SHIVAJI UNIVERSITY, KOLHAPUR

B
Accreditated by NAAC
(2009)

Revised Syllabus for
Master of PHARMACY
I and IInd Year
(Sem. I to IV)

Syllabus to be implemented from June 2013 onwards

A] Ordinance and Regulations

(FOR DEGREE OF MASTER OF PHARMACY IN THE IN THE FACULTY OF ENGINEERING & TECHNOLOGY**)**

B] Shivaji University, Kolhapur

Revised Syllabus For

MASTER OF PHARMACY

1. TITLE: MASTER OF PHARMACY IN,

1.1 Pharmaceutical Chemistry

1.2 Biopharmaceutics

1.3 Pharmaceutics

1.4 Quality Assurance*****

1.5 Pharmacology

1.6 Pharmacognosy

1.7 Pharmaceutical Technology

1.8 Pharmaceutical Analysis

1.9 Quality Assurance Techniques*****

2.0 Pharmaceutics Drug Regulatory Affairs

*** The course structure, examination scheme and syllabus is same.**

Under the Faculty of ENGINEERING & TECHNOLOGY

2. YEAR OF IMPLEMENTATION: - Revised Syllabi will be implemented from June 2013 onwards.

3. PREAMBLE:-

Amongst the health care professionals, pharmacists are considered as major pillars in design, development and supply of quality medicines to the patients. The development of pharmaceuticals/formulations is an outcome of interplay between pharmaceutical and medicinal chemistry (especially synthetic and phytochemistry), pharmaceutics and pharmaceutical technologies, analytical techniques and quality assurance at each and every level. Along with the basics of drug discovery and development, the advanced tools assisting developments of new drug substances and drug products are of paramount importance. Especially, high throughput screening techniques accelerate the pace of API/ excipient developments. The pharmaceuticals which are being developed needs to be guaranteed high degree of quality assurance in it. Simultaneously, to meet the global and diverse needs one has to address requirements of both regulatory and non regulatory markets.

4. GENERAL OBJECTIVES OF THE COURSE (MASTER OF PHARMACY)

1) To understand the drug discovery and development process to enable addition of new drug molecules in the field of pharmaceutical sciences
2) Understanding physico-chemical and biological science of drugs/actives and inactives in design of pharmaceutical formulations.
3) Assuring design of quality pharmaceutical formulations offering improved patient compliance and therapeutic efficacy.
4) To understand techniques and technologies used to manufacture drugs/formulations, and ensure the quality of product by exercising quality assurance tools, in particular analytics.
5) To update the students about the regulatory requirements of pre and post manufacturing of drugs, including post marketing issues.
6) The students shall be envisioned to derive new chemical entities/molecules, drug substances and formulate in to therapeutically efficient dosage forms and meet the ever changing requirements of diverse diseases and disorders in patients across globe

5. DURATION

Master of Pharmacy (M. Pharm) is a full time course.

The duration of Master of Pharmacy Course is of two Years, divided into four semesters.

6. PATTERN:

Pattern of Examination will be Semester type.

7. FEE STRUCTURE:

The Tuition fees, other fees and deposits like Library and Laboratory will be as prescribed by the Shikshan Shulka Samitee, D.T.E., University, from time to time.

8. ADMISSIONS TO M. PHARM. COURSE:

The admission to M. Pharm Course will be given as per guidelines of Directorate of Technical Education, Mumbai & A.I.C.T.E., New Delhi.

The admitted candidate will have to strictly abide by the rules and regulations prescribed by the A.I.C.T.E., D.T.E and the University.

The seats will be allotted to the different categories of the candidates as per the guidelines of D.T.E., A.I.C.T.E. and the University.

9. ELIGIBILITY FOR ADMISSION:-

The candidate seeking admission to M. Pharm. Course must have:

For Non-Sponsored category of students

Admission to fulltime M. Pharm. Course for non-sponsored category of students should be made through GPAT/ CET. When the GPAT/ CET Qualified students are not available, the admission may be given to non GPAT/ CET candidates on Merit who have

passed B. Pharm. degree examination of any statuary/recognized University with at least 50% of aggregate marks or equivalent grade (45% of marks for SC/ST candidates)

For Sponsored category of students

The candidates who possess Bachelors degree in Pharmacy from AICTE approved institutions with at least 50% marks or equivalent grade (45 % marks for those who are teachers in pharmacy college or polytechnic)

10. MEDIUM OF INSTRUCTION:

The medium of instruction shall be in English

11. STRUCTURE OF COURSE:

M. PHARM COURSE STRUCTURE

PHARMACEUTICAL CHEMISTRY

FIRST YEAR (SEMESTER I/II) (NO OF PAPERS: 08)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
I	**MAT**	Modern Analytical Techniques (Common)	80	20	80	20	**200**
	APC-I	Advanced Pharmaceutical Chemistry- I	80	20	80	20	**200**
	DDD	Drug Design and Development	80	20	--		**100**
	ELE-I	Elective – I	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
II	**RMB**	Research Methodology & Biostatistics (Common)	80	20	80	20	**200**
	APC-II	Advanced Pharmaceutical Chemistry- II	80	20	80	20	**200**
	AOC	Advanced Organic Chemistry	80	20	--		**100**
	ELE-II	Elective-II	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
		Total (Sem I & II)	**800**		**400**		**1200**

