Subject: Chemoinformatics

Theory:

30 Hours (2 hrs. /week)

1. Representation of chemical compounds

Chemical nomenclature, line notations, coding the constitution, processing constitutional information, different ways to represent molecular structure, representation of stereochemistry, representation of 3D structures, molecular surfaces, visualization of molecular models, molecular structure drawing softwares.

2. Representation of chemical reactions

Reaction types, reaction center, chemical reactivity, reaction classification, stereochemistry of reactions.

3. The data

Data acquisition, data preprocessing, preparation of data sets for validation of the model quality, training and test data sets, compilation of test sets.

4. Databases and data sources in chemistry

Basic database theory, search engine, classification of databases, literature databases, tutorial using chemical abstract system, property (numeric) databases, crystallographic databases, structure databases, chemical reaction database, patent databases, chemical information on the internet.

5. Calculation of physical and chemical data

Empirical approaches to the calculation of properties, molecular mechanics, molecular dynamics, quantum mechanics.

6. Calculation of structure descriptors

Structure descriptors and their classification, topological descriptors, 3D descriptors, chirality descriptors, chirality codes, comparative molecular field analysis.

7. Methods for data analysis

Machine learning techniques, Decision tree, chemometrics, neural networks, fuzzy steps and fuzzy logic, genetic algorithms, data mining, visual data mining, expert systems.

8. Applications

Prediction of properties of compounds, LFER, QSPR, structure spectra correlation, chemical reactions and synthesis design, drug design.

RECOMMENDED BOOKS:

1. Johann Gasteiger and Thomas Engel, 2003, Chemoinformatics-A Text Book, Wiley-VCH Verlag GmbH & Co. KGaA.
2. Hans Dieter Holtje, Wolfgang Sippl, Didier Rognan, Gerd Folkers, 2003, Molecular Modeling, Wiley-VCH Verlag GmbH & Co. KGaA
3. Jure Zupan, Johann Gasteiger, 1999, Neural Networks in Chemistry and Drug Design, Wiley-VCH Verlag GmbH & Co. KGaA.
4. <http://franklin.chm.colostate.edu/mmac>
5. A.R. Leach, Molecular Modeling- Principles and applications, 2nd edition, Pearson Education, Harlow, UK, 2001.
6. D.M. Cvetkovic, M. Doob, H. Sachs, 1995, Spectra of Graphs: Theory and Applications, 3rd edition, Johann Ambrosius Barth Verlag, Heidelberg.

Subject code: MPCE3

Subject: COMBINATORIAL CHEMISTRY

Theory:

30 Hours (2 hrs. /week)

1. Combinatorial chemistry – principles, methods, drug design and combinatorial methodology, possible limitations of combinatorial chemistry.
2. Organic reactions popular in combinatorial chemistry. This includes amide bond formation, amine alkylation, crosscoupling reactions, alkene metathesis, multicomponent reactions and heterocycle synthesis.
3. Solid-phase organic synthesis. The advantages offered by solid-phase synthesis. Methods for resin immobilization, compound cleavage and analytical methods for monitoring reactions.
4. Solution-phase parallel synthesis. Methods employing phase switching such as fluoruous tags. The applications of resin-bound reagents and scavengers for simplifying reaction workup.
5. Mixture-based compound libraries. Techniques for extracting information from highly pooled samples, including iterative deconvolution, positional scanning and bead-based screening. Methods for bead encoding.
6. Principles of compound library design. Lipinski's rules and other guidelines for drug like properties. The concept of privileged scaffolds, illustrated by benzodiazepines and arylindoles.
7. Natural product and natural product-like libraries. The differences between synthetic compounds and natural products, and methods for exploiting the latter as a source of molecular diversity.

RECOMMENDED BOOKS:

1. W Bannwarth & B Hinzen, *Combinatorial Chemistry, From Theory to Application*. Wiley-VCH Verlag GmbH & Co. KGaA., Vol. 26, 2006
2. P A Bartlett & R M Entzeroth, *Exploiting Chemical Diversity for Drug Discovery*, Royal Society of Chemistry, Vol. 24, 2006.
3. N.K. Terrett, *Combinatorial Chemistry*, Oxford University Press, Vol. 2, 1998.
4. Anthony W Czarnik, *Combinatorial Chemistry: Synthesis and Application*, A Wiley-Interscience Publication, 1997
5. Bing Yan, *Analytical Methods in Combinatorial Chemistry*, Technomic Publication Company, Vol. 6, 2000.
6. Benjamin L. Miller, *Dynamic combinatorial Chemistry in drug Discovery*, *Bioorganic Chemistry and Material Sciences*. Vol. 1-10, Hoboken, N.J. John Wiley & Sons Publication, 2010.
7. Gunther Jung, *Combinatorial Peptide and Non Peptide Library*, Wiley-VCH Verlag GmbH & Co. KGaA., 1996.

Subject code: MPCE4
Subject: GREEN CHEMISTRY
Theory:

30 Hours (2 hrs. /week)

1. Introduction

The costs of waste, the greening of chemistry and its need, specific health and environmental requirements,

2. Principles of sustainable and green chemistry

Green chemistry and industry, Waste minimization and atom economy, reduction of materials use, reduction of energy requirement, reduction of risk and hazard

3. Waste minimization in pharmaceutical process development

Principles, practice and challenges, focus of process chemistry, safety, increasing complexity, means of purification, choice of starting material, number and order of steps, solvents, reagents, reaction temperature, heavy metals.

4. Green solvents for chemistry

Solvent Usage, Global Effects of Solvent Usage, Chemical Properties of Solvents, Solvent Effects and Green Chemistry, Green Solvents and its definition, green solvents for academic and industrial chemistry, criteria for Selection of Green Solvents, green solvents: ecology and economics.

5. Extraction of Natural Products with Superheated Water

Properties of superheated water, extraction of other plant materials, chromatography with superheated water, process development, extraction with reaction.

6. Sonochemistry

Power ultrasound, apparatus available for sonochemistry, sonochemistry in chemical synthesis, ultrasound in electrochemistry, ultrasound in environmental protection and waste control, enhanced extraction of raw materials from plants, large-scale sonochemistry

RECOMMENDED BOOKS:

1. James Clark & Duncan Macquarie, Handbook of Green Chemistry and Technology, Blackwell Publishing
2. William M. Nelson, Green solvents for Chemistry: Perspectives and Practice, Oxford University Press
3. Anastas, P. T., & Williamson, T. C. Green Chemistry: Frontiers in Benign Chemical Syntheses and Processes. Oxford University Press, Oxford,
4. Repic, O. Process Research and Chemical Development in the Pharmaceutical Industry. John Wiley, New York,
5. Jones, D. G. Chemistry and Industry. Applications of Basic Principles in Research and Process Development. Oxford University Press, Oxford
6. Mason, T. J. Sonochemistry: the Uses of Ultrasound in Chemistry. Royal Society of Chemistry, London.

