JAMIA HAMDARD
FACULTY OF PHARMACY

ADMISSION & EXAMINATION RULES
MASTER OF PHARMACY

(To be effective from the academic session 2009-2010 and applicable to all M. Pharm. students)

1. **Programme**: Master of Pharmacy (M. Pharm.) in the following subjects:
   - i) Pharmaceutical Chemistry
   - ii) Pharmaceutics
   - iii) Pharmacognosy & Phytochemistry
   - iv) Pharmacology
   - v) Quality Assurance
   - vi) Pharmacy Practice
   - vii) Pharmaceutical Biotechnology
   - viii) Pharmaceutical Analysis

It shall be a full time regular course. During an academic year, a candidate shall be enrolled only for one programme of study and shall not appear in any other examination of this or any other university.

2. **Duration**: Four semesters, which will be designated as under:

I	Semester	-	July-December
II	Semester	-	January-June
III	Semester	-	July-December
IV	Semester	-	January-June

3. **Medium of instruction and examination:** English
4. **Eligibility of admission:** A candidate seeking admission to M. Pharm. course must have:
   a) Passed Bachelor of Pharmacy form Jamia Hamdard or any other examination recognized by Jamia Hamdard as equivalent thereto, with at least 55% marks or above in aggregate of theory marks of B. Pharm I, II, III and IV year.
   b) For admission to M. pharm. Programme, the merit of GATE qualified candidates will be determined on the basis of the following criteria:

i.	Weightage for percentile scored at GATE	70%
ii.	Written test	30%

   For the Non-GATE candidates, the selection of candidates will be made on merit based on the aggregate marks of theory papers of I, II, III and IV years of B. Pharm. examination or any other examination recognized by Jamia Hamdard as equivalent thereto. Further, the admission of Non-GATE qualified candidates to a particular specialization will depend on the availability of seats in the respective specialization after the selection of the GATE qualified candidates.
   b) Completed the age of 20 years on or before the first day of October of the year of admission.

5. Course Structure: The course work shall be divided into four semesters. The course contents are given in the syllabus.

6. Scheme of Examination:

A. Scheme of Examination for M. Pharm. in: (i) Pharmaceutical Chemistry, ii) Pharmaceutics, iii) Pharmacognosy & Phytochemistry, (iv) Pharmacology, (v) Quality Assurance, (vi) Pharmaceutical Biotechnology, and (vii) Pharmaceutical Analysis.

Pharmaceutical Analytical Techniques Theory and Practical mentioned under section A shall be common for the M. Pharm. course in the following branches:

i) Pharmaceutical Chemistry
ii) Pharmaceutics
iii) Pharmacognosy & Phytochemistry
iv) Pharmacology
v) Quality Assurance
vi) Pharmaceutical Biotechnology
vii) Pharmaceutical Analysis

Semester	Name of the Subject	Paper	Duration of Exam in Hrs.	Marks	Total Marks
		Section-A			
I	Pharmaceutical Analytical Techniques	Theory	3	100	
I	Pharmaceutical Analytical Technique	Practical	6	100	**200**
		Section-B			
Branch Code 518	**Pharmaceutical Chemistry**				
I	Pharmaceutical Chemistry I (Drug Design including Organic Name Reactions)	Theory	3	100	
II	Pharmaceutical Chemistry II (Chemistry of Natural Products)	Theory	3	100	
II	Pharmaceutical Chemistry III (Medicinal Chemistry)	Theory	3	100	
II	Pharmaceutical Chemistry Practical I	Practical	12	100	
III	Pharmaceutical Chemistry Practical II (Synopsis of Project work/Seminar)	Practical	12	100	
IV	Dissertation			300	
	Viva voce			200	
			Total of sections A&B		**1200**

Branch Code 519	**Pharmaceutics**				
I	Pharmaceutics I (Product Development and Quality Assurance)	Theory	3	100	
II	Pharmaceutics II (Industrial Pharmacy and Packaging Technology)	Theory	3	100	
II	Pharmaceutics III (Advances in Drug Delivery Systems)	Theory	3	100	
II	Pharmaceutics Practical I	Practical	12	100	
III	Pharmaceutics Practical II (Synopsis of Project work/Seminar)	Practical	12	100	
IV	Dissertation			300	
	Viva voce			200	
			Total of sections A&B		**1200**
Branch Code 520	**Pharmacology**				
I	Pharmacology I (Basic Principles of Drug Therapy & Clinical Pharmacology)	Theory	3	100	
II	Pharmacology II (Recent Advances & Emerging Trends in Pharmacological Sciences)	Theory	3	100	
II	Pharmacology III (Pharmacological Methods and Toxicology)	Theory	3	100	
II	Pharmacology Practical I	Practical	12	100	
III	Pharmacology Practical II (Synopsis of Project work/Seminar)	Practical	12	100	
IV	Dissertation			300	
	Viva voce			200	
			Total of sections A&B		**1200**
Branch Code 522	**Pharmacognosy and Phytochemistry**				
I	Pharmacognosy and Phytochemistry I (Advances in the Pharmacogonsy)	Theory	3	100	
II	Pharmacognosy and Phytochemistry II (Phyto-chemistry and Biogenesis)	Theory	3	100	
II	Pharmacognosy & Phytochemistry III (Cultivation & Standardisation of Medicinal Plants)	Theory	3	100	
II	Pharmacogonsy Practical I	Practical	12	100	

III	Pharmacogonsy Practical II (Synopsis of project work/seminar)	Practical	12	100	
IV	Dissertation			300	
	Viva voce			200	
			Total of sections A&B		**1200**
Branch Code 523	**Quality Assurance**				
I	Quality Assurance I (Product Development)	Theory	3	100	
II	Quality Assurance II (Packaging)	Theory	3	100	
II	Quality Assurance III (Biological Evaluations and Validations)	Theory	3	100	
II	Quality Assurance Practical I	Practical	12	100	
III	Quality Assurance Practical II (Synopsis of project work/seminar)	Practical	12	100	
IV	Dissertation			300	
	Viva voce			200	
			Total of sections A&B		**1200**
Branch Code 524	**Pharmaceutical Biotechnology**				
I	Pharmaceutical Biotechnology I (Biomolecular Structure Function and Related Techniques)	Theory	3	100	
II	Pharmaceutical Biotechnology II (Molecular Biology and Pharmaceutical Biotechnology)	Theory	3	100	
II	Pharmaceutical Biotechnology III (Pharmaceutical Biotechnology Applications)	Theory	3	100	
II	Pharmaceutical Biotechnology Practical I	Practical	12	100	
III	Pharmaceutical Biotechnology Practical II (Synopsis of Project work/Seminar)	Practical	12	100	
	Dissertation			300	
	Viva voce			200	
			Total of sections A&B		**1200**

Branch Code 525	Pharmaceutical Analysis				
I	Pharmaceutical Analysis I	Theory	3	100	
II	Pharmaceutical Analysis II	Theory	3	100	
II	Pharmaceutical Analysis III	Theory	3	100	
II	Pharmaceutical Analysis Practical I	Practical	12	100	
III	Pharmaceutical Analysis Practical II (Synopsis of Project work/Seminar)	Practical	12	100	
IV	Dissertation			300	
	Viva voce			200	
			Total of sections A&B		**1200**

The dissertation work can be completed in Jamia Hamdard or else in a Pharmaceutical Industry/R&D Laboratory/Analytical Testing House/National Laboratory, in which case a co-supervisor would be from such relevant institution.

B. Scheme of Examination
For M. Pharm. in Pharmacy Practice Branch Code 522

Semester	Name of Subject	Paper	Duration of Exam in Hrs	Marks	Total Marks
I	Pharmacotherapeutics (including Pathophysiology)	Theory	3	100	
I	Basic Principles of Clinical Pharmacy	Theory	3	100	
I	Pharmacotherapeutics Clinical Practical (including Pathophysiology)	Practical	6	100	
					300
II	Hospital and Community Pharmacy	Theory	3	100	
II	Drug Toxicity & Management of Drug Information Service	Theory	3	100	
II	Clinical Practical I (Preparation of Clinical Manual for the treatment of various Disorders)	Practical	12	100	
					300
III	Clinical Practical II (Synopsis of Project work/seminar)	Practical	12	25 25 50	
					100
IV	Dissertation			300	
IV	Viva voce			200	
					500
				Grand Total	**1200**

The dissertation work will be done in the Majeedia Hospital under the supervision of Clinical Pharmacist and Clinician.

7. M.Pharm. Course Structure (Credit System)

There will be at least 90 working days in each semester. Credits are a value allocated course units to describe the student workload required to complete them. They reflect the quantity of work each course requires in relation to total quantity of work required to complete a full semester/year of academic study at the institution, that is, lectures, practical work, seminars, private work in the laboratory, library or at home and examination or other assessment activities.

Course structure that guides the teaching, practical and associated assessment of M.Pharm. programme is described semester wise in the following tables:

L-T-P stands for number of meetings as Lecture-Tutorial-Practical in a week.

Lectures/Tutorials: One lecture/tutorial hour per week per semester is assigned one credit.

Practical: One laboratory hour per week per semester is assigned half credit.

Semester Wise Distribution of Course in M. Pharm. Pharmaceutical Chemistry (Programe Code 518)

Semester-I

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPC 101	Pharmaceutical Analytical Techniques	25	75	100	4-0-2	5
MPC 102	Pharmaceutical Analytical Techniques (Practical)	25	75	100	0-0-12	6
MPC 103	Pharmaceutical Chemistry I (Drug Design including Organic Name Reactions)	25	75	100	4-1-8	9
						Total Credits = 20

Semester -II

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPC 201	Pharmaceutical Chemistry II (Chemistry of Natural Products)	25	75	100	4-0-2	5
MPC 202	Pharmaceutical Chemistry III (Medicinal Chemistry)	25	75	100	4-0-2	5
MPC 203	Pharmaceutical Chemistry Practical I	25	75	100	0-0-20	10
						Total Credits = 20

Semester - III

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPC 301	Pharmaceutical Chemistry Practical II (Synopsis of Project work/seminar)	25	75	100	0-0-40	20
						Total Credits =20

Semester –IV

Code	Title of the Paper	Marks	L-T-P
MPC 401	Dissertation Viva voce	300 200	0-0-40
			Total Credits = 20

Semester Wise Distribution of Course in M. Pharm. Pharmaceutics
(Programme Code 519)

Semester-I

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPH 101	Pharmaceutical Analytical Techniques	25	75	100	4-0-2	5
MPH 102	Pharmaceutical Analytical Techniques (Practical)	25	75	100	0-0-12	6
MPH 103	Pharmaceutics I (Product Development and Quality Assurance)	25	75	100	4-1-8	9
						Total Credits = 20

Semester- II

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPH 201	Pharmaceutics II (Industrial Pharmacy and Packaging Technology)	25	75	100	4-0-2	5
MPH 202	Pharmaceutics III (Advances in Drug Delivery Systems)	25	75	100	4-0-2	5
MPH 203	Pharmaceutics Practical I	25	75	100	0-0-20	10
						Total Credits = 20

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Semester - III

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPH 301	Pharmaceutics Practical II (Synopsis of Project work/seminar)	25	75	100	0-0-40	20
						Total Credits =20

Semester –IV

Code	Title of the Paper	Marks	L-T-P
MPH 401	Dissertation Viva voce	300 200	0-0-40
			Total Credits = 20

Semester Wise Distribution of Course in M. Pharm. Pharmacology
(Program Code 520)

Semester – I

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPG 101	Pharmaceutical Analytical Techniques	25	75	100	4-0-2	5
MPG 102	Pharmaceutical Analytical Techniques (Practical)	25	75	100	0-0-12	6
MPG 103	Pharmacology I (Basic Principles of Drug Therapy and Clinical Pharmacology)	25	75	100	4-1-8	9
						Total Credits = 20

Semester – II

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPG 201	Pharmacology II (Recent Advances and Emerging Trends in Pharmacological Sciences)	25	75	100	4-0-2	5
MPG 202	Pharmacology III (Pharmacological methods and Toxicology)	25	75	100	4-0-2	5
MPG 203	Pharmacology Practical I	25	75	100	0-0-20	10
						Total Credits = 20

Semester -III

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPG 301	Pharmacology Practical II Synopsis of Project work/Seminar)	25	75	100	0-0-40	20
						Total Credits =20

Semester-IV

Code	Title of the Paper	Marks	L-T-P
MPG 401	Dissertation Viva voce	300 200	0-0-40
			Total Credits = 20

Semester Wise Distribution of Course in M. Pharm. Pharmacognosy & Phytochemistry (Program Code 521)

Semester – I

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPP 101	Pharmaceutical Analytical Techniques	25	75	100	4-1-2	5
MPP102	Pharmaceutical Analytical Techniques (Practical)	25	75	100	0-0-12	6
MPP103	Pharmacognosy & Phytochemistry I	25	75	100	4-1-8	9
						Total Credits = 20

Semester –II

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPP 201	Pharmacognosy & Phytochemistry II (Phytochemistry and Biogenesis)	25	75	100	4-0-2	5
MPP 202	Pharmacognosy & Photochemistry III (Cultivation and Standardization of Medicinal Plants)	25	75	100	4-0-2	5
MPP 203	Pharmacognosy & Phytochemistry Practical I	25	75	100	0-0-20	10
						Total Credits = 20

Semester - III

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPP 301	Pharmacognosy & Phytochemistry Practical II (Synopsis of Project work/ seminar)	25	75	100	0-0-40	20
						Total Credits =20

Semester - IV

Code	Tile of the Paper	Marks	L-T-P
MPP 401	Dissertation Viva voce	300 200	0-0-40
			Total Credits = 20

Semester Wise Distribution of Course in M. Pharm. Pharmacy Practice (Program Code 522)

Semester-I

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPR 101	Pharmacotherapeutics (including Pathophysiology)	25	75	100	4-1-8	9
MPR 102	Basic Principles of Clinical Pharmacy	25	75	100	4-0-2	5
MPR 103	Pharmacotherapeutics Clinical Practical	25	75	100	0-0-12	6
						Total Credits = 20

Semester – II

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPR 201	Hospital and Community Pharmacy	25	75	100	4-0-2	5
MPR 202	Drug Toxicity and Management of Drug Information Services	25	75	100	4-0-2	5
MPR 203	Clinical Practical I (Preparation of Clinical Manual for the treatment of various disorders)	25	75	100	0-0-20	10
						Total Credits = 20

Semester-III

Code	Title of the paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPR 301	Clinical Practical II (Synopsis of Project Work/Seminar)	25	75	100	0-0-40	20
						Total Credits=20

Semester-IV

Code	Title of the Paper	Marks	L-T-P
MPR 401	Dissertation Viva voce	300 200	0-0-40
			Total Credits=20

Semester Wise Distribution of Course in M. Pharm. Quality Assurance
(Programe Code 523)

Semester-I

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPQ 101	Pharmaceutical Analytical Techniques	25	75	100	4-0-2	5
MPQ 102	Pharmaceutical Analytical Techniques (Practical)	25	75	100	0-0-12	6
MPQ 103	Quality Assurance I (Product Development and Packaging)	25	75	100	4-1-8	9
						Total Credits=20

Semester-II

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPQ 201	Quality Assurance II (Biological Evaluation and Validation)	25	75	100	4-0-2	5
MPQ 202	Quality Assurance III (Quality Management)	25	75	100	4-0-2	5
MPQ 203	Quality Assurance Practical I	25	75	100	0-0-20	20
						Total Credits=20

Semester –III

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPQ 301	Quality Assurance Practical II (Synopsis of Project work/Seminar)	25	75	100	0-0-40	20
						Total Credits = 20

Semester-IV

Code	Title of the Paper	Marks	L-T-P
MPQ 401	Dissertation Viva voce	300 200	0-0-40
			Total Credits=20

Semester Wise Distribution of Course in M. Pharm. Pharmaceutical Biotechnology (Program Code 524)

Semester-I

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPB 101	Pharmaceutical Analytical Techniques	25	75	100	4-0-2	5
MPB 102	Pharmaceutical Analytical Techniques (Practical)	25	75	100	0-0-12	6
MPB 103	Pharmaceutical Biotechnology I	25	75	100	4-1-8	9
						Total Credits=20

Semester-II

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPB 201	Pharmaceutical Biotechnology II (Molecular Biology & Pharmaceutical Biotechnology)	25	75	100	4-0-2	5
MPB 202	Pharmaceutical Biotechnology III (Pharmaceutical Biotechnology Applications)	25	75	100	4-0-2	5
MPB 203	Pharmaceutical Biotechnology Practical I	25	75	100	0-0-20	10
						Total Credits = 20

Semester – III

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPB 301	Pharmaceutical Biotechnology Practical II (Synopsis of Project work/Seminar)	25	75	100	0-0-40	20
						Total Credits = 20

Semester –IV

Code	Title of the Paper	Marks	L-T-P
MPB 401	Dissertation Viva voce	300 200	0-0-40
			Total Credits=20

Semester Wise distribution of courses in M. Pharm. Pharmaceutical Analysis (Program Code 525)

Semester-I

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPA 101	Pharmaceutical Analytical Techniques	25	75	100	4-0-2	5
MPA 102	Pharmaceutical Analytical Techniques (Practical)	25	75	100	0-0-12	6
MPA 103	Pharmaceutical Analysis I	25	75	100	4-1-8	9
						Total Credits=20

Semester-II

Code	Title of the paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPA 201	Pharmaceutical Analysis II	25	75	100	4-0-2	5
MPA 202	Pharmaceutical Analysis III	25	75	100	4-0-2	5
MPA 203	Pharmaceutical Analysis Practical I	25	75	100	0-0-20	10
						Total Credits=20

Semester-III

Code	Title of the Paper	Marks			L-T-P	Credit
		Internal Assessment	Semester Exams	Total		
MPA 301	Pharmaceutical Analysis Practical II (Synopsis of Project work/Seminar)	25	75	100	0-0-40	20
						Total Credits = 20

Semester-IV

Code	Title of the paper	Marks	L-T-P
MPA 401	Dissertation Viva voce	300 200	0-0-40
			Total Credits=20

At the end of each semester students will be evalulated in theory/practical/research project work/seminar/dissertation and viva voce as per the respective paper code(s) of each semester.