M. PHARM COURSE STRUCTURE

PHARMACEUTICAL CHEMISTRY

SECOND YEAR (SEMESTER III/IV)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
III	**RPP**	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	--	A^+ / A / B / C / D/ F	--
IV	**THESIS**	Colloquium*	A^+ / A / B / C / D/ F		--		--
		Research and Dissertation	--		150	--	**200**
		Defence (viva voce)	--		50	--	
		Total (Sem III & IV)	--		**200**		**200**
						GRAND TOTAL (Sem I to IV)	**1400**

* The seminar / colloquium shall carry 50 marks

M. PHARM COURSE STRUCTURE

BIOPHARMACEUTICS

FIRST YEAR (SEMESTER I/II) (NO OF PAPERS: 08)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
I	**MAT**	Modern Analytical Techniques (Common)	80	20	80	20	**200**
	ABP-I	Advanced Biopharmaceutics- I	80	20	80	20	**200**
	PK	Pharmacokinetics	80	20	--		**100**
	ELE-I	Elective – I	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
II	**RMB**	Research Methodology & Biostatistics (Common)	80	20	80	20	**200**
	ABP-II	Advanced Biopharmaceutics- II	80	20	80	20	**200**
	RNDDS	Recent Advances in Novel Drug Delivery Systems	80	20	--		**100**
	ELE-II	Elective-II	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
		Total (Sem I & II)	**800**		**400**		**1200**

M. PHARM COURSE STRUCTURE

BIOPHARMACEUTICS

SECOND YEAR (SEMESTER III/IV)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
III	**RPP**	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	--	A^+ / A / B / C / D/ F	--
IV	**THESIS**	Colloquium*	A^+ / A / B / C / D/ F		--		--
		Research and Dissertation	--		150	--	**200**
		Defence (viva voce)	--		50	--	
		Total (Sem III & IV)	--		**200**		**200**
						GRAND TOTAL (Sem I to IV)	**1400**

* The seminar / colloquium shall carry 50 marks

M. PHARM COURSE STRUCTURE

PHARMACEUTICS

FIRST YEAR (SEMESTER I/II) (NO OF PAPERS: 08)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
I	**MAT**	Modern Analytical Techniques (Common)	80	20	80	20	**200**
	AP-I	Advanced Pharmaceutics- I	80	20	80	20	**200**
	DDDF	Design and Development of Dosage Forms	80	20	--		**100**
	ELE-I	Elective – I	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
II	**RMB**	Research Methodology & Biostatistics (Common)	80	20	80	20	**200**
	AP-II	Advanced Pharmaceutics- II	80	20	80	20	**200**
	BPK	Biopharmaceutics and Pharmacokinetics	80	20	--		**100**
	ELE-II	Elective-II	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
		Total (Sem I & II)	**800**		**400**		**1200**

M. PHARM COURSE STRUCTURE

PHARMACEUTICS

SECOND YEAR (SEMESTER III/IV)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
III	**RPP**	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	--	A^+ / A / B / C /D/ F	--
IV	**THESIS**	Colloquium*	A^+ / A / B / C / D/ F		--		--
		Research and Dissertation	--		150	--	**200**
		Defence (viva voce)	--		50	--	
		Total (Sem III & IV)	--		**200**		**200**
						GRAND TOTAL (Sem I to IV)	**1400**

***** The seminar / colloquium shall carry 50 marks

M. PHARM COURSE STRUCTURE

QUALITY ASSURANCE

FIRST YEAR (SEMESTER I/II) (NO OF PAPERS: 08)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
I	**MAT**	Modern Analytical Techniques (Common)	80	20	80	20	**200**
	QAT-I	Quality Assurance Techniques - I	80	20	80	20	**200**
	DRIPR	Drug Regulatory Affairs and Intellectual Property Rights	80	20	--		**100**
	ELE-I	Elective – I	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
II	**RMB**	Research Methodology & Biostatistics (Common)	80	20	80	20	**200**
	QAT- II	Quality Assurance Techniques - II	80	20	80	20	**200**
	QMA	Quality Management and Audit	80	20	--		**100**
	ELE-II	Elective-II	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
		Total (Sem I & II)	**800**		**400**		**1200**

M. PHARM COURSE STRUCTURE

QUALITY ASSURANCE

SECOND YEAR (SEMESTER III/IV)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
III	**RPP**	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	--	A^+ / A / B / C / D/ F	--
IV	**THESIS**	Colloquium*	A^+ / A / B / C / D/ F		--		--
		Research and Dissertation	--		150	--	**200**
		Defence (viva voce)	--		50	--	
		Total (Sem III & IV)	--		**200**		**200**
						GRAND TOTAL (Sem I to IV)	**1400**

***** The seminar / colloquium shall carry 50 marks

M. PHARM COURSE STRUCTURE

PHARMACOLOGY

FIRST YEAR (SEMESTER I/II) (NO OF PAPERS: 08)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
I	**MAT**	Modern Analytical Techniques (Common)	80	20	80	20	**200**
	ACOL-I	Advanced Pharmacology - I	80	20	80	20	**200**
	NDDP	New Drug Development Process	80	20	--		**100**
	ELE-I	Elective – I	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
II	**RMB**	Research Methodology & Biostatistics (Common)	80	20	80	20	**200**
	ACOL-II	Advanced Pharmacology - II	80	20	80	20	**200**
	SPT	Safety Pharmacology and Toxicology	80	20	--		**100**
	ELE-II	Elective-II	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
		Total (Sem I & II)	**800**		**400**		**1200**