Subject code: MPCE5

Subject: ORGANIC DRUG SYNTHESIS

Theory:

30 Hours (2 hrs. /week)

1. High Throughput Synthesis

synthesis strategies; combinatorial synthesis techniques; library design; combinatorial approaches for reaction optimization, assays and screening of libraries.

2. Chiral Technology

Introduction to Chirality and Techniques used in asymmetric synthesis of Diltiazem, Timolol, Ampicillin, Dextrapropoxyphen, Citrenalol, Propranolol, Atenolol, and Naproxen.

3. Microorganisms in Drug Synthesis and Development

Microbial conversions of drugs like steroids, prostaglandin, antibiotics, enzyme immobilization Techniques.

4. Synthesis of agents used in neurodegenerative diseases: like Alzheimer's and Parkinsonism

5. Synthesis of agents used in treatment of AIDS: Life cycle of HIV and Drugs used.

6. Proteins and Peptide drugs:

Chemistry, structure, stability and reactivity of proteins and peptides. Different ways to synthesize proteins and peptides - study of Insulin, Relaxin, Somatostatin, DNase Interferon

7. Structure based drug design and synthesis

RECOMMENDED BOOKS:

1. Burger's Medicinal Chemistry and Drug Discovery, Vol. I. Principle and Practice, 5th, Edition, John Wiley Sons, New York.
2. Wilson and Gisvold's Text Book of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Williams and Wilkins.
3. T.L. Lemke, D.A. Williams, V.F. Roche and S.W. Zfto, Foye's Principles of Medicinal Chemistry, 6th edition, Lippincott Williams and Wilkins.
4. Daniel Lednicer, 2008, Strategies for Organic Drug synthesis and Design, John Wiley & Sons New York.
5. Stuart Warren, 2002, Organic Synthesis: The Disconnection Approach, John Wiley & Sons, Ltd.

Subject code: MPCE6

Subject: RATIONAL DRUG DESIGN

Theory:

30 Hours (2 hrs. /week)

1. DRUG DISCOVERY

- a. Historical Perspective
- b. Drug Discovery studies in Direct Drug Design (Structure based) ND Indirect Drug Design
- c. Target Selection and Lead Identification
Natural Product Sources
Fermentation/ microbial sources

Synthetic

d. Introduction to Pharmacogenomics.

2. A general study of co-relation of physicochemical properties and stereochemistry on drug action. Isosterism and bio-isosterism as guides to structural variations, metabolite, antagonism and theory of drug action.
3. An overall treatment of various approaches to drug design including the method of variation, e.g. – Fibonacci search, Topliss tree, Craigs plot, Simplex methods, and Cluster analysis.
4. Quantitative Structure-Activity Relationships (QSAR) with detail coverage of Hansch's Linear method, Free and Wilson methods, mixed approach, principal component analysis and application of above.
5. Drug design based on antagonism and enzyme inhibition.
6. Computer Aided Drug Design, Basic concept of computational chemistry like Quantum Mechanics, molecular mechanics, Force fields, Energy minimization, conformational reaction, Molecular Dynamics. Ligand based drug design based on active site of receptor/enzyme. Indirect Drug Design – Analog approach, Pharmacophore mapping, Template forcing, Excluded volume & shape analysis, artificial intelligence methods.
7. Drug metabolism based drug design: Pro-drug design.
8. Introduction to recent advances in drug design
9. Quantitative structure pharmacokinetic relationship (QSPR), Bioinformatics, Genomic & Proteomics.

RECOMMENDED BOOKS:

1. John Smith & Hywel Williams, Introduction to the Principles of Drug Design, Wright PSG.
2. Burgers Medicinal chemistry-The Basis of Medicinal chemistry by Manfred E. Wolff part-I John Wiley & Sons.
3. Edward. C. Olson, Computer Assisted Drug Design, American Chemical Society..
4. S. M. Roberts and B. J. Price. Medicinal Chemistry – The Role of Organic Chemistry in Drug Research by Principle's of Medicinal Chemistry – Foye.
5. Comprehensive Medicinal Chemistry by Hansch & Leo, Vol. 4.
6. QSAR & Strategies in the design of Bioactive Compound J. K. Seydel Latest after 1984 Deuts che Biblio fech.
7. Propst & Thomas, 1997, Nucleic Acid Targeted Drug Design, Marcel Decker.
8. Pandi veera Pandian, 1997, Structure Based Drug Design, Merck Decker,
9. Burger Alfred, 1997, A Guide to chemical Basis of Drug Design, Wiley Interscience.
10. Patrick Bultinck, 2004, Computational Medicinal Chemistry for Drug Design, 1st edition, Marcel Decker.

GROUP C: PHARMACOLOGY, CLINICAL PHARMACY

Subject code: MPLE1

Subject: ADVANCE MOLECULAR BIOLOGY

Theory:

30 Hours (2 hrs. /week)

1. Introduction to molecular biology.
2. Background: Mendel and genes; genetic terminology; genetic mapping. Cells and chromosomes. Discovery of the role of DNA; overview of how it fills that role. DNA structures. Protein structure; role of weak bonds. Mutations, an introduction.
3. Transcription. How RNA polymerase recognizes (and distinguishes) genes; promoters, σ (sigma) factors. Interaction of transcription and DNA supercoiling. Elongation and termination.
4. Gene regulation; DNA-protein interactions. Proteins interact with DNA and modulate its structure and function. The Lac operon paradigm, plus a sampling of other regulatory systems. Types of DNA-binding proteins; sequence recognition; DNA-bending.
5. Transcription in eukaryotes. An introduction to the complexity of the transcriptional apparatus in higher organisms.
6. Translation. Formation of initiation complex, prokaryotes and eukaryotes. Genetic code: standard and variations; recoding. The players mRNA, tRNA, activating enzymes, ribosomes, "factors".
7. DNA replication, DNA polymerases. Issues of the replication process: getting started, priming, unwinding the template, working accurately, hanging on, finishing and untangling. The replication apparatus, or replisome. Repair processes; topoisomerases.