In Semester III, Practical II of the respective specialization related to research work, synopsis, seminar and corresponding viva of the research envisaged will be evaluated in the final examination. The above examination will be held by a committee consisting of HoD, one external examiner and the respective supervisors, for two days duration and which will submit the marks awarded to the office of Controller of Examination.

It was also resolved that 25% marks earmarked for Internal Assessment will be divided as under.

1. Written examination (Two) (15 marks each, best one will be selected)
2. Seminar/Project/Assignment (10 marks each, best one will be selected)

Grading System

The grade awarded to a student in any particular course will be based on his/her performance in sessionals (usually two written, and one project work) and final examinations. The letter grades and their equivalent numerical points are listed below:

Percentage marks	Letter grade	Grade point	Description of performance
≥80	A	10	Outstanding
75-<80	A(-)	9	Excellent
70-<75	B	8	Very Good
60-<70	B(-)	7	Good
50-<60	C	6	Average
45-<50	C(-)	5	Below Average
40-<45	D	4	Marginal
35-<40	E	3	Poor
<35	F	0	Very Poor
Absent/detained	I	-	Incomplete

If a candidate does not write a paper, he/she will be awarded I grade.

Earned Credits (EC)

The credits for the course in which a student has obtained D (minimum passing grade for a course) or a higher grade will be counted as credits earned by him/her. Any course in which a student has obtained F grade will not counted towards his/her earned credits.

Evaluation of Performance

1. SGPA (Semester Grade Point Average) will be awarded on successful completion of each semester.
2. CGPA (Cumulative Grade Point Average), which is the grade point average for all the completed semester at any point in time, will be awarded in each semester on successful completion of the current semester as well as all of the previous semesters. CGPA is not applicable in Semester I.

Calculation of SGPA and CGPA of a student in a Semester

$$\text{SGPA} = \frac{\sum (\text{Earned Credits} \times \text{Grade Points})}{\sum (\text{Course Credits Registered})}$$

$$\text{CGPA} = \frac{\sum_{i=1}^{m} (\text{Earned Credits} \times \text{Grade Points})}{\sum (\text{Course Credits Registered})}$$

where m is the number of semester passed

For example

Semester I

Subject Code	Subject Credits	Marks	Grade Awarded	Grade Point	Points Secured
MPC 101	5	59	C	6	30
MPC102	6	76	A (-)	9	54
MPC103	9	60	B (-)	7	63
	20				**147**

Total credits = 20
Point secured = 147
SGPA = 147/20=7.35

Semester II

Subject Code	Subject Credits	Marks	Grade Awarded	Grade Point	Points Secured
MPC 201	5	60	B (-)	7	35
MPC 202	5	61	B (-)	7	35
MPC 203	10	70	B	8	80
	20				**150**

Total credits = 20
Points secured = 150
SGPA = 150/20 = 7.5
CGPA = 297/40 = 7.425

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Classification of successful candidates:

The result of successful candidates who fulfill the criteria for the award of M. Pharm. shall be classified at the end of last semester on the basis of his/her CGPA.

Classification shall be done on the basis of following criteria:

He/she shall be awarded "Distinction" if his/her final CGPA is 9 and above and passed all the semester examinations in the first attempts.

He/she shall be awarded "Ist Division" if his/her final CGPA is 6.75 and above but less than 9.

He/she shall be awarded "Second Division" if his/her final CGPA is 6 and above but less than 6.75.

He/she shall be awarded "Pass" if his/her final CGPA is 5 and above but less than 6.

He/she shall be treated as "fail" if his/her final CGPA is less than 5.

8. Attendance

a) All students must attend every lecture and practical class. However, to account for late joining or other such contingencies, the attendance requirement for appearing the examinations shall be a minimum of 75% of the classes actually held.

b) In order to maintain the attendance record of a particular course, a roll call will be taken by the teacher in every scheduled lecture and practical class. For the purpose of attendance, every scheduled practical class will count as one attendance unit, irrespective of the number of contact hours.

c) The teacher incharge will consolidate the attendance record for the lectures and practicals for each term. Attendance on account of participation in the prescribed functions of NCC, NSS, Inter University sports, educational tours/field work record, duly countersigned by the Officer Incharge, has to be sent to the Dean of Faculty within two weeks of the function/activity, etc.

d) The statement of attendance of students shall be displayed on the Department Notice Board at the beginning of every month of University calendar. A copy of the same shall be sent to the Head of Department/Office of Dean of Faculty for record. Notice displayed on Notice Board shall deem to be a proper notification, and no individual notice shall be sent to students.

e) If a student is found to continuously absent from the classes without information for a period of 30 days, the teacher incharge shall report it to the Head of Department/Dean for striking off the name of such student from rolls. Such a student may, however, apply for readmission within 15 days from the date of issue of the notice of striking off the name. The Dean may consider the request for readmission. Such a student shall not be readmitted after the prescribed period. The readmission shall be effected on payment of prescribed readmission fees.

f) A student with less than 75% attendance of the lectures and practicals separately in each subject/course in a semester shall be detained from appearing in the University semester examination. The Dean of Faculty may consider application for the condonation of attendance upto 5% on account of sickness, provided the application for the condonation of attendance on account of illness, duly certified by a Registered Medical Practitioner/Public Hospital had been submitted within 5 days from the recovery from illness. Condonation of attendance on account of any other extenuating circumstances is by documentary evidence.

g) A student detained on account of attendance will be re-admitted to the same class in the next academic year on payment of current fees except enrolment fee, Identity Card fee and Security deposits.

9. Semester Examination

a) Semester examination shall be held as per schedule given in the Academic Calendar of Jamia Hamdard. Along with Semester III papers students will be allowed to appear in the uncleared Semester I papers. The students of Semester IV will be allowed to appear in the uncleared II Semester papers. The students will take uncleared papers of III and IV Semester next year along with the junior batch.

b) The practical examination shall be conducted by an external examiner but two internal examiners instead of one may be appointed to conduct the practical examination, if it becomes necessary in view of the nature of practical exercises.

c) An external examiner shall set the question papers.

d) The subject of dissertation shall be approved on the recommendations of the Supervisor and the Head of Department. One or more than one supervisor may be appointed in a particular case.

e) A candidate shall not be entitled to submit the dissertation unless he/she has pursued his/her research during III and IV Semester under the guidance of supervisor(s). The dissertation shall embody the result of the applicant's own research. It shall indicate in what respect his/her contribution appears to advance the knowledge of subject. The final results of the candidates will be declared only when he/she passed all examinations of Semesters I, II and III.

Every candidate shall submit three printed or typed hardbound copies of his/her dissertation, through the supervisor and Head of Department, normally by the end of fourth Semester. However, an extension for submission of dissertation may be granted upto one month upon the request of the student duly recommended by the supervisor, on receipt of dissertation, the University shall appoint two examiners, one external and one internal, to examine the dissertation and conduct the viva voce.

f) The examiners shall jointly assess the dissertation and award marks for the dissertation and viva voce. In case, the candidate fails to secure the minimum pass marks on the combined performance of the dissertation and viva voce, he/she may be asked to revise the dissertation in the light of the suggestions of examiners or submit a fresh dissertation or his/her being enrolled as an ex-student in relation to the next Semester examination. A re-submitted dissertation will be examined by the same examiner unless they are unable or unwilling to act as examiners. Resubmission of the dissertation shall be permitted after the candidate has put in three months of research work and resubmits the same within six months from the date of publication of result in the first instance and after at least six months of the research work when the dissertation is rejected subsequently.

g) The minimum CGPA required for the award of degree is 5.

10. Promotion

A candidate who fails to secure 75% attendance in any course during a particular semester will have to seek re-admission.

A student shall be promoted to the next semester of the programme if he/she has passed in each of theory and practical separately. However, a student may carry over a maximum of two theory papers or practicals to the next semester. A candidate will be given a total number of three attempts, inclusive of the first attempt, to clear the papers in which he/she fails to qualify.

Promotion to the next higher class will be considered subject to rules relating to the maximum period of stay at the University, viz. passing the first year examination within two academic years, and successfully completing all the requirements of the programme of study within four years from admission.

11. Award of merit

A student shall be eligible for award of Gold Medal subject to the following criteria:

(i) He/she has secured the highest CGPA of the programme of study.
(ii) He/she has passed all examinations, including qualifying courses, if any, in first attempt.

12. Span period

(a) Students admitted to M. Pharm. course must pass the Semester I examination within 24 months from date of admission to the course.
(b) Students must complete all the requirement of M. Pharm. Degree within a total period of four years from their admission.

13. Other Conditions

The Non-GATE qualified candidates admitted to this programme will be required to deposit with Jamia Hamdard an amount equivalent to the contingency grant given by UGC to GATE qualified candidates.

SYLLABUS
FOR M. PHARM
IN
PHARMACEUTICAL CHEMISTRY

(Including the Syllabus of Modern Analytical Techniques {Theory & Practical} common in the Ist Semester of all Branches of M. Pharm expect M. Pharm in Pharmacy Practice)

Semester I **No. of Teaching Hrs. 4 Hrs / Week**
Paper MPC 101 **Duration of Exam 3 Hrs.**
Max. Marks. 100

This Paper (Theory & Practical) is common in Ist semester of all branches of M. Pharm except M. Pharm. in Pharmacy Practice

PHARMACEUTICAL ANALYTICAL TECHNIQUES

ANALYTICAL TECHNIQUES

1. **Chromatographic Tecniques**

Principles of separation and applications of TLC. Column chromatography. Paper chromatography, Ion exchange chromatography, Counter current chromatography, G.C., DCCC, HPTLC & HPLC and electrophoresis.

2. Infrared spectroscopy

Introduction: The IR absorption process; the modes of vibration bond properties and absorption trends. The Hook's Law & calculations of frequencies for different types of bonds; coupled interactions; hydrogen bonding; radiation source, sample handling, qualitative and quantitative applications and introduction about FT-IR

3. Ultraviolet spectroscopy

Introduction: The nature of electronic excitation, the origin of UV band structure; principle of absorption spectroscopy; Beer and Lambert's Law, Chromophore $\sigma \rightarrow \sigma^*$, $\eta \rightarrow \sigma^*$, $\pi \rightarrow \pi^*$ and $\eta \rightarrow \pi^*$ transitions; shifts reagents effects of substituents; effect of conjugation' confirmations and geometry; calculation of Lamda maxima, effect of solvents, qualitative and quantitative applications

4. Nuclear Magnetic Resonance spectroscopy

i. **^{1}H NMR Spectroscopy**: Principle, Instrumentation techniques. Chemical equivalence, spin-spin coupling, The origin of spin-spin splitting, Pascal triangle, the coupling constant chemical shift reagents Pharm. application including interpretation of Proton-NMR spectra.

ii. **^{13}C NMR Spectroscopy:** Peak assignments, off resonance decoupling, selective proton decoupling, chemical shift equivalence, chemical shifts and spin coupling.

5. Mass Spectrometry:

Basic principle and theory involved, Instrumentation, types of ions, fragmentation, rearrangements; mass spectra of representative compounds, recognition of molecular ion peak, chemical ionization mass spectrometry, field desorption mass spectrometry, mass spectrometry, fast atom bombardment mass spectrometry.

6**. Thermal analysis**

Introduction to various thermal methods of analysis, basic principle and theory; differential thermal analysis and differential scanning calorimetry and micro calorimetry. Different types of calorimeters and micro calorimeters.

13. Electron spin resonance spectroscopy

Introduction , derivative curves, δ-values, hyperfine splitting, ESR instrumentation, ESR spectra of free radicals and applications.

8. **Pharmacological evaluation of drugs in biological fluids:** Bioassay.

9. **Microbiological assays.**

10. **Radioimmunoassays.**

11. **Quantitative microscopy of herbal drugs**. Lycopodium spore method, stomatal number, stomatal index, palisade ratio, vein-islet number, and vein-termination number.

12. Pharmacopeal analysis of drugs.

BIOSTATISTICS AND COMPUTER APPLICATION

1. Statistical treatment of data, Graphic & diagrammatic representation of data.
2. Tests of significance, Z-test, t-test, f-test, contingency table, chi-square test.
3. Analysis of variance-one way, two way ANOVA and multiple comparision procedures.
4. Correlation and Regression analysis.
6. Calculation of ED_{50}, LD_{50} and probit analysis.
7. Computer applications

BOOKS RECOMMENDED

1. R.M.Silverstein, F.X.Webster, Spectrometric Identification of organic compounds, 6th ed. John Wiley & sons, New-York, 1998.
2. Remington, The science and practice of pharmacy, Mack publishing company. Easton Pennsylvania.
3. Organic spectroscopy by Willam Kemp
4. E. Heftmann, A laboratory handbook of chromatography, New - York.
5. H.H.Willard, L.L.Merritt and J.A.Dean, Instrumental methods of analysis, Van Nostrend Reinhold, New York.
6. WWM. Wenland, Thermal analysis, John Willy and sons, New-York.
7. Principle of instrumental analysis,V ed. By Skoog, Holler-Niemen.
8. Modern analytical chemistry by David Harvey. (MC Graw-Hill international edition).
9. Q. S. Ahmad, M. Vaseem Ismail & S. A. Khan "Biostatistics", University Science Press, Laxmi Publications Pvt. Ltd, New Delhi, India.

Semester I **Duration of Exam 12 Hrs.**
Paper MPC 102 **Max. Marks. 100**

PRACTICALS

Practicals based on instrumental methods of analysis. A sufficient training will be given through exercises using different kinds of spectral analysis.

Semester No. I **No. of Teaching Hrs. 4 Hrs /week**
Paper MPC 103 **Duration of Exam 3 Hrs.**
Max. Marks. 100

PHARMACEUTICAL CHEMISTRY – I
DRUG DESIGN INCLUDING ORGANIC NAME REACTIONS

1. Physicochemical properties in relation to drug action; metabolic transformation of drugs and its role in development of new drug molecules; Metabolic antagonism.
2. Stereochemical aspects of drug receptor interactions and mechanism of drug interaction. Isosterism and bioisosterism as guides to structural variations; Concepts of conformational analysis and its role in design and development of new drug molecules, configuration-absolute & relative.
3. Principle of drug design: Analogue synthesis versus rational design; discovery of lead compounds, Pharmacophoric identification, Prodrugs and soft drug, recent developments in structure-based drug design; Molecular docking and dynamics. Rigid docking, flexible docking, manual docking, molecular modeling, molecular graphics. Computer methodologies behind molecular molecular modeling including artificial intelligence methods; Pharmacoinformatics –drug design.
4. QSAR, computational chemistry-its role in design and development of new drugs, Hammelt equations, lipophilicity effects, Hanseh equations and steric effcets.
5. In organic chemistry, the following name reactions and molecular rearrangements will be discussed in detail with reference to their application in the synthesis of some medicinal agents, where possible.

(a) Claisen- Schmidt reaction e.g. Sulfisoxazole.
(b) Perkins reaction e.g. sulinadac
(c) Friedal Craft Reaction e.g.fenbufen
(d) Aldol condensation
(e) Mannich reactions e.g. Tolmetin, Atropine, Ethacrynic acid, Dextropropoxyphen.
(f) Beckmann's rearrangement.
(g) Wagner-Meerwein rearrangement
(h) Wittig Reaction
(i) Oppenaur oxidation.
(j) (Meervein- pondroff-verley) M.P.V. Reduction.
(k) Vilsmeier-Haack reaction.
(l) Michael addition

6. Introduction, theory, mechanism of reaction and pharmaceutical application of drug under:
i. Cycloaddition reaction.

Books recommended

1. E.J. Ariens : Drug Design, Academic Press New York (1975).
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, John Willey and Sons. New York.
4. R.F. Doerge, Wilson and Gisvold's Text Book of Organic Medicinal and Pharmaceutical Chemistry, J.Lippincott Co., Philadelphia.
5. J. March, Advanced Organic Chemistry, Reaction Mechanism and Structure, John Wiley and Sons, New York.
6. E.S. Gould, Mechanism and Structure in Organic Chemistry Holt, Rinewart and Winston, New York.