M. PHARM COURSE STRUCTURE

PHARMACOLOGY

SECOND YEAR (SEMESTER III/IV)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
III	**RPP**	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	--	A^+ / A / B / C / D/ F	--
IV	**THESIS**	Colloquium*	A^+ / A / B / C / D/ F		--		--
		Research and Dissertation	--		150	--	**200**
		Defence (viva voce)	--		50	--	
		Total (Sem III & IV)	--		**200**		**200**
						GRAND TOTAL (Sem I to IV)	**1400**

* The seminar / colloquium shall carry 50 marks

M. PHARM COURSE STRUCTURE

PHARMACOGNOSY

FIRST YEAR (SEMESTER I/II) (NO OF PAPERS: 08)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
I	**MAT**	Modern Analytical Techniques (Common)	80	20	80	20	**200**
	ACOG-I	Advanced Pharmacognosy - I	80	20	80	20	**200**
	HDF	Herbal Drug Formulations	80	20	--		**100**
	ELE-I	Elective – I	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
II	**RMB**	Research Methodology & Biostatistics (Common)	80	20	80	20	**200**
	ACOG-II	Advanced Pharmacognosy - II	80	20	80	20	**200**
	RCOG	Recent Advances in Pharmacognosy	80	20	--		**100**
	ELE-II	Elective-II	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
		Total (Sem I & II)	**800**		**400**		**1200**

M. PHARM COURSE STRUCTURE

PHARMACOGNOSY

SECOND YEAR (SEMESTER III/IV)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
III	**RPP**	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	--	A^+ / A / B / C / D/ F	--
IV	**THESIS**	Colloquium*	A^+ / A / B / C / D/ F		--		--
		Research and Dissertation	--		150	--	**200**
		Defence (viva voce)	--		50	--	
		Total (Sem III & IV)	--		**200**		**200**
						GRAND TOTAL (Sem I to IV)	**1400**

* The seminar / colloquium shall carry 50 marks

M. PHARM COURSE STRUCTURE

PHARMACEUTICAL TECHNOLOGY

FIRST YEAR (SEMESTER I/II) (NO OF PAPERS: 08)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
I	**MAT**	Modern Analytical Techniques (Common)	80	20	80	20	**200**
	APT-I	Advanced Pharmaceutical Technology- I	80	20	80	20	**200**
	TT	Technology Transfer	80	20	--		**100**
	ELE-I	Elective – I	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
II	**RMB**	Research Methodology & Biostatistics (Common)	80	20	80	20	**200**
	APT-II	Advanced Pharmaceutical Technology- II	80	20	80	20	**200**
	BPBME	Biopharmaceutics and Biomedical Engineering	80	20	--		**100**
	ELE-II	Elective-II	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
		Total (Sem I & II)	**800**		**400**		**1200**

M. PHARM COURSE STRUCTURE

PHARMACEUTICAL TECHNOLOGY

SECOND YEAR (SEMESTER III/IV)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
III	**RPP**	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	--	A^+ / A / B / C / D/ F	--
IV	**THESIS**	Colloquium*	A^+ / A / B / C / D/ F		--		--
		Research and Dissertation	--		150	--	**200**
		Defence (viva voce)	--		50	--	
		Total (Sem III & IV)	--		**200**		**200**
						GRAND TOTAL (Sem I to IV)	**1400**

***** The seminar / colloquium shall carry 50 marks

M. PHARM COURSE STRUCTURE

PHARMACEUTICAL ANALYSIS

FIRST YEAR (SEMESTER I/II) (NO OF PAPERS: 08)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
I	**MAT**	Modern Analytical Techniques (Common)	80	20	80	20	**200**
	APA-I	Advanced Pharmaceutical Analysis- I	80	20	80	20	**200**
	AIT	Analytical Instrumentation and Technology	80	20	--		**100**
	ELE-I	Elective – I	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
II	**RMB**	Research Methodology & Biostatistics (Common)	80	20	80	20	**200**
	APA-II	Advanced Pharmaceutical Analysis- II	80	20	80	20	**200**
	FBCA	Food, Biologicals and Cosmetic Analysis	80	20	--		**100**
	ELE-II	Elective-II	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
		Total (Sem I & II)	**800**		**400**		**1200**

M. PHARM COURSE STRUCTURE

PHARMACEUTICAL ANALYSIS

SECOND YEAR (SEMESTER III/IV)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
III	**RPP**	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	--	A^+ / A / B / C / D/ F	--
IV	**THESIS**	Colloquium*	A^+ / A / B / C / D/ F		--		--
		Research and Dissertation	--		150	--	**200**
		Defence (viva voce)	--		50	--	
		Total (Sem III & IV)	--		**200**		**200**
						GRAND TOTAL (Sem I to IV)	**1400**

***** The seminar / colloquium shall carry 50 marks

M. PHARM COURSE STRUCTURE

QUALITY ASSURANCE TECHNIQUES

FIRST YEAR (SEMESTER I/II) (NO OF PAPERS: 08)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
I	**MAT**	Modern Analytical Techniques (Common)	80	20	80	20	**200**
	QAT-I	Quality Assurance Techniques - I	80	20	80	20	**200**
	DRIPR	Drug Regulatory Affairs and Intellectual Property Rights	80	20	--		**100**
	ELE-I	Elective – I	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
II	**RMB**	Research Methodology & Biostatistics (Common)	80	20	80	20	**200**
	QAT- II	Quality Assurance Techniques-II	80	20	80	20	**200**
	QMA	Quality Management and Audit	80	20	--		**100**
	ELE-II	Elective-II	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
		Total (Sem I & II)	**800**		**400**		**1200**