RECOMMENDED BOOKS:

- 1 Harvey Lodish, Arnold Berk, Paul Matsudaira and James Darnel. Molecular Biology, W.H Freeman and company, 2000, 4th edition.
- 2 Bruce Albert, Molecular Biology of the cell, Garland Science, 2002, 3rd edition.
- 3 J.D.Watson. Molecular Biology of the Gene, Old spring harbor laboratory press, 2005.
- 4 B.R.Glick, J.J.Pasternak, Cheryl L. Patten. Molecular Biotechnology-Principles and Application of Recombinant DNA, American Society for Microbiology, Washington, 2006.
- 5 Jack J. Pasternack, An introduction to human molecular genetics-Mechanism of inherited disease. John Wiley and sons, 2005.
- 6 A.N.Glazer and H. Nikaïdo, Microbial biotechnology, Cambridge University press, 2007.
- 7 F.C. Neidhardt, Escherichia coli and Salmonella, cellular and Molecular Biology, American Society for Microbiology, Washington, 1987.
- 8 R.C.King. A Dictionary of Genetics, Oxford University press USA. 7th edition.
- 9 K.Drlica, Understanding DNA and Gene cloning-a guide for curious, Public Health Research Institute. 4th edition.

Subject code: MPLE2

Subject: CLINICAL RESEARCH AND DEVELOPMENT

Theory:

30 Hours (2 hrs. /week)

1. Introduction to clinical Trial

History, terminologies, types of clinical research, phases of clinical research, role of clinical trial in new drug developments

2. Regulatory affairs in clinical trials

IND, NDA, ANDA- Parts and contents, Safety monitoring boards, FDA in various countries including India

3. Ethical issues in clinical trials

Principle, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing), Protection of participants, The Nuremberg Code, The Declaration of Helsinki, The Belmont Report

4. Clinical trial design

Designs used in clinical trials with their advantages and disadvantages, hypothesis, risks and benefits, subject selection, inclusion and exclusion criteria, randomization, blinding and controls

5. Clinical trial protocol Development

Required Documentation including Investigator's Brochure, Case Report Forms, Serious Adverse Event (SAE) Reports, Laboratory Certification, data collection and quality control of data, closing out of clinical trial

6. Good Clinical Practice

Concept, importance, and GCP guidelines including ICH guidelines

7. Management of Clinical trials

Role and responsibilities of Stakeholders of clinical trials (FDA, CRO, Sponsor, Physicians, Nurses, Health professionals, Hospitals, Patient), monitoring of clinical trials, Publications of clinical trials

8. Bioavailability, bioequivalence and Therapeutic Drug Monitoring

Concept, organization, advantages, special issues, applications, bioequivalence

9. Data analysis issues in Clinical Trials

Monitoring of data, computer applications, statistical tests used, interpretation, survival analysis, sub-group analysis, Quality control of clinical trials

RECOMMENDED BOOKS:

1. Dipiro, Joseph L.; Pharmacotherapy: A Pathophysiological Approach, Elsevier
2. Davidson's Principles of Internal Medicine, Vol-I And II, 14th Edition, Mc Graw-Hill
3. Harrison's Principle And Practice Of Medicine, 18th Edition, Churchill, Livingston, London
4. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London
5. Herfindal, E.T. and Hirschman, J L.; Clinical Pharmacy and Therapeutics. Tussle, T.G.: Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Chapman and Hall, New York

Subject code: MPLE3

Subject: IMMUNOPHARMACOLOGY

Theory:

30 Hours (2 hrs. /week)

INTRODUCTION

Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity (active and passive). Concept of immunopharmacology and pharmacotherapeutics.

A) IMMUNITY

Hematopoiesis and lymphocyte development: an introduction: Introduction: Blood cell development and immunity, Hematopoietic stem cells, lymphocyte development, T cell development, B cell development, NK cell development.

T cell subsets and T cell-mediated immunity: Introduction, Biology of the T lymphocyte immune response, Mechanisms of T cell activation.

Antibody diversity and B lymphocyte-mediated immunity: Antibodies and immunoglobulins, Structure of immunoglobulins, T cell-independent B lymphocyte activation.

Cytokines: Introduction, Differentiation factors, Activation and growth factors of lymphocytes, Mediators of inflammation, Chemokines, Inhibition of cytokines.

Inflammatory mediators and intracellular signaling: Introduction, Eicosanoids, Platelet-activating factor, Innate immune signalling receptors, Cytokines, Chemokines and their intracellular signalling, Kinins, Reactive oxygen species, Amines.

Cancer immunity: Introduction: Expression of targets for the immune system by cancer cells, Immunotherapy of cancer.

B) IMMUNODIAGNOSIS

Antibody detection: Introduction, Basic principle of immunoassays, Antibody structure, Antibody-detection methods.

Immunoassays: Introduction, Basic principles of assay design, Components of immunoassays.

C) IMMUNOTHERAPEUTICS

Vaccines: Introduction, vaccine categories, Pharmacological effects of vaccination new developments.

Plasma-derived immunoglobulins: Introduction, Glycosylation of immunoglobulins, Pharmacokinetics of immunoglobulins, Immunoglobulin preparations for medical use, adverse reactions to IgG therapy.

Anti-allergic drugs: Introduction, Disodium cromoglycate and nedocromil sodium (cromones), Histamine receptor antagonists, Anti-leukotrienes, Anti-IgE.

Cytotoxic drugs: Background, Azathioprine, Cyclophosphamide, Fludarabine, Methotrexate, Mycophenolic acid

Immunostimulants and Immunosuppressants.

RECOMMENDED BOOKS:

1. Mary Louis Turgeon "Immunology and Serology in Laboratory Medicines" 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
2. Robbins Pathologic basis of disease, WB Saunders Co (1999) 6th edition.
3. Roger Walker, Clinical Pharmacy and Therapeutics; Second edition, Churchill Livingstone publication
4. Harsh Mohan, "Text book of Pathology" 3rd edition, 1998, Jaypee Brothers N. Delhi (2005) 5th edition.
5. War Roitt, Jonathan Brostoff, David male, "Immunology" 3rd edition 1996, Mosby-year book, Europe Ltd, London.
6. D.Satyanarayana, Text book of biochemistry New Central Book Agency (1999) 2nd edition.
7. Lehninger, Principles of biochemistry W.H.Freeman (2005) 4th edition.
8. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London 4th ed., 2007

Subject code: MPLE4

Subject: NEUROBIOLOGY

Theory:

30 Hours (2 hrs. /week)

1. Organization of the nervous system.
2. Introduction to the neurons, the neuron doctrine, components of neurons, types, organization of a neuron, and functions.
3. Developmental Neurobiology.
4. Glial cells : structure and function, types, glial neuronal relationship, importance of astrocytes in glutamate uptake and blood- brain barrier, role of tanycytes in the hypothalamus.
5. Membrane channels, ionic basis of resting potential and action potential, synaptic plasticity.
6. Neurotransmitters, neurotransmitter receptors, chemical transmission, electrical synapses.
7. Neurobiology of sensory systems : taste, olfaction, vision, auditory preparation.
8. Neuroanatomy of the hypothalamus and neuroendocrine regulation. Central regulation of feeding, appetite, stress, and Circadian rhythms, neurobiology of behavior.
9. Learning and memory.