Semester II **No. of Teaching Hrs. 4 Hrs / Week**
Paper MPC 201 **Duration of Exam 3 Hrs.**
Max. Marks. 100

PHARMACEUTICAL CHEMISTRY II
CHEMISTRY OF NATURAL PRODUCTS

1. Natural products as Leads for new pharmaceutical.
2. The natural products obtained from terrestrial and microbial sources will be discussed in the light of various degradative and synthetic approaches supported by spectral data. Important members representing the following classes of natural products shall be discussed.

i. **Alkaloids**

General introduction and classification, isolation and purification methods, general methods employed for determining the structure of alkaloids, constitution of ergot alkaloids, steroidal alkaloids and Opium alkaloids.

ii. **Steroids**

General introduction, stereochemistry, nomenclature and structure elucidation of sterols (cholesterol), sapogenin (diosgenin) and cardiac glycosides.

iii.**Amino acids and peptides, nucleic acids**

General introduction, synthesis of peptides and amino acids. End group analysis, structural features of Insulin, vasopressin and oxytocin, structural features of DNA & RNA.

iv. **Antibiotics**

Classification of antibiotics, structural details of penicillins and tetracyclines, polypeptide antibiotics.

v. **Flavonoids**

Detailed chemical account of rutin and quercetin.

vi. **Triterpenoids**

A general chemical treatment and structural elucidation of terpenoids

vii. **Coumarins**

General methods of isolation and purification and structural determination of xanthotoxin and psoralene.

3. Marine products with therapeutic potential.
4. Naturally occurring carotenoids.

Books Recommended

1. I.L. Finar, Organic Chemistry, Vol.II, The English Language Books Society and Longman Group Limited.
2. G.A. Cordell, Introduction to Alkaloids, John Wiley and Sons, New York.
3. M.L. Wickery and B. Wickery, Secondary Plant Metabolism McMillan Press Ltd. London.
4. L.F. Fieser and M. Fieser, Steroids, Reinhold Publishing Co. New York.
5. K.B.G. Torsell, Natural Products Chemistry, John Wiley and Sons, New York.
6. J.B. Harborne, Phytochemical Methods, Chapman and Hall, London
7. Burger's Medicinal Chemistry and Drug Discovery, Vol. I. Principle and Practice, 5th, Edition, John Wiley Sons, New York.
8. Carotenoids, A Handbook by G. Britton.

Semester II **No. of Teaching Hrs. 4 Hrs / Week**
Paper MPC 202 **Duration of Exam 3 Hrs.**
Max. Marks. 100

Pharmaceutical Chemistry-III
Medicinal Chemistry

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

1. **Receptors and Messengers** :-
   i. Introduction, Classification, The bonding of Ligands to receptors.
   Receptor structure and signal transduction : Receptor families, G. Proteins coupled receptors, Ligand gated ion channel receptors, Kinase linked receptors;
   ii. GABA and glutamate receptor-ligands and their therapeutic potential in CNS disorders.
1. **Parkinsons & Alzheimers disease:** search for therapeutics
2. **Prostaglandins, Chemokine & Cytokine modulators**
3. **Female sex hormones, contraceptives & fertility drugs**
4. **Chemotherapy:**
   i. **Antiviral agents-** including the development in chemotherapy of AIDS and newer agent for the treatment of HIV infection such as HIV entry inhibitors, Chemokine receptor binders, Integrase inhibitors, Inhibitors of gp41 fusion activity.
   ii. **Anti-neoplastic agents** including future anti-neoplastic agents such as Telomerase inhibitors, Antisense technology, Angiogenesis inhibitors, Monoclonal antibodies, Immunotherapy and Signal transduction inhibitors.
5. Drug affecting immune responses.
6. Radioprotective drugs
7. Chemistry of cell membrane.
8. Stereoselective and Regoselective synthesis.

Books Recommended

1. M.E. Wolf, Brugers Medicinal Chemistry, John Wiley and Sons, New York, Vol. II , III, IV, V and VI
2. R.F. Doerge, Wilson and Gisvold's Text Book of Organic Medicinal and Pharmaceutical Chemistry, Lippincott.
3. W.O. Foye, Principles of Medicinal Chemistry, Lea and Febiger, Philadelphia.
4. Lednicer and Mitschler, Drug synthesis, Vol. I, II & III.
5 Martindale, The Extra Pharmacopoeia, Pharmaceutical Press, London
6 T, Albert, Selective Toxicity, Chapman and Hall, London.
7. Burger's Med. Chem. & Drug Discovery, Vol. I.
8. Monographs and relevant Review articles appearing in various periodicals and Journals.

Semester II **Duration of Exam 12 Hrs**
Paper MPC 203 **. Max. Marks. 100**

Practical

Practicals based on some topics covered in the theory part including synthesis of medicinal compounds and analysis of organic mixtures will be carried out.

Semester III
Paper MPC 301 **Max. Marks. 100**

Practical

Practical based on synthesis and spectral analysis of some medicinal compounds.
Synopsis of Research Project
Seminar and viva voce on research methodology and research project.

Semester IV
Paper MPC 401

Dissertation	**300 marks**
Viva voce	**200 marks**

SYLLABUS
FOR M. PHARM
IN
PHARMACEUTICS

SEMESTER-I
Paper MPH 101 & MPH 102
Paper Pharmaceutical Analytical Techniques (Theory & Practical) is common subject in the first semester all branches of M. Pharm course except Pharmacy Practice.

Semester – I **Teaching Hours - 4 Hrs/week**
Paper MPH 103 **Duration of Exam - 3 Hrs**
Max. Marks 100

PHARMACEUTICS-I
PRODUCT DEVELOPMENT AND QUALITY ASSURANCE

1. Preformulation Studies:
Timings and goals of Preformulation, Pre-formulation methodology, solid state properties, partition coefficient, solubility, dissolution, crystal form and stability, 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.

3 . Optimization Techniques in Pharmaceutics, Formulation and Processing
Optimization parameters, statistical design, and other application.

4. Documentation
Relevance and importance of documentation, statuary requirements and procedure for documentation, critical examination of documents.

5. Pharmaceutical Process Validation:
Regulatory basis, Validation of sterile products, Solid dosage forms, Process Validation and non-sterile Analytical method Validation.

6. 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.

Books Recommended :
1. Lachman, Leon and H. A. Lieberman, The theory and Practice of Industrial pharmacy, 3rd edition, Varghese Publishing Co.
2. Gilbert S. Banker and C.T Rhodes, Modern Pharmaceutics, Marcel Decker.
3. Bernard T. L. and Robert A. Narth, Pharmaceutical process validation, volumes 23, Marcel Decker.
4. Norman A., Hodges and Stephen P. Denyer, haul book of Microbiological Quality control, Tayler and Francis, London.
5. Horth Tonneson, Photostability of Drugs and Drug Formulations, Taylor and Francis, London.

Pharmaceutics I Practicals
To illustrate the topics included under theory.

Semester – II **Teaching Hours - 4 Hrs/week**
Paper MPH 201 **Duration of Exam - 3Hrs**
Maximum Marks - 100

Pharmaceutics II
Industrial Pharmacy and Packaging Technology

1. General Consideration, Preparation of Master Manufacturing Procedure
Material Handling, Blending, Granulation, Drying, Slugging Compression, Coating liquid Dosage Forms Contract Manufacturing

2 . Production and Planning Management

Space Allocation, environmental factors, Manufacturing, Materials
Management, Sales forecasting, Cost Control.

3. Drug Regulatory Methods

Definitions ; Federal food, Drug and Cosmetic Act ; Kafaurver Harre's Amendments, New Drug Application, Drug efficacy study, Implementation Review, OTC Drug review, Drug Listing. Drug amendments, Patents, Copy right, Trade Marks, Drug recalls,
product liability, Clinical Trials.

4 . Good Manufacturing Practices

GMP in manufacturing, Processing, Packaging and holding of Drugs ; Control of Components, Containers and closures, Production and process controls : Packaging & labeling controls ; Inspection for compliance with GMP Potable water standards ; Premises : Design, Construction, maintenance, equipment ; maintenance, warehousing, . ISO 9000 certification.

5 . Polymers and their application

Nomenclature, Polymer classification, Physicochemical properties, Chemistry, blends of polymer and properties of blends, Evaluation of polymers, Medical and surgical applications of polymers, polymerization mechanisms, Polymerization methods, Properties of Polymers & their characterization, Mechanism of Drug release from polymers, Applications of Polymers in controlled release of active agents and in other formulations.

6 . Packaging materials science

Packaging design and specifications, packaging validation trials, material of construction, component product validation, Regulatory requirements, Quality control Testing and Standards, GMP requirements & its deficiencies ; In process control during component manufacture Documentation ; Sterilization of packaging components ; Packaging and filling equipment ; Pharmaceutical Packaging including sterile filling area ; customer complaints.

Books Recommended :

1. Lachman Leon & H. A. Liberman, The theory and practice of Industrial Pharmacy, Varghese Publishing Co.
2. Gilber S. Banker and C. T. Rhodes, Modern Pharmaceutics Marcel Dekker Inc.
3. Kenneth Harburn, Quality Control of Packaging materials in the pharmaceutical Industry.
4. Sidney H. Willing, Good Manufacturing Practice for pharmaceuticals, Mercel Decker Inc.
5. Kinam Park, Shalaby. S. W, and Haesun park, Biodegradable Hydrogel for Drug Delivery, Technomic Basel.
6. Armstrong, N. A. and James K. C. , Pharmaceutical Experimental Design and Interpretation, Taylor and Francis, London.
7. Brody, A. L. and Marsh , K.S. , Encyclopedia of Packaging Technology, John wiley and sons, New York.

Pharmaceutics I Practical

To illustrate the topics included under theory.

Semester – II **Teaching Hours - 4 Hrs/week**
Paper MPH 202 **Duration of Exam - 3 Hrs**
Max. Marks 100

Pharmaceutics III
Advances in Drug Delivery Systems

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. Design & Fabrication of Controlled Drug Delivery Systems:

Novel chemical approaches for sustained drug delivery, Design & fabrication of oral controlled release drug delivery systems. Parenteral products, Implantable systems, Transdermal systems, ocular, Intra-vaginal, intra-uterine systems, Cardiovascular drug delivery systems- coated ballon catheters and coated stents.

3. Biochemical and Molecular Biology approaches Controlled Drug Delivery:

Microparticulate drug Carriers ; Liposomes and stealth liposomes, Microspheres and cells, selective endocytosis of macromolecular drug carriers, Antibodies for drug delivery, Resealed erythrocytes, Niosomes,
Nanopharmaceuticals- Methods of preparation, characterization and applications of nanoemulsion, nanoparticles and nanosuspensions.

4. A brief introduction to Intelligent Drug Delivery Systems:

Magnetically modulated, ultrasonically modulated, electrically regulated, photo-responsive, temperature sensitive, systems sensitive to pH, inflammation responsive system, glucose sensitive polymers, urea responsive delivery.

5. Advances in the monitoring of pharmacotherapeutics and in drug delivery system design.

Books Recommended:

1. James Swarbrick, Novel Drug Delivery Systems.
2. Gilbert S. Banker and C. T. Rhodes, Modern Pharmaceutics 2nd Edition.
3. Robinson J. R. and Vincet H. L Lee, Controlled Drug Delivery, Fundamentals and Applications, Volume 29, 2nd edition, Mercel Dekker Inc.
4. Avis, K. E, Leon Lachman, And H. Lieberman, Pharmaceutical Dosage Forms : Parenteral Medications Volume - 2.
5. Lierberman H. A. and Leon Lachman , Pharmaceutical Dosage Forms : Tablets, Volume 3, Marcel Dekker.
6. Kim. C., Controlled Release Dosage form Design, Technomic Publishing Co, Basel.
7. Yie W. Chien- Novel Drug Delivery Systems, 2nd Edition, Marcel Dekker, Inc. New York.
8. Edith Methiowitz- Encyclopedia of Controlled Drug Delivery, Vol 1&2, John Wiley & Sons, Inc.
9.Michael J. Rathbone, Jonathan Hadgraft & Michael S. Roberts, Modified Release Drug Delivery Technology, Marcel Dekker, Inc, New York.
10. A. K. Mitra, Opthalmic Drug Delivery Systems, Vol.58, Marcel Dekker, New York.
11. N.K. Jain, Controlled Drug Delivery, CBS Publisher, New Delhi.
12. S. P. Vyas and Roop K Khar, Targetted and Controlled Drug Delivery: Novel Carrier Systems, CBS Publishers, New Delhi.

Semester – II
Paper MPH 203 **Max. Marks 100**

Practicals

To illustrate the topics included under theory.

SEMESTER-III **Max. Marks: 100**
PAPER MPH 301

Practicals

1. Synopsis of Research Project
2. Seminar and viva voce on Research methodology and Research project.

SEMESTER-IV **Max. Marks: 500**
PAPER MPH 401

1. Dissertation 300 Marks
2. Viva-voce 200 Marks

SYLLABUS
FOR M. PHARM
IN
PHARMACOGNOSY & PHYTOCHEMISTRY

SEMESTER-I
Paper MPP 101 & MPP 102
Paper Pharmaceutical Analytical Techniques (Theory & Practical) is common subject in the first semester all branches of M. Pharm course except Pharmacy Practice.

Semester I **No. of Teaching hrs. 4 hrs/week**
Paper MPP 103 **Duration of Exam. 3 hrs**
Max. Marks 100

Pharmacognosy and Phytochemistry I
(Advances in Pharmacognosy and Phytochemistry)

1. Chemotaxonomy: Significance in classification of medicinal plants, distribution of chemotaxonomical groups of constituents in plant kingdom like alkaloids, glycosides and terpenoids.
2. Biogenetic pathways for the production of phytopharmaceuticals, such as Cardiac glycosides, Coumarins, Flavones, menthol, nicotinic acid, quinidine, papaverine and ergocryptine.
3. Industrially important volatile oils: Natural occurrence, their chemistry, ontogenic variation and trade.
4. Application of UV, IR, NMR, 1HNMR, 13CNMR and Mass spectroscopy for structural elucidation of phytosterols, flavonoids and terpenoids.
5. Recent advances in the field of pharmacognosy and phytochemistry with special reference to anticancer, antidiabetic, anti-inflammatory, hepatoprotective, adaptogenic and immunomodulators, memory enhancers, anti viral agents, antihyperlipidemics.
6. Marine Pharmacognosy: Definition, present status, classification of important bioactive agents, general methods of isolation and purification, study of important bioactive agents, chemistry and uses.
7. Neutraceuticals: Global market prospects and study of five important plants and their products in the international market.

Books recommended

1. Evans WC (2002) Trease & Evans' Pharmacognosy, WB. Saunders & Co., London.
2. Swain T. (1963) Chemical Plant Taxonomy, Academic Press London.
3. Stace C.A. (1985) Plant Taxonomy and Biosystematics, Edward Arnold, London.
4. Cultivation and Utilization of Medicinal Plants by C.K. Atal, R.R. L. Jammu.
5. Street H.E. (1997) Plant Cell and Tissue Culture, Blackwell Scientific, London.
6. Narayanaswami S. (1997). Plant Cell and Tissue Culture, Madras Science Foundation, Madras.
7. Bajaj Y.P.S. "Biotechnology in Agriculture and Forestry-Volumes 4, 7, 8, 9, 15 (1988-91). Springer - Verlag, Berlin.
8. Takashashi N. (1986). Chemistry of Plant Hormones, CRC Press Inc., Florida
9. Gennaro AR (2000). Remington: The Science & Practice of Pharmacy, Lippincott Williams & Wilkins, Philadelphia.
10. Fitoterapia- (last ten years).
11. Planta Medica (last ten years).
12. Plant Cell, Tissue and Organ Culture (last ten years).
13. Journal of Ethnopharmacology (last ten years).
14. Journal of Natural Products (last ten years).
15. Phytochemistry (last ten years).
16. MAPA, NISCAIR (last ten years).
16.Natural Products for Plants by Kaufmann, CRC Press New York
17. Nakanishi K (1977). Chemistry of Natural Products, Kodansha Book Publishing Company, Osaka (Japan).
18. Mohd. Ali (2008) Pharmacognosy (Phytochemistry and Plant Cultivation), Vol. 2, CBS Publishers, New Delhi, Bangalore.
19. Mohd. Ali (2001) Techniques in Terpenoid Identification, Birla Publications (Regd.) Shahdara, Delhi.