M. PHARM COURSE STRUCTURE

QUALITY ASSURANCE TECHNIQUES

SECOND YEAR (SEMESTER III/IV)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
III	**RPP**	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	--	A^+ / A / B / C / D/ F	--
IV	**THESIS**	Colloquium*	A^+ / A / B / C / D/ F		--		--
		Research and Dissertation	--		150	--	**200**
		Defence (viva voce)	--		50	--	
		Total (Sem III & IV)	--		**200**		**200**
						GRAND TOTAL (Sem I to IV)	**1400**

* The seminar / colloquium shall carry 50 marks

M. PHARM COURSE STRUCTURE

PHARMACEUTICS DRUG REGULATORY AFFAIRS

FIRST YEAR (SEMESTER I/II) (NO OF PAPERS: 08)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
I	**MAT**	Modern Analytical Techniques (Common)	80	20	80	20	**200**
	DRA-I	Drug Regulatory Affairs - I	80	20	80	20	**200**
	DDF	Development of Dosage forms	80	20	--		**100**
	ELE-I	Elective – I	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
II	**RMB**	Research Methodology & Biostatistics (Common)	80	20	80	20	**200**
	DRA-II	Drug Regulatory Affairs - II	80	20	80	20	**200**
	NDDS	Novel Drug Delivery Systems	80	20	--		**100**
	ELE-II	Elective-II	80	20	--		**100**
		Seminar*	A^+ / A / B / C / D/ F				--
		Research Work	Monitoring and record keeping				--
		Group discussion	Monitoring and record keeping				--
		Total (Sem I & II)	**800**		**400**		**1200**

M. PHARM COURSE STRUCTURE

PHARMACEUTICS DRUG REGULATORY AFFAIRS

SECOND YEAR (SEMESTER III/IV)

Semester	Subject Code	Subject/Papers	Theory		Practical		Total Marks
			External	Internal	External	Internal	
III	**RPP**	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	--	A^+ / A / B / C / D/ F	--
IV	**THESIS**	Colloquium*	A^+ / A / B / C / D/ F		--		--
		Research and Dissertation	--		150	--	**200**
		Defence (viva voce)	--		50	--	
		Total (Sem III & IV)	--		**200**		**200**
						GRAND TOTAL (Sem I to IV)	**1400**

* The seminar / colloquium shall carry 50 marks

12. SCHEME OF TEACHING AND EXAMINATION

M. PHARM (PHARMACEUTICAL CHEMISTRY)

FIRST YEAR / (SEMESTER – I/ II)

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)								
							Theory				Practical				
							External		Internal		External		Internal		
			Lecture	Tutorial	Practical	Total	Hours	Marks	Hours	Marks	Hours	Marks	Hours	Marks	Total
I	**MAT**	Modern Analytical Techniques (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	APC-I	Advanced Pharmaceutical Chemistry - I	03	--	06	09	3	80	1	20	6	80	3	20	200
	DDD	Drug Design and Development	02	01	--	03	3	80	1	20	--				100
	ELE-I	Elective – I	02	01	--	03	3	80	1	20	--				100
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
II	**RMB**	Research Methodology & Biostatistics (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	APC-II	Advanced Pharmaceutical Chemistry - II	03	--	06	09	3	80	1	20	6	80	3	20	200
	AOC	Advanced Organic Chemistry	02	01	--	03	3	80	1	20	--				
	ELE-II	Elective-II	02	01	--	03	3	80	1	20	--				
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
		Total (Sem I & II)	**20**	**04**	**48@**	**72**	**800**				**400**				**1200**

M. PHARM (PHARMACEUTICAL CHEMISTRY)

SECOND YEAR / SEMESTER – III/IV

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)			
			Lectures	Tutorial	Practical	Total	Theory	Practical		Total
								External	Internal	
III	RPP	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	36	36	--	--	A^+ / A / B / C / D / F	--
		Total	--	--	**36**	**36**	--	--		--
IV	THESIS	Colloquium*	One per student			--	A^+ / A / B / C / D / F			--
		Research and Dissertation	--	--	36	36	--	150	--	200
		Defence (viva voce)	--	--	--	--	--	50	--	
		Total	--	--	**36**	**36**	--	**200**		**200**
		Total (Sem III & IV)	--	--	**72**	**72**	--	**200**		**200**
GRAND TOTAL: Sem I to IV										**1400**

* The seminar / colloquium shall carry 50 marks; @Hours including group discussion.

M. PHARM (BIOPHARMACEUTICS)

FIRST YEAR / (SEMESTER – I/ II)

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)								
							Theory				Practical				
							External		Internal		External		Internal		
			Lecture	Tutorial	Practical	Total	Hours	Marks	Hours	Marks	Hours	Marks	Hours	Marks	Total
I	**MAT**	Modern Analytical Techniques (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	ABP-I	Advanced Biopharmaceutics- I	03	--	06	09	3	80	1	20	6	80	3	20	200
	PK	Pharmacokinetics	02	01	--	03	3	80	1	20	--				100
	ELE-I	Elective – I	02	01	--	03	3	80	1	20	--				100
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24**[@]	**36**	**400**				**200**				**600**
II	**RMB**	Research Methodology & Biostatistics (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	ABP-II	Advanced Biopharmaceutics- II	03	--	06	09	3	80	1	20	6	80	3	20	200
	RNDDS	Recent Advances in Novel Drug Delivery Systems	02	01	--	03	3	80	1	20	--				
	ELE-II	Elective-II	02	01	--	03	3	80	1	20	--				
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24**[@]	**36**	**400**				**200**				**600**
		Total (Sem I & II)	**20**	**04**	**48**[@]	**72**	**800**				**400**				**1200**