10. Neurological disorders.
11. Techniques in neuroscience.

RECOMMENDED BOOKS:

1. Zigmond, Bloom, Landis, Roberts, Squire.(2008). Fundamental neuroscience, Academic Press.
2. Eric Kandel, James Schwartz, Thomas Jessell. (2000). Principles of Neural Science. McGraw Hill.
3. A.Guyton, J. Hall. (2011). Textbook of Medical Physiology, 12th edition, Saundersco, London.
4. Dale P. (2007) Neuroscience, 4th edition, Sinaure Associates
5. Current Protocols in Neuroscience. (2010) Springer Publication.

Subject code: MPLE5

Subject: PHARMACOEPIDEMIOLOGY

Theory:

30 Hours (2 hrs. /week)

1. **Definition and scope:** Origin and evaluation of Pharmacoepidemiology need for Pharmacoepidemiology, aims and applications.
2. **Measurement of outcomes in Pharmacoepidemiology:** Outcome measure and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement
3. **Concept of risk in pharmacoepidemiology:** Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio.
4. **Research methods in Pharmacoepidemiology:** Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta-analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.
5. **Sources of data for pharmacoepidemiological studies:** Ad Hoc data sources and automated data systems.
6. **Selected special applications of pharmacoepidemiology:** Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

RECOMMENDED BOOKS:

1. Textbook of Pharmacoepidemiology. 1st edition. Brian L Strom, Stephen E Kimmel. John Wiley & Sons, Chichester, 2006.
2. Pharmacoepidemiology, 4th edition. Brian L Strom, 2005.
3. Pharmacoepidemiology and Therapeutic Risk Management. Abraham G Hartzema, Hugh H Tilson, K Arnold Chang, 2008.
4. Pharmacoepidemiology: An Introduction, 3rd edition. Abraham G Hartzema, Miquel Porta, Hugh H Tilson, 1998.

5. Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs. Jerry Avorn. Hardcover, 2004.
6. Modern Epidemiology, 3rd edition. Kenneth J Rothman, Sander Greenland, Timothy L Lash. Lippincott Williams & Wilkins, 2008.
7. Epidemiology. An introduction. Kenneth J Rothman, Oxford University Press, 2002.

Subject code: MPLE6

Subject: SAFETY PHARMACOLOGY

Theory:

30 Hours (2 hrs. /week)

1. Definition and scope of safety pharmacology.
2. Regulatory requirements for the new drug safety assessment: ICH, OECD, USFDA, EMEA, Japan, MHW guidelines.
3. Principles and study design of safety evaluation.
 - a. Acute toxicity- rodent and non-rodent
 - b. Repeated dose studies (sub acute and chronic)
 - c. Analysis of safety pharmacological data.
4. Preclinical safety pharmacology: In vitro and in vivo studies including genotoxicity, mutagenicity, carcinogenicity, reproductive and ocular toxicity, Safety testing for dermatological product.
5. Clinical Safety pharmacology: definition, data collection, reporting methods and assessment and analysis of adverse event (AE) monitoring during clinical trials.
6. Pharmacovigilance: Definition, collection of data, reporting, assessment of Post marketing surveillance, periodic safety update reports, Risk-benefit assessment.
7. Safety pharmacology of different body organs and systems

RECOMMENDED BOOKS:

- 1 Sogliero-Gilbert, G., Drug safety assessment in clinical trials. Statistics, textbooks and monographs. 1993, New York: Dekker.
- 2 Marx, U. and V. Sandig, Drug testing in vitro : breakthroughs and trends in cell culture technology. 2007, Weinheim: Wiley-VCH
- 3 Gad, S.C., Safety assessment for pharmaceuticals. 1995, New York: Van Nostrand Reinhold.
- 4 Turner, J.R., New drug development : design, methodology, and analysis. 2007, Hoboken, N.J.: Wiley-Interscience.
- 5 Smith, C.G. and J. O'Donnell, The process of new drug discovery and development. 2nd ed. 2006, New York: Informa Healthcare.
- 6 Bénichou, C., Adverse drug reactions : a practical guide to diagnosis and management. 1994, Chichester, West Sussex, England; New York: Wiley.
- 7 Mann, R.D. and E.B. Andrews, Pharmacovigilance. 2nd ed. 2007, Chichester, England ; Hoboken, NJ: John Wiley & Sons.
- 8 World Health Organization., WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. 2004, Geneva: World Health Organization.
- 9 Cobert, B.L., Manual of drug safety and pharmacovigilance. 2007, Sudbury, Mass.: Jones and Bartlett Publishers.
- 10 Cobert, B.L. and P. Biron, Pharmacovigilance from A to Z : adverse drug event surveillance. 2002, Malden, MA: Blackwell Science.
- 11 Casarett and Doull's Toxicology: The basic science of poisons 6th edition McGraw Hill, New York.
- 12 Helmal Graim and Robert Snyder, Toxicology and risk assessment, a comprehensive introduction. Wiley.

GROUP D: PHARMACOGNOSY, NATURAL PRODUCTS

Subject code: MPGE1

Subject: ADVANCES IN PHYTOCHEMISTRY

Theory:

30 Hours (2 hrs. /week)

1. **Natural products as leads for new drugs:** Approaches to discovery and development of natural products as potential new drugs, selection and optimization of lead compounds for further development with suitable examples from CNS, anticancer, antibiotics and Cardiovascular drugs.
2. **Steroids:** Stereochemistry, SAR, structural modifications and pharmacokinetic properties, Source and structure elucidation of Beta- sitosterol, stigmasterol and diosgenin.
3. **Biogenesis** of cardenolides, bufadienolide, isothiocyanates. General route of biosynthesis of flavonoids, coumarins, and isoprenoids.
4. **Biogenesis of Alkaloids:** Pyridine, Piperidine, Tropane, Quinoline, Isoquinoline, Indole, Phenanthrene types of alkaloids.
5. **Polypeptides and Proteins:** General methods of separation, general methods of degradation and end group analysis, general methods of synthesis of peptides. Sequence analysis, secondary and tertiary structure of proteins; chemistry of Insulin.