Semester II **No. of Teaching hrs. 4h/week**
Paper MPP 201 **Duration of Exam. 3h**
Max. Marks 100

Pharmacognosy and Phytochemistry II
(Medicinal Plant Cultivation and Biotechnology)

1. **Introduction**: Medicinal plant based industry, Export and import of plants, threatened /endangered plants, ecology, biodiversity, geographical variation of plant variety, genotypes.
2. **General aspects involved in cultivation of medicinal plants**: GAP, Conservation of medicinal plants; ex-situ and in-situ cultivation; biodiversity law; WTO and TRIPS agreement; CITES.
3. **Factors involved in production of crude drugs**: exogenous and edaphic factors; mineral supplements; nutrients; growth regulators and inhibitors.
4. **Insect and disease management of medicinal and aromatic plants**: Integrated pest management, plant-based insecticides, microbial phytotoxins as herbicides.
5. **Cultivation technology , post harvest care and processing of medicinal and aromatic plants:** Profile of some high trade value plants: Chirata, Giloe, Gudmar, Isapgol, Jatamansi, Kalmegh, Kesar, Mulethi, Sarpagandha and Tulsi.
6. **Introduction to genetics and molecular biology:** Plant genome and genomic organization, gene families, genetic regulations in transcription and translation in plants; mutation and mutagenesis, transposable elements, genetic manipulations and plant genetic engineering.
7. **Gene mapping and molecular maps of plant genomes:** Plant chromosome analysis, use of PCR in gene mapping, molecular maps-RFLP, RAPD. Physical maps in-situ hybridization.
8. **Tissue culture:** Principle and techniques; organogenesis, embryogenesis, micropropagation, haploids through anther, pollen culture, endosperm culture, induction of triploids, nucellus culture, ovary, ovary and embryo culture, floral bud culture, shoot primordial, stem and root culture, protoplast isolation, fusion and somatic hybridization.
9. **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.
10. **Application of tissue culture in production and enhancement of secondary metabolites:** Strategies involving culture conditions, elicitors, precursors, biotransformation, immobilisation and hairy root cultures.
11. **Transgenic plants:** Approaches for production of transgenic plants and applications.
12. **Enzymes of plant origin:** types, properties, isolation, purification, immobilization, applications and enzyme formulations.

Books recommended

1. Advanced Methods in Plant Breeding and Biotechnology by David R Murray, CAB International Panima Book Distributors, 1991
2. Plant Tissue Culture by Dixon IRL Press Oxford Washington DC, 1985
3. Plant Chromosome Analysis, Manipulation and Engineering by Arun and Archana Sharma, Ist edition, Harwood academic Publishers, 1999
4. Comprehensive Biotechnology by Murray Moo-Young, Volume I-IV, Pergamon Press Ltd., 1985
5. Transgenic Plants by R Ranjan, Agrobotanica, 1999
6. Atal CK and Kapur BM, Cultivation and Utilization of Medicinal and Aromatic Plants, RRL, Jammu

Semester II **No. of Teaching hrs. 4h/week**
Paper MPP 202 **Duration of Exam. 3h**
Max. Marks 100

Pharmacognosy and Phytochemistry III
(Standardization and Evaluation of Natural Product Drugs and Formulations)

1. Introduction: Factors affecting quality of crude drugs, methods for documentation and preservation of crude drugs and their products, detection of common adulterants, microbial contamination, toxic metals, pesticides, insecticides and insect infestation in whole and powdered drugs.

2. Standardization requirements of herbal medicines, traditional and folklore remedies and preparations; their quality, safety and efficacy assessment.
3. Importance of monographs of medicinal plants, their comparative study as per IP, API, Unani Pharmacopoeia, Homoeopathic Pharmacopoeia, Siddha Pharmacopoeia, BHP, Japanese Pharmacopoeia, Chinese Pharmacopoeia, European Pharmacopoeia, USP (dietry supplements), WHO and EMEA guidelines and ESCOP monographs for medicinal products.
4. Quantitative assays to determine extraction efficiency; general methods of analysis; estimation of alkaloids, steroids, terpenoids and flavonoids; active component analysis and purity determination using UV, GLC, HPLC and electrophoretic methods.
5. Quality control of single and multicomponent plant drugs and plant-derived classical Ayurvedic and Unani formulations by study of HPTLC and HPLC fingerprints.
6. Natural products- derived combinatorial libraries and their significance in drug discovery programmes.
7. Shelf life study, protocols to study stabilization of herbal based products. Assessment of physical, physico-chemical and chemical parameters at different stages.
8. Bioavalability and pharmacokinetic significance for herbal drugs with examples of clinically used herbal drugs.
9. Preparation of DMF for herbal medicines
10. Patents:IPR and Regulatory Affairs related to plants and plant products.

Books recommended:

1. Quality Control of Herbal Drugs by Pulok K. Mukherjee, Ist edition, Business Horizons Publishers, New Delhi
2. Indian Herbal Pharmacopoeia, Vol 1&2, RRL, IDMA, 1998, 2000
3. Indian Pharmacopoeia, 2007
4. API, Vol 1-4
5. Standardisation of Botanicals by V Rajpal, Vol. I, Eastern Publishers, New Delhi, 20**02**

Semester II
Paper MPP-203 **Max. marks: 100**

PRACTICALS

List of Experiments (Suggestive)

Isolation of Rutin from *Ruta graveolens*, Hesperidin from Orange peel, Aloin from Aloes, Rhein from rhizome of Rheum species, Piperine from Piper nigrum, Quinine from Cinchona bark, Berberine from Berberis aristata, Caffeine from Tea leaves, Menthol from Mentha species, Diosgenin from Dioscorea and Trigonella species. Determination of Anthracene derivatives in Senna by spectrophotometric method (Fair Buarian 1975), Reserpine in Rauwolfia by photometric method, Carvone content of Umbelliferous fruits, Citral content in Lemon grass oil, Bitter principles of Chirata, Solanaceous drugs, Tropane alkaloids using Vitali Morin reaction, quanititative estimation of Saponin as per W.H.O. protocol in suitable plant material, Resin content in sample of Podophyllum by B.P.C. method, Optical rotation of oil of Lemon, Acid value of Colophony resin by B.P. method. Antimicrobial activity of some volatile oils, Examination of Rhubarb for the presence of Rhapontic Rhubarb by the use of paper chromatography and ultraviolet light. Separation of Solanaceous alkaloids from Belladonna leaf by TLC using hyoscine and hyoscyamine as reference compound. To initiate and develop callus culture and root culture of *Trigonella foenum-graecum* on Murashige and Skoog's and Street & McGroger medium respectively, Determination of Ascorbic acid (Vitamin C) by UV. Spectroscopic method in crude drugs, Determination of Hyoscymine/Hyoscine in Datura species by UV. Spectroscopic method, Quantitative estimation of Reserpine in Rauwolfia serpentina by HPLC method, Quantitative estimation of Quinine in Cinchona bark by HPLC method, quantitative estimation of Ephedrine in Ephedra extracts by HPTLC, Quantitative estimation of glycyrrhizine in Glycyrrhiza glabra by HPTLC, Exercises on Identification of simple Naturally occurring molecules by UV. & IR spectroscopy, Exercises on interpretation of at least 5-different known compounds of Natural origin by using spectroscopic data (NMR & MASS), Preparation of permanent microscopic slides and section cutting by microtone, Determination of Microbial load in Crude drugs, Separation and identification of aflotoxins in Crude drugs, Preparation of detailed monograph of at least one medicinal plant covering taxonomy, phytochemical and pharmacological investigation and its use in traditional system of medicine.

Semester-III

Paper MPP-301 **Max. marks: 100**

1. Allotment of research topic
2. Literature survey of the allotted research topic
3. Preparation and submission of synopsis based on literature survey, objectives, and preliminary research work.
4. Presentation and Viva voce on the submitted synopsis.

Semester- IV

Paper MPP-401 **Max. marks: 500**

Thesis	300 Marks
Viva Voce	200 Marks

SYLLABUS
FOR M. PHARM
IN
PHARMACOLOGY

SEMESTER-I
Paper MPG 101 & MPG 102
Paper Pharmaceutical Analytical Techniques (Theory & Practical) is common subject in the first semester all branches of M. Pharm course except Pharmacy Practice.

Semester-1 **Teaching hrs: 4 hrs/week**
MPG-103 **Duration of Exam 3 hrs.**
M. Marks: 100

PHARMACOLOGY- I
(Basic Principles of Drug Therapy and Clinical Pharmacology)

1. a) Discovery of new receptors
   b) Pharmacological Analysis of Drug-Receptor interactions (*Invitro* - Molecular and Cellular models), Receptor downregulation and upregulation
   c) Cellular transduction mechanisms
   d) Cellular Mechanisms of contraction and relaxation
   e) Cellular mechanisms of cell proliferation and apoptosis
   f) ABC transporters in drug absorption, distribution and excretion, variation in Biotransformation due to genetic polymorphism
   g) Models for studying drug transport (CaCo2 Cells, CHO Cells)
   h) Pharmacokinetic parameters (BA/BE) Role of Physicochemical property and Pharmacokinetic in Drug Discovery.
   i) Effects of liver and renal diseases on pharmacokinetics.

2. Basic principles of pre-clinical evaluation, GLP, IND, NDA, IRBs , Regulatory bodies, ICH.
3. Clinical trials (Phase I,II,III,IV) GCP
4. Pharmacovigilance in India.
5. Pharmacogenetics
6. Drug interactions
7. Pharmacoepidemiology
8. Drug therapy in Pregnancy and Nursing Women
9. Drug therapy in Neonates and Pediatric Patients
10. Drug therapy in elderly
11. Drugs acting on the Autonomic Nervous System
    a). Discovery of neurotransmitters in the ANS
    b) Co-transmission
    c) Pre-synaptic and post-synaptic modulation
    d) Cholinergic transmission
    e) Adrenergic transmission
    f) 5-Hydroxytryptamine receptor agonists and antagonists
    g) Clinical uses of muscarinic receptor agonists and antagonists
    h) Clinical uses of adrenergic receptor agonists and antagonists
    i) Anticholinesterase agents

12. Drug acting on the Central Nervous Systems
    a) Aminoacid transmitters
    Noradrenaline, Dopamine, 5HT, Acetylcholine histamine, Melatonin, NO, lipid mediators, peptides.
    b) Benzodiazepine and Inverse Agonists
    c) Atypical neuroleptics
    d) SSRIs
    e) Pharmacotherapy of epilepsies
    f) Pathophysiology and therapy of migraine
    g) Treatment of Central nervous system neurodegenerative disorders (uses of vaccines)
    h) Opioids

13. Addiction and drug abuse
14. Autacoids
    a) H2, H3 agonists and antagonists
    b) Lipid derived autocoids
    c) COX-1,COX-II, COX-III modulators, Febuxostat
    d) Inflammatory mediators involved in asthma and Pharmacotherapy of asthma.
15. Drugs affecting renal and Cardiovascular function
    a) Diuretics (CA inhibitors, High ceiling, K+ sparing)
    b) Renin angiotensin modulators (Renin inhibitors, ACEI, ARBs)
    c) Treatment of myocardial Ischemia (organic nitrates, Ca^{++}channel blockers, β-blockers, K^{+} channel openers)
    d) Therapy of Hypertension
    e) Pharmacotherapy of Congestive Heart Failure (Digoxin, PDE inhibitors)
    f) Antiarrhythmic drugs
    g) Drug therapy for Hypercholesterolemia and Dyslipidemia (Statins, Fibric acid derivatives, Ezetimibe)
16. Drug acting on the blood and the blood forming organs
    Low molecular weight heparins
    Glycoprotein 11b/111a inhibitors
    Growth Factors

Books recommended:

1. Goodman and Gilman's: The Pharmacological Basis of Therapeutics, edited by Laurence L. Brunton, John, S.L., K.L. Parker 11th Edition
2. D.R. Laurence and P.N. Benett, Clinical Pharmacology
3. H.P. Rang and M.M., Dale, Pharmacology.
4. James Crossland, Lewis's Pharmacology revised.
5. D.G. Grahame-Smith and J.K. Aronson, Oxford Textbook of Clinical Pharmacology and Drug Therapy.
6. Bertram G Katzung : Basic and Clinical Pharmacology 10th Edition.

Semester –II **Teaching hrs: 4 hrs/week**
MPG-201 **Duration of Exam 3 hrs.**
M. Marks: 100

PHARMACOLOGY-II
(Recent Advances and Emerging Trends in Pharmacological Sciences

1. Emerging Trends and Recent advances in:
    a. Receptor and G-Protein
    b. Cyclic nucleotides
    c. Cell Cycle
    d. Ion channel modulators
    e. Neurosteroids
    f. Cannabinoids
    g. Nitric oxide
    h. Antioxidants
    i. Chiral pharmacology
    j. Gene therapy
    k. Neuropeptides
    l. Cytokines
2. Drugs affecting gastrointestinal function
    a. H2-blockers
    b. Protonpumpinhibitors
    c. Prokinetic agents

d. 5HT3-Antagonists

3. Drugs used for Inflammatory Bowel Disease
4. Basic Principles of Chemotherapy
5. Mechanisms of antibiotic resistance in bacteria, Biofilim
6. Antimicrobial agents
7. Antiviral drugs
8. Antifungal drugs
9. Therapy of chloroquine resistant malaria. Vaccine for malaria
10. Pharmacotherapy of Cancer, Monoclonal antibodies, Recombinant interleukin-2
11. Pharmacotherapy of MDR tuberculosis. Vaccine for TB
12. Immunomodulators Anti TNF reagents
13. Newer chemotherapeutic agents (Amoebiasis, Leishmaniasis)
14. Drugs used in obesity
15. Hormones secreted by the hypothalamus, the anterior pituitary and the posterior pituitary.
16. Pharmacotherapy of thyroid disorders
17. Antifertility agents
18. Oral hypoglycaemic agents, Recombinant insulin, Glitazone, DPP-4 inhibitors, Insulin resistance
19. Bisphosphonates
20. Vaccines for autoimmune diseases.

Books recommended:

1. Goodman and Gilman's: The Pharmacological Basis of Therapeutics, edited by Laurence L. Brunton, John, S.L., K.L. Parker 11th Edition
2. D.R. Laurence and P.N. Benett, Clinical Pharmacology
3. H.P. Rang and M.M., Dale, Pharmacology.
4. James Crossland, Lewis's Pharmacology revised.
5. D.G. Grahame-Smith and J.K. Aronson, Oxford Textbook of Clinical Pharmacology and Drug Therapy.
6. Bertram G Katzung : Basic and Clinical Pharmacology 10th Edition.

Journals recommended

Annual Review Pharmacology and Toxicology
Drugs
Pharmacological Reviews
Trends in Pharmacological Sciences
Indian Journals of Physiology and Pharmacology
Indian Journals of Experimental Biology
Indian Journals of Pharmacology

Semester II **Teaching hrs: 4 hrs/week**
MPG-202 **Duration of Exam 3 hrs.**
M. Marks : 100

Pharmacology-III
Pharmacological Methods and Toxicology

1. Preclinical drug development High throughput screening
   In vitro models: Cell based assays (CHO cells), Molecular Methods
   In vivo models: Isolated tissues, organs.
2. Applications of PCR, Northern, Western and Southern blotting, Microarrary technology, Proteomics, Pharmacogenomics
3. Transgenic animals
4. Genetically modified animals
5. Regulatory Toxicology (As per Schedule Y)
6. Prediction of Toxicity.

7. Toxicity Tests: *In vitro* and *In vivo* Acute, subacute and chronic toxicity tests, Mutagenicity, Carcinogenicity, Teratogenicity
8. Mechanisms of drug toxicity
9. Regulations for laboratory animal care and ethical requirements.
10. Pharmacological techniques to evaluate drugs belonging to the following categories.

a. Antipsychotic, antianxiety, anticonvulsants antidepressants, antiparkinsonian, nootropics, anti-inflammatory, analgesic, local anaesthetics.
b. Antihypertensives, anti arrhythmic, antiatherosclerotics, drugs for myocardial infarction
c. Evaluation of antioxidants
d. Evaluation of anticancer agents
e. Evaluation of antifertility agents
f. Evaluation of biotechnology products
g. Evaluation of antidiabetic agents

Books recommended

1. M.N. Ghosh, Fundamentals of Experimental Pharmacology
2. Robert A Turner : Screening Methods in Pharmacology
3. Laurence, D.R. Evaluation of drug activities Pharmacometrics Vol. I and Vol.II
4. Seth, U.K. Selected Topics in Experimental Pharmacology
5. Vogel, H.G. and Vogel, W.H. Drug Discovery and Evaluation Pharmacological Assays.