M. PHARM (BIOPHARMACEUTICS)

SECOND YEAR / SEMESTER – III/IV

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)			
			Lectures	Tutorial	Practical	Total	Theory	Practical		Total
								External	Internal	
III	RPP	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	36	36	--	--	A^+ / A / B / C / D / F	--
		Total	--	--	**36**	**36**	--	--		--
IV	THESIS	Colloquium*	One per student			--	A^+ / A / B / C / D / F			--
		Research and Dissertation	--	--	36	36	--	150	--	200
		Defence (viva voce)	--	--	--	--	--	50	--	
		Total	--	--	**36**	**36**	--	**200**		**200**
		Total (Sem III & IV)	--	--	**72**	**72**	--	**200**		**200**
GRAND TOTAL: Sem I to IV										**1400**

* The seminar / colloquium shall carry 50 marks; @Hours including group discussion.

M. PHARM (PHARMACEUTICS)

FIRST YEAR / (SEMESTER – I/ II)

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)								
							Theory				Practical				
							External		Internal		External		Internal		
			Lecture	Tutorial	Practical	Total	Hours	Marks	Hours	Marks	Hours	Marks	Hours	Marks	Total
I	**MAT**	Modern Analytical Techniques (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	AP-I	Advanced Pharmaceutics - I	03	--	06	09	3	80	1	20	6	80	3	20	200
	DDDF	Design and Development of Dosage Forms	02	01	--	03	3	80	1	20	--				100
	ELE-I	Elective – I	02	01	--	03	3	80	1	20	--				100
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
II	**RMB**	Research Methodology & Biostatistics (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	AP-II	Advanced Pharmaceutics - II	03	--	06	09	3	80	1	20	6	80	3	20	200
	BPK	Biopharmaceutics and Pharmacokinetics	02	01	--	03	3	80	1	20	--				
	ELE-II	Elective-II	02	01	--	03	3	80	1	20	--				
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
		Total (Sem I & II)	**20**	**04**	**48@**	**72**	**800**				**400**				**1200**

M. PHARM (PHARMACEUTICS)

SECOND YEAR / SEMESTER – III/IV

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)			
			Lectures	Tutorial	Practical	Total	Theory	Practical		Total
								External	Internal	
III	RPP	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	36	36	--	--	A^+ / A / B / C / D / F	--
		Total	--	--	**36**	**36**	--	--		--
IV	THESIS	Colloquium*	One per student			--	A^+ / A / B / C / D / F			--
		Research and Dissertation	--	--	36	36	--	150	--	200
		Defence (viva voce)	--	--	--	--	--	50	--	
		Total	--	--	**36**	**36**	--	**200**		**200**
		Total (Sem III & IV)	--	--	**72**	**72**	--	**200**		**200**
GRAND TOTAL: Sem I to IV										**1400**

* The seminar / colloquium shall carry 50 marks; @Hours including group discussion.

M. PHARM (QUALITY ASSURANCE)

FIRST YEAR / (SEMESTER – I/ II)

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)								
							Theory				Practical				
							External		Internal		External		Internal		
			Lecture	Tutorial	Practical	Total	Hours	Marks	Hours	Marks	Hours	Marks	Hours	Marks	Total
I	MAT	Modern Analytical Techniques (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	QAT-I	Quality Assurance Techniques - I	03	--	06	09	3	80	1	20	6	80	3	20	200
	DRIPR	Drug Regulatory Affairs and Intellectual Property Rights	02	01	--	03	3	80	1	20	--				100
	ELE-I	Elective – I	02	01	--	03	3	80	1	20	--				100
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
II	RMB	Research Methodology & Biostatistics (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	QAT- II	Quality Assurance Techniques-II	03	--	06	09	3	80	1	20	6	80	3	20	200
	QMA	Quality Management and Audit	02	01	--	03	3	80	1	20	--				
	ELE-II	Elective-II	02	01	--	03	3	80	1	20	--				
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
		Total (Sem I & II)	**20**	**04**	**48@**	**72**	**800**				**400**				**1200**

M. PHARM (QUALITY ASSURANCE)

SECOND YEAR / SEMESTER – III/IV

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)			
			Lectures	Tutorial	Practical	Total	Theory	Practical		Total
								External	Internal	
III	RPP	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	36	36	--	--	A^+ / A / B / C / D / F	--
		Total	--	--	**36**	**36**	--	--		--
IV	THESIS	Colloquium*	One per student			--	A^+ / A / B / C / D / F			--
		Research and Dissertation	--	--	36	36	--	150	--	200
		Defence (viva voce)	--	--	--	--	--	50	--	
		Total	--	--	**36**	**36**	--	**200**		**200**
		Total (Sem III & IV)	--	--	**72**	**72**	--	**200**		**200**
GRAND TOTAL: Sem I to IV										**1400**

* The seminar / colloquium shall carry 50 marks; @Hours including group discussion.