RECOMMENDED BOOKS:

1. Natural products chemistry by Nakanishi Golo, Univ Science Books, 1984.
2. Introduction to Molecular Phytochemistry by CHJ Wells (Chapman and Hall).
3. Comparative Phytochemistry, edited by T. Swain, Academic Press, New York, 1966.
4. Phytochemistry, Vol. I to IV, Miller Jan Nostrant Reinhold, Van Nostrand-Reinhold, 1976.
5. Burger's medicinal chemistry, Drug Discovery and development, edited by Alfred Burger, John Wiley and Sons.
6. Modern methods of plant analysis by Peach & M.V. Tracey, Vol. I to VII, Springer, berlin, 1955.
7. Recent advances in Phytochemistry, Vol. I to IV, Scikel Runeckles, Appletaon Century Crofts.
8. Chemistry of Natural Products by SV Bhat, Alpha Science International Ltd., 2005.
9. Natural products – A Laboratory guide by Raphel Ikhan, 2 nd edition, Academic Press.
10. The essential oils by Ernest Guenther and Robert E. Kreiger
11. The Alkaloids, Chemistry and Physiology by Von R. H. F. Manske und H. L. Holmes. Band I. Academic Press Inc., Publishers, New York.

Subject code: MPGE2

Subject: HERBAL COSMETICS

Theory:

30 Hours (2 hrs. /week)

1. Introduction, classification of cosmetics. Economic aspects and Factors affecting stability of herbal formulations, ICH and other guidelines, methods of stabilizations and methods of stability testing.
2. **Herbal cosmetics for skin:** Manufacturing and formulations aspects of herbal cosmetics for Skin: Powders, creams, lotions, deodorants, suntan preparations and makeup preparations
3. **Herbal cosmetics for Hair:** Manufacturing and formulations aspects for Hair preparations, shampoos, rinses and conditioners, oily scalp hair tonics, hair dressings and depilatories preparations.
4. **Herbal cosmetics for Nail:** Manufacturing and formulations aspects of nail preparations
5. **Analysis of cosmetics:** Nail enamel, shampoos, hair dyes and aerosol preparations
6. **Toxicity methods for cosmetics**

RECOMMENDED BOOKS:

1. Cosmeceuticals and active ingredients: Drug vs Cosmetics, 2nd Edition, Cosmetic Science and Technology, Peter Elsner (Ed.), Informa Healthcare.
2. Cosmetic analysis- Selective methods and techniques by P. Borque, Cosmetic Science and Technology Series, CRC Press, 1985.
3. Herbal cosmetics Handbook by H Panda, Asia Pacific Business Press, New Delhi.
4. Cosmetics- Formulation, Manufacturing and Quality control by PP Sharma, 2nd Ed., Vandana Publications.
5. Harry's Cosmeticology by Ralph Gordon Haqrry, 8th Edition, Chemical Publishing Company, 2000.
6. Indian Herbal Pharmacopoeia, Vol. I- II, SS Handa, RRL Jammu Tawi, and IDMA Mumbai.

Subject code: MPGE3

Subject: HERBAL DRUG TECHNOLOGY

Theory:

30 Hours (2 hrs. /week)

1. Importance of monographs of medicinal plants as per IP, API, Unani Pharmacopoeia, Homoeopathic Pharmacopoeias, Siddha Pharmacopoeia, BHP, Japanese Pharmacopoeia, Chinese Pharmacopoeia, European Pharmacopoeia, USP (dietary supplements), WHO and EMEA guidelines and ESCOP monographs for medicinal products.
2. Natural products used as coloring pigments, excipients, biopolymers, photosensitizing agents, flavors and biofuels.

3. Profiles for commercial cultivation technology/ and post-harvest care of following medicinal plants- Cinchona, Rauwolfia, Pyrethrum, Belladonna, Dioscorea, Vinca.
4. Technology for commercial scale cultivation and processing of following aromatic plants- Lemon grass, Geranium, Basil, Palmrosa, Vetiver, Patchouli, Japanese Mint, Rose, Hops, Jasmine, Sandal, Dill, Celery, Anise, Davana.
5. Reverse pharmacology approach to develop herbal drugs/ phytopharmaceuticals from herbs known in Traditional knowledge like Ayurveda / TCM etc. Examples of successful drugs developed in India and abroad, case studies. Emerging regulations like USFDA Guide to Industry for Botanical drugs and how to comply with them.
6. Phytopharmacy and phytogeographical distribution of medicinal plants with special reference to India.

RECOMMENDED BOOKS:

1. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons Limited, New Delhi.
2. Indian Herbal Pharmacopoeia, Vol. I-II, SS Handa, RRL Jammu Tawi, and IDMA Mumbai.
3. British pharmacopoeia, 2008. The department of Health, Vol I- IV, British Pharmacopoeia Commission, London.
4. The Aurvedic Pharmacopoeia of India, 1999. Government of India, Ministry of Health and Family Welfare, Department of Indian Systems of Medicine and Homeopathy, New Delhi.
5. Quality Control Methods for medicinal plant material, WHO Geneva.
6. Herbal Drug technology by SS Agrawal and M Paridhavi, Orient Longman

Subject code: MPGE4

Subject: MEDICINAL PLANT BIOTECHNOLOGY

Theory:

30 Hours (2 hrs. /week)

- 1. Introduction to genetics & molecular biology:** a. Structural and molecular organization of Cell; b. Genetic Material-DNA, RNA, Protein, Replication, Genetic Code, Regulation of Gene Expression, Structure & Complexity of Genome; c. Cell Cycle, Cell signaling; d. Mutation; e. Recombinant DNA Technology –Principles, Tools, Process & Applications.
- 2. Germplasm Conservation:** a. In-situ Conservation; b. In-vitro methods of Conservation.
- 3. Applications of Transgenic Plants:** a. Resistance of herbicide; b. Resistance to insect, fungus, & virus; c. Resistance to Physiological stress; d. Production of Phytopharmaceuticals; e. Edible vaccine.
- 4. Enzymes:** a. Types & Properties of enzymes; b. Isolation & Purification of enzymes; c. Immobilization of enzymes & its applications; d. Enzyme reactors; e. Detailed study of Plant enzymes– Papain & Bromelain.

5. **DNA bar code development** adopting various techniques and their application to differentiate authentic herb from their other species, and substitutes and adulterants. Applications with examples, limitations of technique, and emerging scenario.

RECOMMENDED BOOKS:

1. Pharmaceutical biotechnology SP Vyas and VK Dixit, CBS Publishers and Distributors, 2001.
2. Advanced methods in plant breeding & biotechnology by David R. Murray. CAB. International Panima book distributors.1991.
3. Plant tissue culture by Dixon IRL Press Oxford Washington DC, 1985.
4. Role of Biotechnology in Medicinal and Aromatic Plants Vol I & II By Irfan A Khan and Atiya Khanum Ukaoz Publications.1998.
5. Plant Chromosome analysis, manipulation and engineering by Arun And Archana Sharma 1st Edition Harwood Academic Publishers 1999.
6. Comprehensive Biotechnology by Murray Moo-Young Vol I- IV Pergamon Press LTD, 1985. Transgenic Plants by R Ranjan Agrobotanica.1999.
7. Medicinal Plant Biotechnology by C.D. Veeresham, C.B.S. Publisher.