Semester II **M.Marks: 100**

MPG-203

Pharmacology III Practical
(Pharmacological Methods and Toxicology)

1. Determination of pA2 value, pD2 value
2. 5HT bioassay
3. Blind Screening of drugs
4. Screening methods in Pharmacology
5. Evaluations of Antidiabetic agents
6. Evaluation of Neuroleptics
7. Evaluation of Antidepressants
8. Evaluation of Antiparkinsonian agents
9. Evaluation of Anticonvulsants
10. Evaluation of Antihypertensive agents
11. Evaluation of Anti-inflammatory agents
12. Evaluation of Antiulcer drugs
13. Evaluation of Cardioprotective
14. Evaluation of Hypolipidemic agents
15. Cell based assays for screening of drugs
16. Isolated tissues for screening of drugs

Books recommended

1. M.N. Ghosh, Fundamentals of experimental Pharmacology
2. Robert A. Turner and Peter Hebborn, Screening Methods in Pharmacology, Vol I & II
3. Ian Kitchen, Textbook of invitro Practical Pharmacology
4. D.R. Laurence and A.L. Bacharah, Evaluation of Drug Acativities: Pharmacometrics, Vol, I and II
5. U.K. Sheth, N.K. Dadkar and Usha G Kamat, Selected Topics in Experimental Pharmacology.
6. Pharmacological Experiments of Isolated preparations by Edinburgh University Pharmacology Staff, 1968
7. Randall C. Baselt, Analytical procedures for Therapeutics Drug Monitoring and Emergency Toxicology.
8. Gianni Tagnoni, Roberto Latini and William J Jusko Frontiers in Therapeutics Monitoring

9. Drug Bioscreening Drug Evaluation Techniques in Pharmacology in Emmanuel B. Thompson.
10. K .K. Pillai : Experimental Pharmacology.

Semester III **Research Project Planning**
Paper MPG: 301 **Max. Marks: 100**

1. Selection of thrust area of research
2. Literature Survey of research in the thrust area
3. Project Planning
4. Preparation of brief Synopsis
5. Submission of Form-B of CPCSEA for obtaining permission from JHEAC to Conduct Experiments on animals
6. Evaluation of protocol by external experts.

Semester IV
Paper MPG 401

Dissertation	300 marks
Viva –Voce	200 marks

SYLLABUS
FOR M. PHARM
IN
QUALITY ASSURANCE

SEMESTER-I
Paper MPQ 101 & MPQ 102
Paper Pharmaceutical Analytical Techniques (Theory & Practical) is common subject in the first semester all branches of M. Pharm course except Pharmacy Practice.

Semester - I **Teaching Hours** : 4 Hrs/Week
Paper MPQ 103
Maximum Marks : 100 **Section – A :** 50 Marks **Section – B :** 50 Marks

QUALITY ASSURANCE – I
(Product Development and Guidelines)

Product Development and guidelines
1. Preformulation Studies : pKa and solubility kinetics, pH profile, partition coefficient, crystal morphology, polymorphism, powder flow, surface characteristic, dissolution, compatibility studies, protocol for Preformulation studies.
2. Drug stability: Solution stability, solid state stability, parameters for physical stability testing. Accelerated stability & shelf life assignment of drugs and pharmaceuticals.
3. Dissolution Technology: Dissolution testing devices viz. forced convection non-sink devices, continuos flow through methods, effect of environmental factors during dissolution testing. Dissolution rate test apparatus for suspensions, topical and transdermal products, suppositories and controlled release products.
4. BCS Classification and In vitro-in vivo correlation.
5 . Optimization Techniques in Pharmaceutics, Formulation and Processing
Optimization parameters, statistical design, and other application.
6. 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.
Section 2: GUIDELINES
1. FDA guidelines: drug approval, schedule Y, Introduction to USFDA, NDA, ANDA
2. WHO guidelines
3. USP guidelines for GAMP laboratory
4. Quality risk management guidelines.

	Lectures
Prof. Asgar Ali	2
Dr. Farhan Jalees	1
Dr. Saima	1
Dr. Zeenat	1
Dr. Javed Ali	1

BOOKS RECOMMENDED

1. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
2. Handbook of Pharmaceutical granulation technology, Vol. 81, by Patrich, Marcel Dekker.
3. Microparticulate Systems for the delivery of proteins & vaccines, Vol. 77, by Smadar Cohen & H. Bernstan, Marcel Dekker.
4. Controlled Drug Delivery : Concepts & Advances by Prof. S. P. Vyas & Prof. Roop K Khar, Vallabh Prakashan, Delhi.
5. Targeted & Controlled Drug Delivery ; Novel Carrier Systems, By Prof. S. P. Vyas && Prof. Roop K Khar, CBS Publishers, Delhi.
6. Pharmaceutical dosage Forms - Disperse Systems, Vol. 1, 2 & 3, Herbert A. Lieberman, Martin M. Reiger, Gilbert S. Banker, Marcel & Dekker Inc, New York.
7. Pharmaceutical Dosage forms - Parenteral Medications, Vol 1 -3, Kenneth E. Avis, Herbert A. Leiberman, Leon Lachman, Marcel Dekker Inc., New York.
8. Introduction to Pharmaceutical Dosage Forms, Hourared C. Ansel, 4th edition, Varghese Publishing, Bombay.
9. Pharmaceutical Dosage forms - Tablets, Vol. 1-3, Herbert A. Lieberman, Leo Lachman, Joseph B. Schurartz, Marcel Dekker, Inc., New York.
10. Quality control of Packaging Materials in the Pharmaceutical Industry, Kenneth Herburn, Marcel Dekker, Inc., New York.
11. Pharmaceutical Peletilization Technology, Vol. 37, by Ghebre -Sellassie, Marcel Dekker. New York.
12. Controlled Drug Delivery, Fundamentals of Application, 2nd edition, Vol. 29, # Joseph R. Robinson, Vincent H. L. Lee, Marcel Dekker Inc., New York.
13. Controlled Drug Delivery Vol. I by N. K. Jain, CBS Publisher, New Delhi. 25 Controlled Drug Delivery Vol. II by N. K. Jain, CBS Publisher, New Delhi.
14. Ophthalmic Drug Delivery Systems, Vol. 58 by A. K. Mitra, Marcel Dekker., New York.
15. Bioadhesive drug delivery systems, Vol. 98, by Mathiowitz., Marcel Dekker.
16. Pharmacokinetics, Vol. 15, 2nd edition, by Gibaldi & Perrier, Marcel Dekker.
17. Controlled drug bioavailability, Vol. 3, by Smolen Ball, Witley Interscience.
18. Textbook of Biopharmaceutics and Pharmacokinetics by Javed Ali, Roop K Khar and Alka Ahuja, Birla Publications, New Delhi
19. Clinical Pharmacokinetics, by Rowland, Malcolm and Tozer, Lea Febigar, Philadeliphia, 1980.
20. Textbook of Hospital and clinical Pharmacy by Pratibha Nand and Roop K Khar Birla Publications, New Delhi
21. Pharmaceutical Dispensing by Pratibha Nand and Roop K Khar CBS Publishers, New Delhi
22. P.P.Sharma, Cosmetics-Formulation Manufacturing and Quality Control, Vandana Publications, Delhi,1998.
23. E.A.Rawlins, Bentley's Textbookn of Pharmaceutics, University Printing House, Oxford, 1998
24. Inhalation Delivery of Therapeutic Peptides & Proteins, by Adjel, (Marcel Dekker).
25. Liposomes: Rational Design, by Janoff, (Marcel Dekker).
26. Peptide and Protein Drug Delivery, by Lee, (Marcel Dekker).

Semester – II **Teaching Hours:** 4 Hrs/Week
Paper MPQ 201

Maximum Marks: 100 **Section – A:** 50 Marks **Section – B:** 50 Marks

QUALITY ASSURANCE – II
(Biological Evaluation and Validation)

Section A : Biological Evaluation

1. Microbiological Limit Tests.
2. Sterility Tests: Methodology & Interpretation
3. Tests for effectiveness of antimicrobial preservatives
4. Preclinical Drug Evaluation, acute, subacute and chronic toxicity, Evaluation of a compound for its biological activity, and ED 50 determination. Special toxicity tests like teratogenicity and mutagenecity, Clinical Trials. Introduction to G.C.Ps
5. Biological standardization: General principles, scope and limitations of bioassays, Bioassays of some official drugs.
6. Radio immunoassay: General principles, scope and limitations, radio immunoassay of some drugs like insulin, digitalis etc.
7. Pyrogen - chemistry and properties of bacterial pyrogens and endotoxins, Mechanisms of action of pyrogens. Pharmaceutical aspects, pyrogens test of IP compared to that of BP & USP. Interpretation of data, Comparison of LAL & other pyrogens tests.
8. Animal Studies.

Section B : Validation

1. Validation master planning.
2. FDA 21 CFR Part 11
3. Cleaning validation
4. Process validation: Sterile and non sterile products. Validation of sterilization methods equipment, Autoclaves, dry heat sterilisers, aseptic membrane filtration.
5. Equipment validation and calibration: glass ware, oven, pH meter, UV, HPLC, Dissolution apparatus.
6. Validation of purified water system, distilled water and water for injection
7. Validation of air handling ‘system, sterile’ and non sterile areas
8. Analytical validation: sampling and sample handling.
9. Regulatory considerations in validation

BOOKS RECOMMENDED

1. Introduction to the environmental Monitoring of Pharmaceutical Areas by Michel Jahnke, Davis Harwood International Publishing.
2. Microbiological Risk Assessment in Pharm. Clean rooms by Bengt Ljunggvist and Berit Davis Harwood International Publishing.
3. Microbiology in Pharmaceutical Manufacturing by Richard Prince, Davis Harwood International Publishing.
4. Understanding Active Pharmaceutical ingredients by Siegfried Schmitt, Davis Harwood International Publishing.
5. Quality control of Packaging Materials in the Pharmaceutical Industry, Kenneth Herburn, Marcel Dekker, Inc., New York
6. Pharmaceutical Process Validation, Volume 23, 2nd edition, Bernard T. Lofters, Robert A. Nash, Marcel Dekker, Inc. New York.
7. Parenteral Quality Control: Sterility, Pyrogen, and Package Integrity Testing, 2nd Edition by Akers, (Marcel Dekker).
8. Handbook of Polymer testing, by Brown, (Marcel Dekker).
9. Pharmaceutical Excipients, by Bugay, (Marcel Dekker).
10. Peptide and Protein Drug Analysis, by Reid, (Marcel Dekker).
11. Lipoproteins as Carriers of Pharmaceutical Agents, by Shaw, (Marcel Dekker).
12. Stability Indicating HPLC Methods for Drug Analysis, by XU, (Pharmaceutical Press Titles).

Semester – II **Teaching Hours : 4 Hrs/Week**
Paper MPQ 202 **Maximum Marks:** 100

QUALITY ASSURANCE – III
(Quality Management)

1. Concept of Total quality management philosophy, ISO 9000, Introduction to ICH process
2. GMPs: Organization and personnel, responsibilities, training, hygiene, personnel, records
3. Premises: Location, Design, plant layout. Construction maintenance and sanitation environmental control, utilities and services like gas, water maintenance of sterile areas control of contamination
4. Equipment, selection, purchase specifications, maintenance, clean in place and sterilize in place methods (TP and STP)
5. Raw materials, purchase, specifications, stores, selection of venders Control of Raw materials.
6. Manufacture of and control on dosage forms. Manufacturing documents. Master formula. Batch formula records, standard operating procedure.
7. In process quality controls on various dosage forms sterile and non-sterile standard operating procedure for various operations like cleaning, filling, drying, compression, coating, disinfection, fumigation, sterilization, membrane filtration etc.
8. Packaging and labeling controls. Line clearance, reconciliation of labels, cartons and other packaging materials (refer section B-Validation).
9. Quality control laboratory, responsibilities, good laboratory practices, routine controls, instruments, reagents, sampling plans, standard test procedure, protocols, non-clinical testing, controls on animal house.
10. Data generation and storage. Quality control documentation. Retention samples, records, audits of quality control facilities
11. Finished products release, quality review, quality audits, batch release documents
12. Warehousing, good Warehousing practices, materials management.
13. Distribution and distribution records. Handling of returned goods. Recovered materials and processing.
14. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents
15. Waste disposal, scrap disposal procedures and records
16. Regulatory aspects of pharmaceutical and bulk drug manufacturing, Dossiers for Pharmaceutical Registration of different Countries
17. Loan licenses (contract manufacture)
18. Recent amendments to drugs and cosmetics Acts and other relevant rules. Consumer protection. Environmental protection. Factory Act. Certificate and licensing procedures.
19. WHO Certification, Globalization of drug industry, Introduction to export and import policy of drugs

20. Quality Audits: Raw Materials, Finished Products & Analytical Procedures, manufacturing processes.

BOOKS RECOMMDNED

1. The internal quality audit by Monica Girmaldi and Janet Gough Davis Harwood International Publishing.
2. Validation Master plan by Terveeks or Deeks, Davis Harwood International Publishing.
3. Validation of Asceptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
4. Statistical Design and Analysis in Pharmaceutical Science, by Chow, (Marcel Dekker).
5. Automation & Validation of Information in Pharmaceutical Processing, by deSPAUTZ, (Marcel Dekker).
6. Guidelines for Laboratory Quality Auditing, by Singer,(Marcel Dekker).
7. Pharmaceutical Experimental Design, by Lewis, (Marcel Dekker).
8. New Drug approval process, 2nd edition, Vol. 56, by Guarino, Marcel Dekker., New York.
9. Hosting a compliance Audit by Janet Gough Davis Harwood International Publishing.

Semester – II
Paper MPQ 203 **Maximum Marks:** 100

PRACTICALS

LIST OF EXPERIMENTS FOR M. PHARM.
To illustrate the topic included under theory.

SEMESTER – III **Max. Marks: 100**
PAPER MPQ 301

1. Synopsis of research Project
2. Seminar and vivo-voce on Research Methodology and Research Project

SEMESTER – IV **Max. Marks: 500**
PAPER MPQ 401

1. Dissertation 300 Marks
2. Viva-voce 200 Marks

SYLLABUS
FOR M. PHARM
IN
PHARMACY PRACTICE

Semester- I **No. of Teaching hrs: 4 hrs/week**
MPR- 101 **Duration of Exam. 3 hrs.**
Max. Marks: 100

PHARMACOTHERAPEUTICS
(INCLUDING PHATHOPHYSIOLOGY)

Pathophysiology and applied therapeutics of diseases associated with following system/diseases with special reference to the drugs of choice.

1. **Cardiovascular system** – Hypertension, Congestive cardiac failure, ischaemic heart disease, arrhythmias, hyperlipidemias.
2. **Respiratory system** – Asthma, chronic obstructive airways disease, drug induced pulmonary diseases.
3. **Renal system –** Acute renal failure, chronic renal failure, renal dialysis and transplantation, drug dosing in renal impairment, drug induced renal disease, electrolytes and fluid balance**.**
4. **Haematological disease** – Anaemia, thrombo-embolic disorders, drug induced haematological disorders.
5. **Endocrine system –** Diabetes, thyroid diseases, oral contraceptive, hormone replacement therapy, osteoporosis.
6. **Nervous system** – Epilepsy, Parkinson's disease, stroke and transient ischaemic attacks, headache, Alzheimer's disease, Huntington's chorea.
7. **Psychiatric disorders –** Schizophrenia, depression, anxiety disorders, sleep disorders.
8. **Gastrointestinal system –** Ulcer diseases, inflammatory bowel diseases, hepatitis, jaundice, drug dosing in liver dysfunction, diarrhoea and constipation.
9. **Pathophysiology of Inflammation** and repair, immunology basic principles.
10. **Rheumatic diseases** – Rheumatoid arthritis, gout, juvenile rheumtoid arthritis, systemic lupus erythematostasis (SLE), ankylosing spondylitis.
11. **Infectious diseases –** Meningitis, respiratory tract infections, gastroenteritis, pneumonia, bacterial endocarditis, septicaemia, otitis media, urinary tract infections, tuberculosis, leprosy, protozoal infections, helmenthiasis, HIV, opportunistic infections, other viral infections and fungal infections.
12. **Skin and Sexually transmitted diseases –** Psoriasis, acne, eczema, scabies, syphilis and gonorrhoea.
13. **Oncology cell cycle General principles of Cancer Chemotherapy –** Commonly used cytotoxic drugs, Chemotherapy of lung cancer, Breast cancer, head and neck cancer, prostate cancer, cervical cancer, haematological malignancies.
14. **Ophthalmology –** Glaucoma and eye infections.
15. **Pain management –** Pain pathways, analgesics and NSAIDs, opiates, local anaesthetics, neuralgia including trigeminal and glosso-pharyngeal neuralgias.
16. **Nutrition Malnutrition and deficiency states** – Enteral and parentral nutrition.