M. PHARM (PHARMACOLOGY)

FIRST YEAR / (SEMESTER – I/ II)

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)								
			Lecture	Tutorial	Practical	Total	Theory				Practical				Total
							External		Internal		External		Internal		
							Hours	Marks	Hours	Marks	Hours	Marks	Hours	Marks	
I	**MAT**	Modern Analytical Techniques (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	ACOL-I	Advanced Pharmacology - I	03	--	06	09	3	80	1	20	6	80	3	20	200
	NDDP	New Drug Development Process	02	01	--	03	3	80	1	20	--				100
	ELE-I	Elective – I	02	01	--	03	3	80	1	20	--				100
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
II	**RMB**	Research Methodology & Biostatistics (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	ACOL- II	Advanced Pharmacology - II	03	--	06	09	3	80	1	20	6	80	3	20	200
	SPT	Safety Pharmacology and Toxicology	02	01	--	03	3	80	1	20	--				
	ELE-II	Elective-II	02	01	--	03	3	80	1	20	--				
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
		Total (Sem I & II)	**20**	**04**	**48@**	**72**	**800**				**400**				**1200**

M. PHARM (PHARMACOLOGY)

SECOND YEAR / SEMESTER – III/IV

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)			
			Lectures	Tutorial	Practical	Total	Theory	Practical		Total
								External	Internal	
III	RPP	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	36	36	--	--	A^+ / A / B / C / D / F	--
		Total	**--**	**--**	**36**	**36**	**--**	**--**		**--**
IV	THESIS	Colloquium*	One per student			--	A^+ / A / B / C / D / F			--
		Research and Dissertation	--	--	36	36	--	150	--	200
		Defence (viva voce)	--	--	--	--	--	50	--	
		Total	**--**	**--**	**36**	**36**	**--**	**200**		**200**
		Total (Sem III & IV)	**--**	**--**	**72**	**72**	**--**	**200**		**200**
GRAND TOTAL: Sem I to IV										**1400**

* The seminar / colloquium shall carry 50 marks; @Hours including group discussion.

M. PHARM (PHARMACOGNOSY)

FIRST YEAR / (SEMESTER – I/ II)

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)								
			Lecture	Tutorial	Practical	Total	Theory				Practical				Total
							External		Internal		External		Internal		
							Hours	Marks	Hours	Marks	Hours	Marks	Hours	Marks	
I	**MAT**	Modern Analytical Techniques (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	ACOG-I	Advanced Pharmacognosy - I	03	--	06	09	3	80	1	20	6	80	3	20	200
	HDF	Herbal Drug Formulations	02	01	--	03	3	80	1	20	--				100
	ELE-I	Elective – I	02	01	--	03	3	80	1	20	--				100
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
II	**RMB**	Research Methodology & Biostatistics (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	ACOG- II	Advanced Pharmacognosy - II	03	--	06	09	3	80	1	20	6	80	3	20	200
	RCOG	Recent Advances in Pharmacognosy	02	01	--	03	3	80	1	20	--				
	ELE-II	Elective-II	02	01	--	03	3	80	1	20	--				
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
		Total (Sem I & II)	**20**	**04**	**48@**	**72**	**800**				**400**				**1200**

M. PHARM (PHARMACOGNOSY)

SECOND YEAR / SEMESTER – III/IV

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)			
			Lectures	Tutorial	Practical	Total	Theory	Practical		Total
								External	Internal	
III	RPP	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	36	36	--	--	A^+ / A / B / C / D / F	--
		Total	--	--	**36**	**36**	--	--		--
IV	THESIS	Colloquium*	One per student			--	A^+ / A / B / C / D / F			--
		Research and Dissertation	--	--	36	36	--	150	--	200
		Defence (viva voce)	--	--	--	--	--	50	--	
		Total	--	--	**36**	**36**	--	**200**		**200**
		Total (Sem III & IV)	--	--	**72**	**72**	--	**200**		**200**
GRAND TOTAL: Sem I to IV										**1400**

* The seminar / colloquium shall carry 50 marks; @Hours including group discussion.

M. PHARM (PHARMACEUTICAL TECHNOLOGY)

FIRST YEAR / (SEMESTER – I/ II)

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)								
			Lecture	Tutorial	Practical	Total	Theory				Practical				Total
							External		Internal		External		Internal		
							Hours	Marks	Hours	Marks	Hours	Marks	Hours	Marks	
I	**MAT**	Modern Analytical Techniques (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	APT-I	Advanced Pharmaceutical Technology - I	03	--	06	09	3	80	1	20	6	80	3	20	200
	TT	Technology Transfer	02	01	--	03	3	80	1	20	--				100
	ELE-I	Elective – I	02	01	--	03	3	80	1	20	--				100
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
II	**RMB**	Research Methodology & Biostatistics (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	APT-II	Advanced Pharmaceutical Technology - II	03	--	06	09	3	80	1	20	6	80	3	20	200
	BPBME	Biopharmaceutics and Biomedical Engineering	02	01	--	03	3	80	1	20	--				
	ELE-II	Elective-II	02	01	--	03	3	80	1	20	--				
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
		Total (Sem I & II)	**20**	**04**	**48@**	**72**	**800**				**400**				**1200**

M. PHARM (PHARMACEUTICAL TECHNOLOGY)

SECOND YEAR / SEMESTER – III/IV

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)			
			Lectures	Tutorial	Practical	Total	Theory	Practical		Total
								External	Internal	
III	RPP	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	36	36	--	--	A^+ / A / B / C / D / F	--
		Total	--	--	**36**	**36**	--	--		--
IV	THESIS	Colloquium*	One per student			--	A^+ / A / B / C / D / F			--
		Research and Dissertation	--	--	36	36	--	150	--	200
		Defence (viva voce)	--	--	--	--	--	50	--	
		Total	--	--	**36**	**36**	--	**200**		**200**
		Total (Sem III & IV)	--	--	**72**	**72**	--	**200**		**200**
GRAND TOTAL: Sem I to IV										**1400**

* The seminar / colloquium shall carry 50 marks; @Hours including group discussion.