Subject code: MPGE5

Subject: Natural Product Management

Theory:

30 Hours (2 hrs. /week)

1. **Role of Medicinal Plants in National Economy:** Economic growth potential in natural health and cosmetic products. Future economic growth. Development of herbal medicine industry.
2. **Worldwide trade in medicinal plants and derived products:** Demand for medicinal plants and herbal medicine. Trends in worldwide trade of Medicinal plants. International trade. Major importing-exporting regions and countries.
3. **Indian trade in medicinal and aromatic plants:** Export potential of Indian medicinal herbs. Indian medicinal plants used in cosmetics and aromatherapy. Spices and their exports.
4. **Study of infrastructure:** For different types of industries involved in making standardized extracts and various dosage forms including traditional Ayurvedic dosage forms and modern dosage forms.
5. **Global regulatory status of herbal medicines: Patents:** Indian and international patent laws, Recent amendments as applicable to herbal/ natural products and processes Plant breeders right.
6. **Management of natural sources**

RECOMMENDED BOOKS:

1. Textbook of Industrial Pharmacognosy, by A. N. Kalia, CBS Publishers and Distributors. New Delhi.
2. Chaudhari R D, Herbal Drug Industry, Eastern publication.
3. PDR for Herbal Medicines, Second Ed., Medicinal Economic Company, New Jersey.
4. Herbal Drug technology by SS Agrawal and M Paridhavi, Orient Longman.
5. The Aurvedic Pharmacopoeia of India, 1999. Government of India, Ministry of Health and Family Welfare, Department of Indian Systems of Medicine and Homeopathy, New Delhi.
6. G.E. Trease and W.C. Evans., Pharmacognosy, W.B. Saunders Co. Ltd., Harcourt Publishers Ltd. UK.

Subject code: MPGE6

Subject: Plant Tissue Culture Techniques

Theory:

30 Hours (2 hrs. /week)

1. **Introduction and Methods employed in plant tissue culture:** Techniques of organ, tissue and free cell culture: a. Excised root culture; b. Excised shoot apices; c. Excised leaf primordia cultures; d. Culture of flowers and floral organs, e. Embryo culture, f. Pollen cultures, g. Callus culture, h. Suspension and continuous culture and i. Culture of isolated cells.
2. The nutrition and Metabolism of plant tissue and organ culture. Growth differentiation and organogenesis in plant tissue and organ culture. Cytogenetics of differentiation in tissue and cell culture. Different parameters used to measure the growth of cultures.
3. **DNA amplification and Tissue culture protoplast:** Somatic hybridization and engineering, Protoplast isolation, protoplast culture and somatic hybridization.
4. **Gene mapping and molecular maps of plant genomes:** Plant chromosome analysis, use of PCR in gene mapping, molecular maps- RFLP, RAPD.
5. **Application of tissue culture in improvement of medicinal plants:** Yield improvement, stress tolerant plants, disease resistant plants, pesticide tolerant plants, synthetic seed production, germplasm storage and cryopreservation for conservation of plants.
6. **Transgenic plants:** Approaches for production of transgenic plants.

RECOMMENDED BOOKS:

1. Cells and Tissues in Culture, Vol. III by E.N. Willman, Academic Press.
2. Plant cell, Tissue and Organ Culture by J. Reinert and Y.P.S. Bajaj, Springer Verlag.
3. Tissue culture and plant science, 1974, by H.E. Street, Academic Press.
4. The cultivation of animal and plant cells, 1954, White P.R., Ronald Press.
5. A handbook of plant culture, 1943, White P.R., Cattell and Co.
6. Modern methods of plant analysis by Peach and Tracey, Vol. II, IV, Springer Verlag.
7. Herbal Drug technology by SS Agrawal and M Paridhavi.
8. Practical Evaluation of Phytopharmaceuticals by Brain and Turner.

**GROUP E: QUALITY ASSURANCE, PHARMACEUTICAL MANAGEMENT,
PHARMACOINFORMATICS**

Subject code: MQAE1

**Subject: ACTIVE PHARMACEUTICAL INGREDIENTS (APIS): MANAGEMENT
TECHNOLOGY**

Theory:

30 Hours (2 hrs. /week)

- 1. Introduction to basic pharmaceutical and fine chemical chemistry:** Definitions of basic pharmaceuticals, intermediates, fine chemicals, heavy chemicals. Technology involved in manufacturing of pharmaceuticals. Unit processes in synthesis, biochemical processes in synthesis.
- 2. Unit processes:** Study of the following chemical processes (with references to reagents, mechanisms, equipments and manufacture of drugs given below): Acylation, esterification, alkylation, amination, halogenation, hydrolysis, nitration, oxidation and reduction.
- 3. Industrial processes & scale up techniques**
The process design, technology transfer and first manufacture. Industrial manufacturing methods and flow charts of Sulphamethoxazole, Ciprofloxacin, Benzocaine, Adrenaline, Rifampicin, Aspirin and Pentothal sodium.
- 4. Bioethics and Bio-Safety**
Health hazards in manufacturing facility, The forms of Atmospheric contaminants, Chemical mixtures, Detection and sampling, Atmospheric contamination, industrial noise, criteria for hearing damage, Noise measuring instruments, effects of sound and ultrasound, the control of noise, vibration, Radiation Hazards, Radiation detection and measurement, personal protection, eye protection, Types of eye protection equipment. Finger & Arm protection, Foot & leg protection. Environmental protection laws related to industry.

RECOMMENDED BOOKS:

1. Stanley H. Nusim. Active Pharmaceutical Ingredients: Development Manufacturing and Regulation. Taylor and Francis, New York.
2. L. Lachman. The Theory and Practice of Industrial Pharmacy, 3rd Ed., Warghese Publishing House, Mumbai.
3. W.L. McCabe and J.C.Smith. Unit Operations of Chemical Engineering, 5th Ed., McGraw-Hill, Inc., NY.
4. C.L. Dryden, 1973, Outlines of Chemical Technology, 2nd edition, Affiliated East-East Press.
5. Groggin P.K. Unit Process in Organic Synthesis, 2nd edition, Mc Graw-Hill, Inc., NY.