Books recommended

1. Roger and Walker, Clinical Pharmacy and Therapeutics, Churchill Livingstone Publication.
2. Joseph T. Dipiro, Pharmacotherapy: A Pathophysiological Approach, Appleton Lange.
3. Cotran RS, Kumar V, Collins T., Robbins Pathological basis of disease, WB Saunders 6th Editd.
4. Green RJ, Harris ND, Pathology and Therapeutics, for Pharmacist: A Basis for Clinical Pharmacy Practice, Chapman and Hall Publication.
5. Eric T Herfindal, Clinical Pharmacy and Therapeutics, William and Wilkins Publication.
6. Avery's Drug Treatment 4th Edn 1997, Adis International Limited.
7. Relevant review articles from recent Medical and Pharmaceutical literature.

Semester- I **No. of Teaching hrs: 4 hrs/week**
Paper MPR- 102 **Duration of Exam: 3 hrs.**
Max. Marks: 100

BASIC PRINCIPLES OF CLINICAL PHARMACY

1. Definition, development and scope of Clinical Pharmacy.

2. **Clinical Pharmacokinetics and Pharmacodynamics** (Volume of distribution, Clearance, Plasma protein binding, Concentration dependent clearance, flow dependent clearance, multicompartment models, physiologic model, pharmacodynamic models, time course of drug action, cumulative effects of drugs, steep concentration effect curves).
    i. Hysteresis
    ii. Proteresis
    iii. Target Concentration Strategy
    iv. Variability and control Strategies in quantitative therapeutics Bioavailability
    v. Drug Biotransformation
    vi. PK- PD Correlations

3. **a. Clinical Evaluation of New Drugs:** Clinical trials, various phases of clinical trials, design and execution of trials in different clinical settings.
    b. Good Clinical Practice: Ethical, legal and social aspects of clinical research, regulatory aspects of clinical research, impact of clinical pharmacology on various aspects of drug development, quality control and quality assurance in clinical trials.
4. **Clinical laboratory tests**: Used in the evaluation of disease states, and interpretation of test results. Haematological, liver function, renal function tests, tests associated with cardiac disorders, fluid and electrolyte balance, common tests in urine, sputum, faeces, CSF.
   Sensitivity screening for common pathogenic micro-organisms, its significance, resistance in disease states and selection of appropriate anti-microbial regimens.
5. **Studies of Imaging Pharmaceuticals (contrast media**): Introduction, Parenteral injection methods, Types of contrast media, characteristics of Iodinated contrast media, Pharmacodynamics, and Pharmacokinetics of contrast media & clinical applications), preventive care and emergency, response to contrast media, patient education and assessment, patient preparations, pre-medication, types of contrast medium reactions.
6. **Drugs in Special Patient Groups** (Pregnancy and Nursing, Neonates and Children, Elderly).
7. **Clinical Importance of Genetics in Drugs Effects.**
8. **Drug therapy Monitoring:** Medication chart view, Medication errors, Clinical review, TDM Pharmacist interventions, Ward round participation. Adverse drug reaction management. Medication history and patient counseling. Drug utilization evaluation (DUE) and review (DUR), Quality assurances of Clinical Pharmacy Services. Patient data analysis.

Books recommended

1. Hasan WE, Hospital Pharmacy, Lee and Febiger publication.
2. Allwood MC and Blackwell, Textbook of Hospital Pharmacy.
3. Avery's drug treatment 4th Edn 1997, Adis International Ltd.
4. Parthasarthi G, Nyfort- Hasen K, Nahata MC, A textbook of Clinical Pharmacy Practice, Chennai, Orient Longman Pvt. Ltd.
5. Stone P and Stephen J Curtis, Pharmacy Practice, Viva Books Private Limited.

Semester- I **No. of teaching hrs: 6 hrs/week**
Paper MPR- 103 **Max. Marks: 100**

PHARMACOTHERAPEUTICS CLINICAL / PRACTICALS I (INCLUDING PATHOPHYSIOLOGY)

The students are required to be posted in various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical condition.

1. **Cardiology**
   (i.)Arrhythmias (ii.) Ischaemic heart disease (iii.) Congestive heart failure (iv.) Myocardial Infarction (v.) Hypertension (vi.) Thromboembolic disease (vii.) Endocarditis.
2. **Gastroenterology**
   (i.)Diarrhoea, Constipation (ii.) Acid peptic disease (iii.) Hepatic disease-hepatitis Cirrhosis and drug Induced hepatic disorder (iv.) Oesophageal reflux (v.) *Helicobacter pylori* induced gastric disorders.

3. **Rheumatology**
   (i.)Rheumatoid arthritis (ii.) Gout (iii.) Degenerative joint disease- Temporal arthritis, Polymyalgia rheumatic (iv.) Systemic lupus erythematosis.
4. **Respiratory medicine**
   (i.)Asthma (ii.) Congestive obstructive airway disease (COAD) (iii.) Acute respiratory failure (iv.) Respiratory tract infections (v.) Interstitial lung disease (vi.) Respiratory aids.
5. **Surgery**
   (i.)Prophylactic antibiotics (ii.) Anticoagulants-Heparin, warfarin (iii.) Thrombolytic Adjunctive therapy (iv.) Pre-operative medications (v.) Analgesia.
6. **Geriatric Medicine**
   (i.)Postural hypotension (ii.) Dementia & delirium (iii.) Compliance assessment.
7. **Paediatrics**
   (i.)Acute otitis media (ii.) Tonsillitis (iii.) Paediatric asthma (iv.) Paediatric gastroenteritis (v.) Colic (vi.) Immunisation (vii.) Attention deficit disorder (viii.) Febrile neutropenia.
8. **Oncology**
   (i.)Breast Cancer (ii.) Lung Cancer-Small cell, Non small cell (iii.) Gastric Cancer (iv.) Colon Cancer (v.) Genitourinary tract, bladder, prostate, testicular cancer (vi.) Skin Cancer, radiation therapy (vii.) Adjunctive therapy- Anti emetics, Mouth care, Nutrition extravasations, pain control, blood products (viii) Colony stimulating factors (ix.) Infectious disease in immuno-compromised patients (x.) Hypercalcemia (xi.) Cerebral Oedema (xii.) Malignant effusions.
9. **Renal**
   (i.) Acute renal failure (ii.) Chronic renal failure (iii.) Drug induced renal disease.
10. **Haematology**
    (i.)Leukaemias (ii.) Lymphomas-Hodgkin's, Non-Hodgkin's (iii.) Multiple myeloma (iv.) Anaemia (v.) Bleeding disorders.
11. **Infections Disease**
    (i.)Respiratory tract infections (ii.) Tuberculosis (iii.) Urinary tract infections (iv.) Joint and bone infections (v.) Skin and soft tissue infections.
12. **Critical Care**
    (i.)Haemodynamic monitoring (ii.) Parenteral & enteral nutrition (iii.) Pharmacotherapy ventilated patients (iv.) Shock-Septic, Cardiogenic.
13. **Endocrinology**
    (i.)Diabetes (ii.) Osteoporosis (iii.) Thyroid disorders (iv.) Syndrome of inappropriate antidiuretic hormone secretion (v.) Adrenal disorders.
14. **Dermatology**
    (i.)Psoriasis (ii.) Dermatitis (iii.) Drug induced skin disorders.
15. **Neurology**
    (i.)Convulsive disorders (ii.) Parkinsons's disease (iii.) Neurodegenerative disorders (iv.) Stroke.
16. **Psychiatry**
    (i.)Unipolar and bipolar disorders (ii.) Anxiety (iii.) Psychosis (iv.) Alcohol abuse (v.) Drug Abuse.
17. **Ophthalmology**
    (i.)Ocular infections (ii.) Conjunctivitis (iii.) Glaucoma (iv.) Post-operative management.

Books recommended

1. Cotran RS, Kumar V, Collins T., Robbins Pathological basis of disease, WB Saunders 6th Editd.
2. Green RJ, Harris ND, Pathology and Therapeutics for Pharmacist : A basis for clinical Pharmacy Practice, Chapman and Hall Publication.
3. Eric T Herfindal, Clinical Pharmacy and Therapeutics, William and Wilkins Publication.
4. Avery's drug treatment 4th Edn 1997, Adis International Ltd.
5. Relevant review articles from recent Medical and Pharmaceutical literature.

Semester- II | **No. of Teaching hrs: 4 hrs/week**
Paper MPR- 201 | **Duration of Exam: 3 hrs.**
Max. Marks: 100

HOSPITAL AND COMMUNITY PHARMACY

A. COMMUNITY PHARMACY

1. Introduction to the concept of community pharmacy – its activities and professional responsibilities.
2. The role of the community pharmacy and its relationship to other local health care providers.
3. Prescribed medication order-interpretation and legal requirements.
4. Patient counseling in community pharmacy (safe use of medicine, risk associated with the use of medicine).
5. Over the Counter (OTC) sales.
6. Services to Nursing homes / Clinics.
7. Community Pharmacy Management: Financial material and staff management infrastructure requirements, drug information resources computers in community pharmacy.
8. Code of ethics for community pharmacists.
9. Polypharmacy and its implication.
10. Patient Compliance.

B. HOSPITAL PHARMACY

11. The role of hospital pharmacy department and its relationship to other hospital departments and staff.
12. Hospital Drug Policy: Drug Committee formulary and guidelines, other hospital committee such as infection control committee and research & ethics committee.
13. Hospital Pharmacy Management: Staff (professional and non professional), Materials (drugs, non drugs, consumables) financial (drug budget, cost centers, sources of revenue collection), Policy and Planning, infrastructure requirements (building furniture and fittings, specialized equipment, maintenance and repair) Workload statistics, Hospital Formulary.
14. Organization of Hospital Pharmacy Services.
15. Drug Distribution: Purchasing warehousing (storage conditions, expiry date control, recycling of drugs, stocktaking drug recalled, Drug distribution method, ward stock individual patient dispensing unit dose, specific requirements for inpatients, outpatients, casualty emergency, theatre, ICU/ICCU, Drugs, of dependence.
16. Radio Pharmaceuticals: I.V. additive service, pre packing and labeling, quality control.
17. Collecting and providing latest information on recently introduced drugs to the health professionals (Doctors, Nurses etc.) in the hospital.
18. Pharmacoepidemiology: Definitions and methods (Qualitative, Quantitative and meta analysis models).
19. Pharmacovigilance: Definitions and scope methods for pharmacovigilence study and its advantages and disadvantages.
20. Pharmacoeconomics: Definitions and scope, type of economic evaluation, cost models and application of Pharmacoeconomics in health care system.
21. Public Health Policy and Health Care System.
22. Rational Drug use and the Essential Drug Concept.

Books recommended

1. Hasan WE, Hospital Pharmacy, Lee and Febiger publication.
2. Allwood MC and Blackwell, Textbook of Hospital Pharmacy.
3. Avery's drug treatment 4th Edn 1997, Adis International Ltd.
4. Parthasarthi G, Nyfort- Hasen K, Nahata MC, A textbook of Clinical Pharmacy Practice, Chennai, Orient Longman Pvt. Ltd.
5. Stone P and Stephen J Curtis, Pharmacy Practice, Viva Books Private Limited.

Semester- II **No. of teaching hrs: 4 hrs/week**
Paper MPR- 202 **Duration of Exam: 3 hrs.**
Max. Marks: 100

DRUG TOXICITY AND MANAGEMENT OF DRUG INFORMATION SERVICES

1. Introduction to toxicology, occupational and environmental toxicology**,** chelators and heavy metal intoxication, insecticide poisoning, toxic potentials of over the counter agents, dermatological toxicity, ototoxicity, nephrotoxicity, hemopoietic toxicity, carcinogenecity & teratogenecity, ocular toxicity, cardiotoxicity, hepatotoxicity, pulmonary toxicity, neurotoxicity, management of patient during drug toxicity (emergency treatment of poisoning) management & functioning of poisons Information centre (day & night).
2. Adverse drug reactions: Incidence of adverse drug reactions, recognizing of adverse drug reactions, types of adverse drug reactions, hypersensitivity reactions, selected adverse effect on selected organs, methods for estimating the probability of adverse drug reactions (conventional categories, WHO categories, Naranjo scale, Hertwig scale), Drug addiction and drug abuse.
3. Drug interactions: Definition of drug interactions, principles of prevention of adverse drug interactions, clinical importance of drug interactions involving enzyme induction and enzyme inhibition.
4. Drug information centre (DIC): Management of drug information services, introduction of drug information sources available (IDIS, IDIN, Micromedex, USP-D1, Poisondex etc.), evidence based medicine (EBM).
5. Critical evaluation of drug information and literature preparation of writing and verbal reports.

Semester- II
Paper MPR- 203 **Max. Marks 100**

PRACTICAL

1. Preparation of Clinical Manual for the treatment of various disorders (in the hospital).
2. a. Estimation of drugs in blood samples: INH, Theophylline, Phenytoin, Valproate, Lithium.
   b. Demonstration of microbial sensitivity test for antibiotics.
   c. Estimation of biomarkers for: liver function, kidney function, cardiac function.
   d. Determination of parameters for pulmonary function.
   e. ELISA method use for analysis of biomarkers of various diseases.

Semester- III
Paper MPR- 301 **Max. Marks 100**

RESEARCH PROJECT PLANNING

- Identification of thrust areas of research in hospital and clinical pharmacy
- Literature survey of research in thrust area
- Preparation of review of literature
- Project design
- Project planning
- Submission of final protocol for IRB approval
- Evaluation of research project by external experts

Semester- IV
Paper MPR- 401

Dissertation	300 marks
Viva Voce	200 marks

SYLLABUS
FOR M. PHARM
IN
PHARMACEUTICAL BIOTECHNOLOGY

SEMESTER-I
Paper MPB 101 & MPB 102
Paper Pharmaceutical Analytical Techniques (Theory & Practical) is common subject in the first semester all branches of M. Pharm course except Pharmacy Practice

Semester-I **No. of teaching hrs 4h/week**
MPB 103 **Duration of Exam: 3h**
Max. Marks:100

PHARMACEUTICAL BIOTECHNOLOGY I
FUNDAMENTALS OF PHARMACEUTICAL BIOTECHNOLOGY

Cell & Molecular Biology:

Organization of bacterial genome; Structure of eukaryotic chromosomes; Role of nuclear matrix in chromosome organization and function; Matrix binding proteins; Heterochromatin and Euchromatin; DNA reassociation kinetics(Cot curve analysis); Repetitive and unique sequences; Satellite DNA; DNA melting and buoyant density; Nucleosome phasing; DNase I hypersensitive regions; DNA methylation Structure of DNA; Measurement of properties-Spectrophotometric, critical dimension atomic force microscopy (CD-AFM) and Electron microscope analysis of DNA structure; Replication initiation, elongation and termination in prokaryotes and eukaryotes; Enzymes and accessory proteins; Fidelity; Replication of single stranded circular DNA; Gene stability and DNA repair- enzymes; Photo reactivation; Nucleotide excision repair; Mismatch correction; SOS repair; Recombination: Homologous and non-homologous; Site specific recombination; Chi sequences in prokaryotes; Gene targeting; Prokaryotic Transcription; Transcription unit; Promoters-Constitutive and Inducible; Operators; Regulatory elements; Initiation; Attenuation; Termination-Rho-dependent and independent; Anti-termination; Transcriptional regulation-Positive and negative; Operon concept-lac, trp, ara, his, and gal operons, Eucaryotic transcription and regulation; RNA polymerase structure and assembly; RNA polymerase I, II, III; Eukaryotic promoters and enhancers; General Transcription factors; TATA binding proteins (TBP) and TBP associated factors (TAF); Activators and repressors; Transcriptional and post-transcriptional gene silencing.

Genetic Engineering:

Basics Concepts: Restriction Enzymes; DNA ligase, Klenow enzyme, T4 DNA polymerase, Polynucleotide kinase, Alkaline phosphatase; Cohesive and blunt end ligation; Linkers; Adaptors; Homopolymeric tailing; Labeling of DNA: Nick translation, Random priming, Radioactive and non-radioactive probes, Hybridization techniques: Northern, Southern and Colony hybridization, Fluorescence in situ hybridization; Chromatin Immunoprecipitation; DNA-Protein Interactions-Electromobility shift assay; DNase I footprinting; Methyl interference assay.

Cloning Vectors: Plasmids; Bacteriophages; M13 mp vectors; PUC19 and Bluescript vectors, Phagemids; Lambda vectors; Insertion and Replacement vectors; EMBL; Cosmids; Artificial chromosome vectors (YACs; BACs); Animal Virus derived vectors-SV-40; vaccinia/bacculo & retroviral vectors; Expression vectors; pMal; GST; pET-based vectors; His-tag; GST-tag; MBP-tag etc.; Intein-based vectors; Inclusion bodies; Methodologies to reduce formation of inclusion bodies; Baculovirus and pichia vectors system, Plant based vectors, Ti and Ri as vectors, Yeast vectors, Shuttle vectors.