M. PHARM (PHARMACEUTICAL ANALYSIS)

FIRST YEAR / (SEMESTER – I/ II)

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)								
			Lecture	Tutorial	Practical	Total	Theory				Practical				Total
							External		Internal		External		Internal		
							Hours	Marks	Hours	Marks	Hours	Marks	Hours	Marks	
I	**MAT**	Modern Analytical Techniques (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	APA-I	Advanced Pharmaceutical Analysis- I	03	--	06	09	3	80	1	20	6	80	3	20	200
	AIT	Analytical Instrumentation and Technology	02	01	--	03	3	80	1	20	--				100
	ELE-I	Elective – I	02	01	--	03	3	80	1	20	--				100
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
II	**RMB**	Research Methodology & Biostatistics (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	APA-II	Advanced Pharmaceutical Analysis- II	03	--	06	09	3	80	1	20	6	80	3	20	200
	FBCA	Food, Biologicals and Cosmetic Analysis	02	01	--	03	3	80	1	20	--				
	ELE-II	Elective-II	02	01	--	03	3	80	1	20	--				
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
		Total (Sem I & II)	**20**	**04**	**48@**	**72**	**800**				**400**				**1200**

M. PHARM (PHARMACEUTICAL ANALYSIS)

SECOND YEAR / SEMESTER – III/IV

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)			
			Lectures	Tutorial	Practical	Total	Theory	Practical		Total
								External	Internal	
III	RPP	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	36	36	--	--	A^+ / A / B / C / D / F	--
		Total	--	--	**36**	**36**	--	--		--
IV	THESIS	Colloquium*	One per student			--	A^+ / A / B / C / D / F			--
		Research and Dissertation	--	--	36	36	--	150	--	200
		Defence (viva voce)	--	--	--	--	--	50	--	
		Total	--	--	**36**	**36**	--	**200**		**200**
		Total (Sem III & IV)	--	--	**72**	**72**	--	**200**		**200**
GRAND TOTAL: Sem I to IV										**1400**

* The seminar / colloquium shall carry 50 marks; @Hours including group discussion.

M. PHARM (QUALITY ASSURANCE TECHNIQUES)

FIRST YEAR / (SEMESTER – I/ II)

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)								
							Theory				Practical				
							External		Internal		External		Internal		
			Lecture	Tutorial	Practical	Total	Hours	Marks	Hours	Marks	Hours	Marks	Hours	Marks	Total
I	MAT	Modern Analytical Techniques (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	QAT-I	Quality Assurance Techniques - I	03	--	06	09	3	80	1	20	6	80	3	20	200
	DRIPR	Drug Regulatory Affairs and Intellectual Property Rights	02	01	--	03	3	80	1	20	--				100
	ELE-I	Elective – I	02	01	--	03	3	80	1	20	--				100
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
II	RMB	Research Methodology & Biostatistics (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	QAT- II	Quality Assurance Techniques-II	03	--	06	09	3	80	1	20	6	80	3	20	200
	QMA	Quality Management and Audit	02	01	--	03	3	80	1	20	--				
	ELE-II	Elective-II	02	01	--	03	3	80	1	20	--				
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
		Total (Sem I & II)	**20**	**04**	**48@**	**72**	**800**				**400**				**1200**

M. PHARM (QUALITY ASSURANCE TECHNIQUES)

SECOND YEAR / SEMESTER – III/IV

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)			
			Lectures	Tutorial	Practical	Total	Theory	Practical		Total
								External	Internal	
III	RPP	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	36	36	--	--	A^+ / A / B / C / D / F	--
		Total	--	--	**36**	**36**	--	--		--
IV	THESIS	Colloquium*	One per student			--	A^+ / A / B / C / D / F			--
		Research and Dissertation	--	--	36	36	--	150	--	200
		Defence (viva voce)	--	--	--	--	--	50	--	
		Total	--	--	**36**	**36**	--	**200**		**200**
		Total (Sem III & IV)	--	--	**72**	**72**	--	**200**		**200**
GRAND TOTAL: Sem I to IV										**1400**

* The seminar / colloquium shall carry 50 marks; @Hours including group discussion.

M. PHARM (PHARMACEUTICS DRUG REGULATORY AFFAIRS)

FIRST YEAR / (SEMESTER – I/ II)