Subject code: MQAE2

Subject: HUMAN BEHAVIOR IN ORGANIZATION

Theory:

30 Hours (2 hrs. /week)

- 1. Foundations of organizational behavior:** Understanding behavior in organizations, OB model.
- 2. Introduction to Individual Motivation Needs, contents and processes;** Maslow's hierarchy of human needs, Herzberg's two factor theory of motivation, Vroom's expectancy theory.
- 3. Group processes:**
Importance of values: Types of values, attitudes and consistency (cognitive dissonance theory)
Group dynamics and teams.
Leadership: Trait theories, behavioural theories, Ohio state studies, university of Michigan studies, the managerial grid, contingency theories; Hersey and Blanchard's situational theory and path goal theory.
- 4. Transactional analysis.**
- 5. Organizational culture:** What is organizational culture, what does cultures do, creating, and sustaining culture, how employees learn culture.
- 6. Organizational change:** Forces of change, resistance to change, and approaches to managing organizational change.
- 7. Conflict management:** Transitions in conflict thought, functional Vs dysfunctional conflict, the conflict process.

RECOMMENDED BOOKS:

1. Organisational Behaviour, Dr. K. Aswathappa, Published by : Himalaya Publishing House, Revised and Enlarged Edition, 1994
2. Fred Luthans, Organisational Behaviours, Mc-Graw Hill, 8th International Edition.
3. Subba Rao S.V., Human Resource Management and Industrial Relation, Himalaya Publishing House, 1st Edition, 1997.

Subject code: MQAE3

Subject: MATERIAL MANAGEMENT AND INVENTORY CONTROL

Theory:

30 Hours (2 hrs. /week)

- 1. Purchasing:** Introduction, purchasing activities, purchasing policies, value analysis, procurement by manufacture, discount and terms of payment, hedging, evaluating purchasing performance.

2. **Materials handling:** Introduction, objectives of material handling, materials handling analysis, guiding principles of material handling, small part handling, packing, transportation, materials handling equipments.
3. **Inventory planning and control:** Introduction, lead time, inventory cushions, reorder point, order quantity, quantity discount, Fifo and Lifo system, materials identification, storage facilities, purging inventories, pilferage protection, symptoms of mismanaged inventories, basic inventory model, inventory model with uncertain demand, inventory control systems, ABC classification of inventory items.
4. **Statistical quality control:** Introduction, frequency distribution, statistical measures, normal distribution, process control, establishing control charts, control charts in use, use of samples, relation of control limits to tolerance limits, control charts computations, control charts of attributes, accepting sampling, operative characteristics curve, average outgoing quality, double and multiple sampling plans, diversified applications of statistical techniques.
5. **Storage:** Storage room management, Shelf stripping and floor marking, marking of merchandise, storage of pharmaceuticals.

RECOMMENDED BOOKS:

1. Effective Industrial Management, J.L.Lundy, Eurasia Publishing House, ND.
2. Hospital Pharmacy, W.E.Hassan, Lea and Febiger, Philadelphia.
3. Modern Production/ Operations Management, E.S.Buffa and R.K.Sarin, John Wiley & sons.
4. Production Planning Control and Industrial management, K.C. Jain and L.N. Aggarwal, Khanna Publishers, Delhi.
5. Modern Business Organization and Management, S.A. Sherlekar and V.S. Sherlekar, Himalaya Publishing House.

Subject code: MQAE4

Subject: PACKAGING TECHNOLOGY

Theory:

30 Hours (2 hrs. /week)

1. **Introduction to pharmaceutical packaging:** Introduction, Some factors influencing pharmaceutical packaging, protection, sterilization.
2. **The packaging function:** Management, development and product shelf life, packaging management, product and pack development, drug substance, shelf life, packaging specifications.
3. **Regulatory aspects of pharmaceutical packaging:** Definition of the pack, product license specifications, data requirements on the package.

4. **Specifications and quality:** material specifications and quality standards, sampling, supplier evaluation, manufacture and qualification controls.
5. **Glass containers:** composition of glass and types, manufacturing process, quality control and quality assurance, bottles and production lines, special pharmaceutical containers.
6. **Plastics:** thermosets, thermoplastics, chemical type evaluation, permeability of plastic to gasses and organic substances, fabrication and moulding processes, sterilization of plastics, WHO guidelines.
7. **Films, foils and laminations:** shrink wrapping, stretch wrapping, combination materials covering flexible and rigid applications, paper, coatings, aluminum foils, lamination and lamination processes, decoration and printing.
8. **Metal containers:** modern packaging metals, types of metal containers, built up containers, aerosols.
9. **Closure and closure systems:** basis of closure system, closure evaluation, assessment and control, prethreaded screw caps, specific closures for containers, non-reclosables, adhesive sealings, closure evaluation.
10. **Sterile products:** sterilization of parenteral products, rubber and elastomers, ampoules and vials, prefilled syringes, auto-injectors, selection of rubber formulation and component design.
11. **Blister, strip and sachet packaging:** blister packs, strip packs, package integrity, sachets, recent developments in blister and strip packaging.
12. **The packaging line:** materials in packaging line, common filling methods, container based filling, labeling and other requirements.
13. **Warehousing, handling and distribution:** hazards in warehousing, handling and distribution, handling, moving and storage methods, load stability, modes of distribution and transport.
14. **Printing and decoration:** decoration, graphic reproduction, mechanical graphic printing, printing machines, recent trends.

RECOMMENDED BOOKS:

1. Pharmaceutical Packaging technology, Edited by: D. A. Dean, E. R. Evans, H. Hall, 2000, Taylor and Francis, New York.
2. Pharmaceutical Packaging handbook, Edward J. Bauer, 2003, Informa Healthcare, New York.
3. The Wiley encyclopedia of packaging technology, Kenneth S. Marsh, Aaron L. Brody, Published by Wiley Interscience, New York.
4. Packaging of pharmaceuticals and healthcare products, H Lockhart and F. A. Paine, Blackie academic and professional, Chapman and Hall UK, 1996.
5. Fundamentals of packaging technology, Walter Soroka, Edition 2, Institute of Packaging Professionals, 1999, The University of Virginia.