Cloning Methodologies: Insertion of Foreign DNA into Host Cells; Transformation; Construction of libraries; Isolation of mRNA and total RNA; cDNA and genomic libraries; cDNA and genomic cloning; Expression cloning; Jumping and hopping libraries; Southwestern and Farwestern cloning; Protein-protein interactive cloning and Yeast two hybrid system; Phage display; Principles in maximizing gene expression

PCR and Its Applications: Primer design; Fidelity of thermo stable enzymes; DNA polymerases; Types of PCR – multiplex, nested, reverse transcriptase PCR, real time PCR, touchdown PCR, hot start PCR, colony PCR, cloning of PCR products; T-vectors; Proof reading enzymes; PCR in gene recombination; Deletion; addition; Overlap extension; and SOEing; Site specific mutagenesis; PCR in molecular diagnostics; Viral and bacterial detection; PCR based mutagenesis, Mutation detection: SSCP, DGGE, RFLP, Oligo Ligation Assay (OLA), MCC (Mismatch Chemical Cleavage, ASA (Allele-Specific Amplification), PTT (Protein Truncation Test)

Sequencing Methods: Enzymatic DNA sequencing; Chemical sequencing of DNA; Automated DNA sequencing; RNA sequencing; Chemical Synthesis of oligonucleotides; Introduction of DNA into mammalian cells; Transfection techniques; Gene silencing techniques; Introduction to siRNA; siRNA technology; Micro RNA; Construction of siRNA vectors; Principle and application of gene silencing.

Cancer Biology:

Nonsense, missense and point mutations; Intragenic and Intergenic suppression; Frameshift mutations; Physical, chemical and biological mutagens; Transposition - Transposable genetic elements in prokaryotes and eukaryotes; Mechanisms of transposition; Role of transposons in mutation; Viral and cellular oncogenes; Tumor suppressor genes from humans; Structure, function and mechanism of action of pRB and p53 tumor suppressor proteins; Activation of oncogenes and dominant negative effect; Suppression of tumor suppressor genes; Oncogenes as transcriptional activators; Mechanisms of action of anti cancer drugs.

Modern methods in Biotechnology:

Immunodiffusion; Immunoblot; Immunofluorescence; Immunoaffinity; ELISA; Agglutination; Immunoprecipitation; Immunoelectrophoresis; Biotinylation; Avidin-streptavidin cross-linking; immunogens; Immunomodulations, RIA, Flow cytometry; Micro arrays, Gel electrophoresis , Pulse field gel electrophoresis, Protein purification techniques, Protein sequencing , SDS-PAGE, 2D electrophoresis, MALDI-TOF MS. Classification of chromatographic techniques; Normal and reversed phase; Bonded phase; Separation mechanisms. Short-column chromatography and flash chromatography; Vacuum liquid chromatography (VLC); Medium pressure liquid chromatography; Over pressure layer chromatography (OPLC); Centrifugal chromatography, Counter-current chromatography; Droplet counter-current chromatography; Ion-exchange; Affinity; Size exclusion and ion pair chromatography, FPLC, GC-MS and LC-MS techniques. Differential centrifugation, Density Gradient centrifugation, Florescence microscopy, Autoradiography

BOOKS RECOMMENDED:

1. S.B. Primrose, R.M. Twyman and R.W.Old; Principles of Gene Manipulation. 6th Edition, S.B.University Press, 2001
2. J. Sambrook and D.W. Russel; Molecular Cloning: A Laboratory Manual, Vols 1-3, CSHL, 2001.
3. Brown TA, Genomes, 3rd ed. Garland Science 2006
4. Benjamin Lewin, Gene IX, 9th Edition, Jones and Barlett Publishers, 2007.
5. J.D. Watson, N.H. Hopkins, J.W Roberts, J. A. Seitz & A.M. Weiner; Molecular Biology of the Gene, 6th Edition, Benjamin Cummings Publishing Company Inc, 2007.
6. Ronald W Rousseau, Handbook of separation process technology, Wiley Intersciences Publication, New York, 1987.
7. Kuby, RA Goldsby, Thomas J. Kindt, Barbara, A. Osborne Immunology, 6th Edition, Freeman, 2002.
8. Brostoff J, Seaddin JK, Male D, Roitt IM., Clinical Immunology, 6th Edition, Gower Medical Publishing, 2002.
9. G.M. Cooper, The Cell, 2nd edition, Sinaver publications

Semester-II **No. of teaching hrs 4h/week**
MPB 201 **Duration of Exam: 3h**
Max. Marks:100

PHARMACEUTICAL BIOTECHNOLOGY II
ADVANCED PHARMACEUTICAL BIOTECHNOLOGY

Molecular Biotechnology:

RNA interference, Processing of hnRNA, tRNA, rRNA; 5'-Cap formation; 3'-end processing and poly adenylation; Splicing; RNA editing; Nuclear export of mRNA; mRNA stability; Catalytic RNA. Translation machinery; Ribosomes; Composition and assembly; Universal genetic code; Degeneracy of codons; Termination codons; Iso accepting tRNA; Wobble hypothesis; Mechanism of initiation, elongation and termination; Co- and post-translational modifications; Genetic code in mitochondria; Transport of proteins and molecular chaperones; Protein stability; Protein turnover and degradation, Protein engineering and design. Functional genomics, proteomics, DNA micro arrays, Gene expression profiling; Protein micro arrays and BioChips; Antibody micro arrays; Protein-protein and protein-DNA interaction, Drug-DNA binding, telomere biology and the DNA damage, Antisense technology, Development of drug resistance,

Strategies for drug resistance reversal, gene probes and the diagnosis of disease, molecular mechanism of action of anti microbial drugs, Gene therapy; pharmacogenomics; metabolonomics.

Immuno Biotechnology:

Hybridoma; DNA Vaccines; Viral, bacterial peptides; genetically engineered production of lymphokines; Second generation antibodies, antibody engineering and design, Development of therapeutic monoclonal antibodies, Immunosuppression; Autoimmune disorders: its molecular mechanism; Immunodeficiency disorders (AIDS); Tumor immunology; Dendritic cells in cancer immunotherapy; Development of diagnostic kit using monoclonal antibodies; Development of new vaccine against Tumor and viral infections

Formulation of Biotech Products:

Formulation development, stability, quality control and quality assurance study of pharmaceuticals containing monoclonal antibodies, peptide and proteins; drug targeting by using monoclonal antibodies, Development of DNA and Gene delivery system. Pharmaceutical formulation development for probiotics

Drug Designing and Bioinformatics:

Database concepts; Protein and nucleic acid databases; Structural databases; Biological XML DTD's; Pattern matching algorithm basics; Computational tools for DNA sequence analysis; Identification of protein sequence from DNA sequence; Searching of databases similar sequence; The NCBI; Publicly available tools; Resources at EBI; Resources on the web; Database mining tools. DNA sequence analysis: The gene bank sequence database; Submitting DNA sequence to the databases and database searching; Sequence alignment; Pair wise alignment techniques; Multiple sequence analysis; Multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package; Use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment; Submitting DNA protein sequence to databases; Protein Modeling: Introduction; Force field methods; Energ, Buried and exposed residues; Side chains and neighbors; Fixed regions; Hydrogen bonds; Mapping properties onto surfaces; Fitting monomers; rms fit of conformers; Assigning secondary structures; Sequence alignment- methods, evaluation, scoring; Protein completion: backbone construction and side chain addition; Small peptide methodology; Software accessibility; Building peptides; Protein displays; Substructure manipulations, Annealing. Peptidomimetics: Introduction, classification; Conformationally restricted peptides, design, pseudo peptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics. Protein Structure Prediction: Protein folding and model generation; Secondary structure prediction; Analyzing secondary structures; Protein loop searching; Loop generating methods; Loop analysis; Homology modeling: potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions; Threading techniques; Topology fingerprint approach for prediction; Evaluation of alternate models; Structure prediction on a mystery sequence; Structure aided sequence techniques of structure prediction; Structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence-sequence scoring. QSAR study for predicting and classifying the biological activity of untested chemicals such as drug resistance, toxicity prediction, physicochemical properties prediction, ADME properties prediction

IPR, Biosafety & Regulatory Affairs:

Types of IP: Patents, Trademarks, Copyright & Related Rights, Protection of GMOs, IP as a factor in R&D; IPs of relevance to Biotechnology and few Case Studies; Introduction to Patents; Types of patent applications: Ordinary, PCT, Conventional, Divisional and Patent of Addition; Specifications: Provisional and complete; Forms and fees; Invention in context of "prior art"; Patent databases; Searching International Databases; Country-wise patent searches (USPTO, esp@cenet(EPO), PATENT Scope (WIPO), IPO, etc.) National & PCT filing procedure; Time frame and cost; Status of the patent applications filed; Precautions while patenting – disclosure/non-disclosure; Financial assistance for patenting - introduction to existing schemes; Patent licensing and agreement, Patent infringement- meaning, scope, litigation, case studies; Biosafety Levels; Biosafety Levels of Specific Microorganisms; Recommended Biosafety Levels for Infectious Agents and Infected Animals; Biosafety guidelines - Government of India; Roles of Institutional Biosafety Committee, Standard Operating Procedures (SOPs), Auditing and Compliance Functions, Regulatory strategies, Regulatory agencies, legislation and documentation systems as required for USFDA, UKMCA/UKMHRA, MCC & WHO. Drug Trials and Vaccine Trials Guidelines, Formatting, assembling and submitting the NDA, Human Genetic Research, Indian Ethics Committee, Clinical Trial Regulation in

India; Pharmaco-vigilance and ADR reporting; Product Registration for Regulated and Non Regulated Markets

BOOKS RECOMMENDED:

1. Benjamin Lewin, Gene IX, 9th Edition, Jones and Barlett Publishers, 2007.
2. J.D. Watson, N.H. Hopkins, J.W Roberts, J. A. Seitz & A.M. Weiner; Molecular Biology of the Gene, 6th Edition, Benjamin Cummings Publishing Company Inc, 2007.
3. Kuby, RA Goldsby, Thomas J. Kindt, Barbara, A. Osborne Immunology, 6th Edition, Freeman, 2002.
4. Brostoff J, Seaddin JK, Male D, Roitt IM., Clinical Immunology, 6th Edition, Gower Medical Publishing, 2002.
5. Janeway et al., Immunobiology, 4th Edition, Current Biology publications., 1999.
6. Paul, Fundamental of Immunology, 4th edition, Lippencott Raven, 1999.
7. Goding, Monoclonal antibodies, Academic Press. 1985.
8. S.B. Primrose, R.M. Twyman and R.W.Old; Principles of Gene Manipulation. 6th Edition, S.B.University Press, 2001
9. J. Sambrook and D.W. Russel; Molecular Cloning: A Laboratory Manual, Vols 1-3, CSHL, 2001.
10. Brown TA, Genomes, 3rd ed. Garland Science 2006
11. BAREACT, Indian Patent Act 1970 Acts & Rules, Universal Law Publishing Co. Pvt. Ltd., 2007
12. Kankanala C., Genetic Patent Law & Strategy, 1st Edition, Manupatra Information Solution Pvt. Ltd., 2007
13. David W. Mount, Bioinformatics: Sequence and Genome Analysis 2nd Edition, CSHL Press, 2004.
14. Jonathan Pevsner, Bioinformatics and Functional Genomics, 1st Edition, Wiley-Liss, 2003.
15. P. E. Bourne and H. Weissig, Structural Bioinformatics, 2nd Edition, Wiley, 2008.

Semester-II **No. of teaching hrs 4h/week**
MPB 202 **Duration of Exam: 3h**
Max. Marks:100

PHARMACEUTICAL BIOTECHNOLOGY III
APPLICATIONS OF PHARMACEUTICAL BIOTECHNOLOGY

Industrial Microbiology:

Distinguishing features of various groups of microorganisms Actinomycetes, bacteria, moulds, yeasts and algae; and microorganisms of extreme environment and marine microorganisms; Pure culture concept and cultural characteristics; Isolation, development, preservation and improvement of industrially important micro-organisms; Isolation of auxotrophic mutants; Isolation of revertant mutants and use of recombinant systems for the improvement of industrial microorganisms; Growth measurement techniques; Assimilation of carbon, nitrogen and sulphur; Isolation of organisms from various sources and long term preservation and improvement of cultures; Process technology for the production of microbial secondary metabolites such as cephalosporins, vitamins, statins, and new generation therapeutic molecules. Production of probiotics; Microbial biotransformation of natural products; Bioreactor designing and types, different fermentation techniques, Kinetics of microbial growth; Substrate utilization and product formation; Structured and unstructured model of growth; Equations for substrate utilization and product formation; Yield coefficients; Fermentation media designing, Characteristics of biological materials: pretreatment methods; Separation of cell mass: centrifugation, clarification and filtration; Different equipment use related to various unit operations; Different methods of cell disruption; Advantages; Disadvantages; Solid shear method and liquid shear method; Different concentration methods: evaporation, distillation, crystallization, SCFE, solvent extraction, phase separation, drying etc., whole broth extraction, protein precipitaiton; extraction; adsorption; Ultrafiltration; Reverse osmosis; Cross flow filtration; Microfiltration; Isoelectric focusing; Affinity based separations

Enzyme Technology:

Production, isolation and purification of enzymes; Characterization in terms of pH, temperature, ionic strength, substrate and product tolerance, effects of metal ions etc.; Enzyme kinetics: Enzymes as

biological catalysts; Microbial production of therapeutic enzymes. Immobilized enzyme technology: Different techniques of immobilization of enzymes and whole cells; Advantages and disadvantages of immobilization; Kinetics of immobilized enzymes; Design and operation of immobilized enzyme reactors; Multi step immobilized enzyme systems; Application and future of immobilized enzyme technology; Enzymes in organic solvents and ionic liquids: Various organic solvents and ionic liquids used in biocatalysis; Potential of biocatalysis in organic solvents and ionic solvents; Enzyme engineering; Directed evolution and its applications in the field of biocatalysis; Various approaches of creating variant enzyme molecules; Future of biocatalysis; Ideal Biocatalyst. Biocatalysis; Advantages and disadvantages of biocatalysis over chemical catalysis; Different types of biocatalysis: Microbial, enzymatic and immobilized system of biocatalysis; Current industrial biocatalysis; Biocatalysis with different enzymes: Lipase, amidase/aminopeptidase, Acylase, Hydantoinase, lyases, Oxidoreductase, Nitrilase, Epoxide hydrolase, Hydroxylase, Aldolases, Decarboxylase; Stereoselective production of drug intermediates; Biocatalysis for the synthesis of some chiral pharmaceutical intermediates such as synthesis of ACE inhibitors; Synthesis of anti-cholesterol drugs by biocatalytic routes; Calcium channel blocking drugs; Potassium channel openers; Anti arrythmic compounds; Anti-psychotic compounds; Anti-infective drugs; Anti-inflammatory drugs; Antiviral agents; Prostaglandin synthesis.

Cell Culture Technology:

Animal cell growth characteristics and kinetics;Substrate and product transport through mammalian cell;Growth and mass transfer: Micro-carrier attached growth; Cell culture in continuous, perfusion and hollow-fiber reactor; Mass transfer in mammalian cell culture. Plant products of industrial importance; Biochemistry of major metabolic pathways and products; Cell suspension culture development; Kinetics of growth; Product formation and examples; Large scale production of secondary metabolites from suspension cultures-nutrient optimization; Cell growth regulators; Plant cell reactors; Types of reactors; Comparison of reactor performance; Immobilized plant cell reactors; Novel design concepts

Biopharmaceuticals:

Production and purification Viral vaccines such as polio, rabies, Rubella, influenza, Measles from cell culture, Production, purifications of different cellular biochemicals such as angiogenic factor, Interferon, Immunoregulatory biochemicals such as Interleukin-2; hormones such as growth hormone, Follicle-Stimulating Hormone, ACTH, erythropoietin from cell lines; production and purification monoclonal antibody from hybridoma clone. Production and purification of Biopharmaceuticals such as Human growth hormone, Insulin, streptokinase, TNF,IGF, fibroblast growth factor, plasminogen activator, Epidermal growth factor, Platelet derived growth factor, granulocyte colony stimulating factor obtained through rDNA technology; scale up, down streaming and quality control of biopharmaceuticals.