Subject code: MQAE5

Subject: PHARMACEUTICAL MARKETING AND MARKET RESEARCH

Theory:

30 Hours (2 hrs. /week)

1. Indian Pharmaceutical Industry- An overview
2. The Pharmaceutical Market
3. Nine P's
4. Marketing New Products
5. Marketing Planning
6. Modern Marketing
 - a. The field of marketing
 - b. Career in Marketing
 - c. The changing marketing environment
 - d. Strategic planning and forecasting
 - e. Marketing research and Information
7. Marketing in Special Field
 - a. Services marketing by For-Profit and Nonprofit Organization
 - b. International Marketing
8. Managing the sales force

RECOMMENDED BOOKS:

1. Subba Rao, Pharmaceutical Marketing in India, Published by Asian Institute of Pharmaceutical Marketing, Hyderabad.
2. William J. Stanton, Michael J. Etzel, Bruce J. Walker, Fundamentals of Marketing, McGRAW-HILL International Edition, Marketing and Advertising series.
3. Philip Kotler, Marketing Management, Prentice-Hall of India Private Limited, New Delhi
4. Walker, Boyd and Larreche, Marketing Strategy- Planning and Implementation, Tata MC Graw Hill, New Delhi.
5. Dhruv Grewal and Michael Levy, Marketing, Tata MC Graw Hill
6. Arun Kumar and N Menakshi, Marketing Management, Vikas Publishing, India
7. Shanker, Ravi, Service Marketing, Excell Books, New Delhi
8. Memoria C. B., Principle and Practice of Marketing in India
9. Mickey Smith, Principles of Pharmaceutical Marketing, C.B.S. Publications.

Subject code: MQAE6

Subject: QUALITY PLANNING AND ANALYSIS

Theory:

30 Hours (2 hrs. /week)

1. **Basic concepts of Quality**
Definition of Quality, The Quality function, Managing for Quality, Perspective on Quality- Internal versus External
2. **Quality Improvement and Cost Reduction**
Sporadic and chronic quality problems, Need for quality improvement & cost reduction, Causes of poor quality and high cost, Remedy to prove effectiveness for improving quality, Resistance to change.
3. **Control of Quality**
Definition of Control, Self control, The control subject for Quality, Units of measure

Setting a goal for the control subject, The sensor, Measuring actual performance, Interpreting the difference between actual performance and goal, Taking action on the difference, Continuous process regulation.

4. Developing Quality culture

Technology and cultures, Theories of motivation, Create and maintain awareness of Quality, Provide evidence of management and empowerment, Time to change the culture.

5. Manufacturing

Importance of manufacturing planning for quality, Initial planning for Quality, Concept of controllability, self control, Defining quality responsibilities, Self inspection Automated manufacturing, Overall review of manufacturing planning, Process quality audits, Quality and production floor culture

6. Statistical Process control

Definition and importance of SPC, Quality measurement in manufacturing, Statistical control charts-general, Advantages of statistical control, Process capability, Estimating inherent or potential capability from a control chart analysis, Measuring process control and Quality improvement

7. Inspection, test and Measurement

The terminology of inspection, Conformance to specification and fitness for use, Disposition of non conforming product, Inspection planning, Automated inspection, How much inspection is necessary?, Inspection accuracy, Errors of measurement, Economics of Inspection.

8. Quality assurance general concepts

Definition of Quality Assurance, Concept of Quality Assurance, Quality Audit- The concept, Structuring the audit programme, Planning and performance of audit, Human relations in auditing, Audit reporting, Essential elements of quality audit programme Quality surveys, Product audit, Sampling for audit, Reporting the results of audit

RECOMMENDED BOOKS:

1. Quality Planning and Analysis, 5th ed., J.M.Juran and F.M.Gryna, Tata Mc-Graw Hill, India
2. Improving Quality through planned experimentation by Meon, Tata Mc-Graw Hill, India
3. Statistical Quality control by Grant, Tata Mc-Graw Hill, India
4. Juran's Quality Handbook, 5th ed, J.M.Juran, Tata Mc-Graw Hill, India.

Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur

M. Pharm. Syllabus

Credit-grade based performance and assessment system (CGPA)

Features of the Credit System

With effect from Academic Session 2012- 2013

Scheme of Absorption & Matchable Subjects

OLD SYLLABUS		NEW SYLLABUS	
Subject Code	Name of Subject	Subject Code	Name of Subject
CP-1	Biostatistics	MC-S2	Research Methodology and Biostatistics
CP-2	Product Development and Formulation	MPHE6	Sterile Product Formulation and Technology
Pharmaceutics			
PH-1	Advanced Physical Pharmacy	MPH-S4	Advanced Pharmaceutics
PH-2	Biopharmaceutics and Pharmacokinetics	MPH-S13	Biopharmaceutics and Pharmacokinetics
PH-3	Pharmaceutical Dosage Form Technology	MPH-S9	Product Development and Formulation
PH-4	Selected Topics in Pharmaceutics	MPH-S10	Novel Drug Delivery Systems
PH-5	Practicals In Pharmaceutics	MPH-P4	Advanced Pharmaceutics
Pharmaceutical Chemistry			
PC-1	Advanced Pharmaceutical Chemistry-I	MPC-S9	Advanced Pharmaceutical Chemistry- II
PC-2	Advanced Pharmaceutical Chemistry-II	MPC-S10	Advanced Pharmaceutical Chemistry-III
PC-3	Advanced Pharmaceutical Chemistry-III	MC-S1	Advanced Analytical Techniques
PC-4	Selected Topics in Pharmaceutical Chemistry	MPC-S13	Advanced Pharmaceutical Chemistry-IV
PC-5	Practicals in Pharmaceutical Chemistry	MPC-P9	Advanced Pharmaceutical Chemistry-II
Pharmacology			
PL-1	Advanced Physiology and Pathophysiology	MPL-S4	Advanced Physiology and Pathophysiology
PL-2	Advanced Systemic Pharmacology	MPL-S9	Advanced Systemic Pharmacology
PL-3	Biological Evaluation Methods and Toxicology	MC-S8	Biological Evaluation
PL-4	Selected Topics in Pharmacology	MPL-S13	Molecular Pharmacology and Toxicology
PL-5	Practicals in Pharmacology	MPL-P9	Advanced Systemic Pharmacology
Pharmacognosy			
PG-1	Advance Pharmacognosy and Tissue Culture	MPGE6	Plant Tissue Culture Techniques
PG-2	Plant Biochemistry and Biogenesis	MPGE1	Advances in Phytochemistry
PG-3	Comparative Phytochemistry and Taxonomy	MPGE3	Herbal Drug Technology
PG-4	Selected Topics in Pharmacognosy	MPG-S13	Selected Topics in Pharmacognosy
PG-5	Practicals in Pharmacognosy	MPG-P4	Advanced Pharmacognosy and Phytochemistry
Quality Assurance			
QA-1	Cosmetic Preparation & Evaluation	MQA-S9	Quality Assurance of Cosmeceuticals
QA-2	Quality Management	MQA-S13	Quality Management
QA-3	Modern Analytical Techniques	MC-S1	Advanced Analytical Techniques
QA-4	New Drug Delivery System	MQA-S10	Novel Drug Delivery Systems
QA-5	Practicals in Quality Assurance	MC-P1	Advanced Analytical Techniques