In vitro Cell Culture Assay Systems

Correlation between in-vitro and in-vivo screens; Special emphasis on cell-based assay, biochemical assay, radio ligand binding assay; High through put screening; High through put pharmacokinetic analysis; Specific use of reference drugs and interpretation of results; Drug bioavailability study in caco2 model; in vitro evaluation and screening of anti viral, anti cancer and anti protozoal drugs. In vitro toxicity study, in vitro metabolism study of newer drug molecules; Screening of natural products using micro arrays

BOOKS RECOMMENDED:

1. Nelson and Cox, Principles of Biochemistry, 4th Edition, W. H. Freeman, 2004.
2. Donald Voet and Judith Voet, Biochemistry, 3rd Edition, JohnWiley, 2007.
3. J. Rehm and G. Reed, Enzyme Technology, Vol. 7a, VCH-Verlag.
4. Michael L. Shuler and Fikret Kargi, Bioprocess Engineering: Basic Concepts, 2nd Edition, Prentice Hall, 2001.
5. Pauline M. Doran, Bioprocess Engineering Principles, 1st Edition, Academic Press, 1995.
6. James E. Bailey and David F. Ollis, Biochemical Engineering Fundamentals, 2nd Revised Edition, McGraw-Hill, 1986.
7. Pelczar MJ Jr., Chan ECS and Kreig NR., Microbiology, 5th Edition, Tata McGraw Hill, 1993.
8. Crueger and Crueger, Biotechnology: A Textbook of Industrial Microbiology, Sinaeur Associates, 1990.
9. G Reed, Prescott and Dunn's, Industrial Microbiology, 4th Edition, CBS Publishers, 1987.

10. M.T. Madigan and J.M. Martinko, Biology of Microorganisms, 11th Edition, Pearson Prentice Hall, USA, 2006
11. P. F. Stanbury & A. Whitaker, Principles of fermentation technology, Pergamon Press.
12. S. J. Pirt, Principles of microbe and cell cultivation, 3rd Edition, Wiley, 1975.
13. Thomas F. Woolf, Handbook of Drug Metabolism, Marcel Dekker, New York, 1999.
14. S N Mukhopadhay, Process biotechnology fundamentals, Viva Books, 2001.
15. Doran, Bioprocess Engineering, Academic Press, 2005.
16. Biotol series, Product Recovery in Bioprocess Technology, 1st Edition, Butterworth Heinemann Ltd., 1992.
17. Biotol series, In vitro Cultivation of Plant cell, Butterworth Heinemann Ltd., 1994
18. Biotol series, In vitro Cultivation of Animal cell, Butterworth Heinemann Ltd. 1994.
19. M. M. Ranga, Animal Biotechnology, 3rd Revised Edition, Agrobios, 2007.
20. Bhojwani & Rajdhan, Animal and Plant Biotechnology.
21. D.P.Katare, A. Ahmad & V. Aeri, Pharmaceutical biotechnology basics & fundamental, Capital publishers, New Delhi
22. D.J.A. Crommelin & R.D.Sindelar, Pharmaceutical biotechnology, Taylor Francis, New York

Semester-II **No. of teaching hrs 4h/week**
MPB 203 **Duration of Exam: 3h**
Max. Marks:100

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL

Practical on Biochemistry and Analytical Techniques

1. To prepare an Acetic-Na Acetate Buffer system and validate the Henderson-Hasselbach equation.
2. To determine an unknown protein concentration by plotting a standard graph of BSA using UV-Vis Spectrophotometer and validating the Beer- Lambert's Law.
3. Titration of Amino Acids and separation of aliphatic, aromatic and polar amino acids by TLC.
4. An Enzyme Purification Theme
   (a) Preparation of cell-free lysates
   b) Ammonium Sulfate precipitation
   c) Ion-exchange Chromatagraphy
   (d) Gel Filtration
   (e) Affinity Chromatography
   (f) Generating a Purification Table
   (g) Assessing purity by SDS-PAGE Gel Electrophoresis
   (h) Assessing purity by 2-D gel Electrophoresis
   (i) Enzyme Kinetic Parameters: Km, Vmax and Kcat.

Practical on Molecular Biology

1. Plasmid DNA isolation and DNA quantitation: Plasmid minipreps
2. Restriction digestion
3. Preparation of competent cells.
4. Agarose gel electrophoresis
5. Restriction Enzyme digestion of DNA
6. Purification of DNA from an agarose gel
7. DNA Ligation
8. Transformation of E.coli with standard plasmids, Calculation of transformation efficiency
9. Cloning of genomic DNA in standard plasmid vectors
10. Confirmation of the insert, Miniprep of recombinant plasmid DNA Restriction mapping
11. RFLP analysis of the PCR product
12. Transformation of yeast *Saccharomyces cerevisia*

Practical on Immunology

1. Selection of animals, Preparation of antigens, Immunization and methods of bleeding, Serum separation, Storage.
2. ELISA method.
3. Double diffusion, Immuno-electrophoresis and Radial Immuno diffusion.
4. Complement fixation test.

5. Isolation and purification of IgG from serum or IgY from chicken egg.
6. SDS-PAGE, Immunoblotting, Dot blot assays
7. Immunodiagnostics using commercial kits

Practical on Microbiology

1. Sterilization, disinfection, safety in microbiological laboratory.
2. Preparation of media for growth of various microorganisms.
3. Identification and culturing of various microorganisms.
4. Staining and enumeration of microorganisms.
5. Growth curve, measure of bacterial population by turbidometry and studying the effect of temperature, pH, carbon and nitrogen.
6. Assay of antibiotics production and demonstration of antibiotic resistance.
7. Isolation and screening of industrially important microorganisms.
8. Determination of thermal death point and thermal death time of microorganisms.

Practical on Fermentation Technology

1. Sterilization of air and calibration of DO electrode.
2. Calibration of pH electrode and pH regulation.
3. Manipulation of DO with air flow and stirrer speed regulation.
4. Preparation of inoculum and production of ethanol by *S. cerevisiae*.
5. Analysis of ethanol produced by enzymatic method.
6. Immobilizing of microbial cells

Practical on Plant Cell and Animal Cell Culture

1. Preparation and sterilization of liquid and solid medium for animal and plant cell culture
2. Callus induction from different explants under aseptic conditions
3. Development of suspension culture for plant cell
4. Maintenance of mammalian cell lines
5. Evaluation of cytotoxicity by MTT assay

Semester III
Paper MPB-301 **Max. marks: 100**

1. Allotment of research topic
2. Literature survey of the allotted research topic
3. Preparation and submission of synopsis based on literature survey, objectives, and preliminary research work.
4. Presentation and Viva voce on the submitted synopsis.

Semester IV
Paper MPB-401
Max. marks: 500

Thesis	300 Marks
Viva Voce	200 Marks

SYLLABUS
FOR M. PHARM
IN
PHARMACEUTICAL ANALYSIS

SEMESTER-I

Paper MPA 101 & MPA 102

Paper Pharmaceutical Analytical Techniques (Theory & Practical) is common subject in the first semester all branches of M. Pharm course except Pharmacy Practice

Semester I **No. of Teaching Hrs. 4 Hrs / Week**

Paper MPA 103 **Duration of Exam 3 Hrs.**

Max. Marks. 100

PHARMACEUTICAL ANALYSIS-I

1. Seperation Techniques (and other separation techniques if any)

Normal and reversed phase, bonded phase, separation mechanism, flash chromatography, vacuum liquid chromatography (VLC), medium pressure liquid chromatography, over pressure layer chromatography (OPLC), Phase HPLC and UPLC (Ultra performance liquid chromatography)

2. Mass spectrometry

Principle, theory, procedure and application involved in GC-MS, LC-MS and Tandem mass $[MS\text{-}MS]^n$ spectrometry, Newer mass analyzer and newer ionization sources, MALDI; Magnetic sector mass analyzer, double focusing mass analyzer, Newer detector (Microchannel plate detector)

3. NMR (2-D NMR)

Principle of two dimentional NMR (2D-NMR); Pulse sequence, Homonuclear 2D-NMR (^1H-^1H COSY), Hetronuclear 2D-NMR (^1H-^{13}C COSY: HETCOR; HMBC), HMCQ, INADEQUATE (^{13}C-^{13}C correlations); TOCSY; DEPT;NOESY

4. Electrometric methods of analysis

Principle, procedure and pharmaceutical applications of the following methods

i. Conductometric titrations
ii. Amperometric titration
iii. Controlled potential electrolysis

5. Light scattering methods in quantitative analysis

i. Turbidometry.
ii. Nephelometry.
iii. FT Raman spectroscopy.

6. Quantitative analysis based on molecular luminescence

i. Fluorimetry.
ii. Phosphorimetry.

7. X-ray spectroscopy :

Introduction, production and properties of the x-ray, x-ray emission, x-ray absorption, principles of x-ray diffraction, x-ray diffraction method, application of x-ray diffraction technique in Pharmaceutical sciences.

8. Optical rotatory dispersion and circular dichroism, introduction, cotton effect, stereochemistry, octane rule & applications.

Books Recommended

1. Indian Pharcopoeia, Controller of publications, Govt of India.
2. Beckett & Stanlake, Practical pharmaceutical chemistry, Part I & II, IV edition.
3. Douglas. A. Skoog, Principles of instrumental analysis, Saunder's college publishing, Philadelphia.
4. Kealey and Haines, Analytical chemistry, Viva books Pvt. Ltd, New Delhi.
5. Bochmman and Hassan, Pharmaceutical Analysis, edited by Higuchi.
6. K. A. Connors, Textbook of Pharmaceutical Analysis, III edition , John Wiley and sons, New York. (reprinted)
7. Gearin, Graboski, Methods of drug analysis.
8. R. V. Smith, JT Stewart, Textbook of biopharmaceutical analysis.
9. JW Munson, Pharmaceutical Analysis-Modern methods Part A and B.
10. Hashmi, Analysis of vitamins in Pharmaceutical formulations.

11. D. C. Garrott, Quantitative Aanlysis of Drugs, III edition, CBS Publishers and Distributors, New Delhi.
12. P. D. Sethi, Quantitative Analysis of Drugs in Pharmaceutical Formulations.
13. Gerhard Schomburg, Gas chromatography, VCH, Weinheim, New York.
14. British Pharmacopoeia, Department of Health, UK.

Semester II **No. of Teaching Hrs. 4 Hrs / Week**
Paper MPA 201 **Duration of Exam 3 Hrs.**
Max. Marks. 100

Pharmaceutical Analysis-II

1. Detection and quantitative determination of preservatives, antioxidants, colouring materials, emulsifiers and stabilizers in pharmaceutical formulations.
2. Principles and procedures involving the use of the following reagents in the pharmaceutical analysis with suitable examples:
i. MBTH (3-methyl-1,2-benzothiazolone hydrazone) reagent.
ii. FC (Folin-Ciocalteu) reagent.
iii. 2,6-dichloroquinone chlorimide reagent.
iv. 1,2-Naphthaquinone-4-sulfonate reagent.
v. 2,3,5-triphenyl tetrazolium salt.
vi. p-Dimethyl aminobenzaldehyde (PDAB) reagent.
vii. Carr-price reagent.
3. Technology development/transfer/commercialization related aspects; technology development-meaning, drug related technology development, clinical trial phase-I, phase-II and phase-III approval bodies and agencies, scale up.
4. Principle and procedure involved in quantitative determination of the following functional groups viz. hydroxyl, carboxylic, aldehyde, ketone, methoxyl, ester and amine
5. A detailed study of principle and procedures involved in various phsico-chemical methods of analysis (microbiological and biological methods excluded) of pharmaceutical dosage forms containing sulphonamides, barbiturates, analgesics and anti-pyretic, local anesthetics, adrenergic drugs, anti-tubercular drugs, diuretics and anti-malarial.
6. Principle and procedure involved in the analysis of pharmaceutical preparations and dosage forms containing alkaloids, glycosides, vitamins, antibiotics, steroid hormones.
7. Validation of analytical methods, calibration of instruments and equipments, quality assurance of raw materials and regulatory affairs, statistical analysis.
8. Regulatory aspects of pharmaceutical and bulk drug manufacturing.
9. Stability testing as per ICH guidelines.

Books Recommended

1. Indian Pharmacopoeia, Controller of Publications, Govt of India, Delhi.
2. Beckett & Stanlake, Practical Pharmaceutical Chemistry, Part I & II, IV edition (Reprinted 2000)
3. Bochmann and Hassan, Pharmaceutiocal Analysis, edited by Higuchi.
4. Gearin, graboski, Methods of Drug Analysis.
5. R. V. Smith and JT Stewart, Textbook of biopharmaceutical analysis.
6. L.C. Chatten, Pharmaceutical Chemistry, Vol. I & II.
7. D. C. Garrott, Quantitaive analysis of drugs. CBS publishers and distributors, New Delhi.
8. P. D. Sethi, Quantitative analysis of drugs in Pharmaceutical formulations.
9. British Pharmacopoeia, Department of health, UK
10. Howard C. Ansel, Michell J. Stoklosa, Lippincott Williams & Wilkins, Pharmaceutical calculations.
11. Spilker, A guide to clinical trial.

Semester II **No. of Teaching Hrs. 4 Hrs / Week**
Paper MPA 202 **Duration of Exam 3 Hrs.**
Max. Marks. 100

Pharmaceutical Analysis-III

1. Detailed study of principles and procedures involved in biological assay of:
a. Heparin, amylase, hyaluronidase, insulin, posterior pituitary.

b. Vaccines, diphtheria, tetanus, pertusis, plague, rabies, small pox, typhoid etc.
2. Principle and procedures involved in biological tests of the following;
i. Living contaminants in vaccines.
ii. Absence of pyrogens.
iii. Histamine like substances.
iv. Determination of toxic elements.
v. Presence of Mycobacterium tuberculosis.
3. Quantitative determination of drugs in biological fluids with special emphasis on therapeutic drugs monitoring and bioequivalences studies.
4. Standardization of natural products, drugs and formulations :
Standardization requirements of herbal medicines, traditional and folk remedies/preparation and their quality, safety and efficacy assessment and intended use for acceptance by FDA.
5. Chemical and bacteriological analysis of water supplies and effluents with special reference to public health. Determination of metal ions as essential and contaminating species in biological fluids, foodstuffs and pharmaceutical preparations.
6. Concept of total quality management (TQM), GMP, GLPs, ISO 9000, introduction to ICH guidelines.
7. Impurity profiling, stability indicating assay, stress decomposition.

Books Recommended

1. Indian Pharmacopoeia, Controller of publications, Govt of India.
2. Beckett & Stanlake, Practical pharmaceutical chemistry, Part I & II, IV edition.
3. Douglas. A. Skoog, Principles of instrumental analysis, Saunder's college publishing, Philadelphia.
4. Kealey and Haines, Analytical chemistry, Viva books Pvt. Ltd, New Delhi.
5. Bochmman and Hassan, Pharmaceutical Analysis, edited by Higuchi.
6. K. A. Connors, Textbook of Pharmaceutical Analysis, III edition , John Wiley and sons, New York. (reprinted)
7. Gearin, Graboski, Methods of drug analysis.
8. R. V. Smith, JT Stewart, Textbook of biopharmaceutical analysis.
9. JW Munson, Pharmaceutical Analysis-Modern methods Part A and B.
10. Hashmi, Analysis of vitamins in Pharmaceutical fotmulations.
11. D. C. Garrott, Quantitative Aanlysis of Drugs, III edition, CBS Publishers and Distributors, New Delhi.
12. P. D. Sethi, Quantitative Analysis of Drugs in Pharmaceutical Formulations.
13. Gerhard Schomburg, Gas chromatography, VCH, Weinheim, New York.
14. Pulok. K. Mukherjee, Quality control of herbal drugs, Business Horizons Pharmaceutical Publishers, New Delhi.
15. British Pharmacopoeia, Department of Health, UK
16. Clark's isolation and identification of drugs, The Pharmaceutical Press, London.

Semester II **Max. Marks: 100**
MPA 203

Practical

1. Analysis of drugs in blood and urine sample.
2. Assay of calcium gluconate injection.
3. Assay of mercuric chloride.
4. Assay of amoxycillin.
5. Potentiometric estimation of chloroquine phosphate (potentiometry)
6. pH measurement of various buffers and calibration of instruments.
7. Assay of phenylhydrazine HCl (potassium iodate titrations)
8. Determination of methylene blue ($TiCl_3$ titrations)
9. Nephelometric estimation of calcium phosphate (Nephelometry)
10. Estimation of moisture by Karl-Fischer titrations.
11. Assay of pyrazinamide (acidimetry).

12. Assay of frusemide tablets (Diuretic)
13. Assay of rifampicin (antitubercular)
14. Assay of lignocaine HCl injection (local anaesthetics)
15. Assay of quinine sulphate (antimalarial)
16. Assay of ephedrine HCl (alkaloid)
17. Assay of nicotine (alkaloid)
18. Assay of calcium pantethonate/Vit B_{12}/folic acid in vitamin preparations.
19. Estimation of cotrimazole tablets (Sulpha and trimethoprim)
20. Bioassay of insulin, histamine, acetylcholine and heparin.
21. Bioassay of antibiotics and vitamins, one each.
22. Determination of hardness of water
23. Drug analysis by UV, IR and NMR spectroscopy.
24. Herbal drug analysis by HPTLC.
25. Interpretation of compound by UV, IR, ^{1}H-NMR & 2D-NMR.
26. Determination of toxic elements.

Semester III **Max Marks- 100**
MPA 301

Practical

Synopsis of research project
Seminar and viva voce on research methodology and research project.

Semester IV
MPA 401

Dissertation	**300 marks**
Viva voce	**200 marks**