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)								
							Theory				Practical				
							External		Internal		External		Internal		
			Lecture	Tutorial	Practical	Total	Hours	Marks	Hours	Marks	Hours	Marks	Hours	Marks	Total
I	**MAT**	Modern Analytical Techniques (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	DRA-I	Drug Regulatory Affairs - I	03	--	06	09	3	80	1	20	6	80	3	20	200
	DDF	Development of Dosage forms	02	01	--	03	3	80	1	20	--				100
	ELE-I	Elective – I	02	01	--	03	3	80	1	20	--				100
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
II	**RMB**	Research Methodology & Biostatistics (Common)	03	--	06	09	3	80	1	20	6	80	3	20	200
	DRA-II	Drug Regulatory Affairs - II	03	--	06	09	3	80	1	20	6	80	3	20	200
	NDDS	Novel Drug Delivery Systems	02	01	--	03	3	80	1	20	--				
	ELE-II	Elective-II	02	01	--	03	3	80	1	20	--				
		Seminar*	One per student			--	A^+ / A / B / C / D / F								--
		Research Work	--	--	09	09	--				--				--
		Group discussion	03(01+01+01)			03	Monitoring and record keeping								--
		Total	**10**	**02**	**24@**	**36**	**400**				**200**				**600**
		Total (Sem I & II)	**20**	**04**	**48@**	**72**	**800**				**400**				**1200**

M. PHARM (PHARMACEUTICS DRUG REGULATORY AFFAIRS)

SECOND YEAR / SEMESTER – III/IV

Semester	Subject Code	Subject/paper	Teaching Scheme (Hrs/Week)				Examination Scheme (Marks)			
			Lectures	Tutorial	Practical	Total	Theory	Practical		Total
								External	Internal	
III	RPP	Research proposal/synopsis preparation, Research proposal presentation and viva voce	--	--	36	36	--	--	A^+ / A / B / C / D / F	--
		Total	--	--	**36**	**36**	--	--		--
IV	THESIS	Colloquium*	One per student			--	A^+ / A / B / C / D / F			--
		Research and Dissertation	--	--	36	36	--	150	--	200
		Defence (viva voce)	--	--	--	--	--	50	--	
		Total	--	--	**36**	**36**	--	**200**		**200**
		Total (Sem III & IV)	--	--	**72**	**72**	--	**200**		**200**
GRAND TOTAL: Sem I to IV										**1400**

* The seminar / colloquium shall carry 50 marks; @Hours including group discussion.

13. SCHEME OF EXAMINATION:-

- The examination shall be conducted at the end of each term of semester. There shall be a university examination at the end of First & Second semester. One internal examination shall be conducted on Research proposal/synopsis preparation at the end of Third semester and university examination will be conducted at the end of Fourth semester. The examination shall be as per the scheme mentioned above.
- To ensure uniform attention of the students of their work throughout each semester of their study, one internal test will be conducted for Semester I and Semester II seperately and conducting authority shall be institute conducting the course. For the examination scheme, See 12. SCHEME OF TEACHING AND EXAMINATION. The students who are unable to appear for the scheduled internal test may be permitted for the internal test in the same semester only if approved by institutional examination committee and paying fees prescribed by the institution. The institutional examination committee shall consist of Principal, who is a chairman.
- Time Schedule of internal test: After completion of at least two thirds of the semester instruction weeks. The Retest/ Improvement test/ or supplementary test for the internal tests will be allowed for the failed candidates in the University examination in the respective subject head. The Retest/ Improvement test/ or supplementary test shall be carried by the respective institution and the marks obtained by the candidate shall be forwarded to the University. Any candidates remaining absent for the test for any reason what so ever will be treated as not appeared for the test and no separate examination will be conducted. Only not appeared in the test will be mentioned in the mark sheet and the maximum marks prescribed for this test will be counted in the semester aggregate.
- The institute conducting the course must submit the internal test marks of the respective semester to the Controller of Examinations before the commencement of theory or practical examination whichever is later.
- Question Paper will be set in the view of the /in accordance with the entire syllabus and preferably covering each unit of syllabi, as per the marks weigthtage given in syllabus.
- The student with a backlog of paper of previous semester can appear for those papers at the next subsequent semester examination along with the papers of that semester.

14. STANDARD OF PASSING:-

- The student will be declared to have passed first and Second Semester Examinations, if he has obtained at least 50% marks separately in all Theory Papers and Practicals and at least ‘D’ Grade in Seminars. In addition, he should have obtained at least 50% of the aggregate marks assigned to the examination of each semester.
- The student will be declared to have passed Third & Fourth Semester Examinations, if he has obtained at least ‘D’ grade in Third semester for research proposal preparation, and at least 50% of the total marks and at least ‘D’ grade in colloquium on his/her dissertation.

15. NATURE OF QUESTION PAPER AND SCHEME OF MARKING:-

M. Pharmacy (Semester-I/II) (Revised) Examination

Name of Subject

Day and Date: **Total Marks:** 80

Time:

Instructions:

1. Answers to both sections should be written in separate sheet.
2. Question No.1 and 6 are compulsory
3. Answer any three questions from remaining questions from section I and any three questions from the remaining questions from section II.

SECTION-I

Que 1.		10
Que 2.		10
Que 3.		10
Que 4.		10
Que 5.		10
	SECTION-II	
Que 6.		10
Que 7.		10
Que 8.		10
Que 9.		10
Que 10.		10

16. EQUIVALENCE IN ACCORDANCE WITH TITLES AND CONTENTS OF PAPERS- (FOR REVISED SYLLABUS)

Sr. No.	Discipline	Desired Qualification	Equivalent Discipline		
			Bachelor Degree	**Master Degree**	**Ph. D**
1	**Pharmaceutics**	Bachelors & Masters Degree in Pharmacy with First Class or equivalent either in Bachelors or Master Degree	Pharmacy	Pharmaceutics/ Industrial Pharmacy/ Quality Assurance/ Quality Assurance Techniques/ Biopharmaceutics/ Pharmaceutical Technology/ Pharmaceutics (Drug Regulatory Affairs)/ Pharmaceutical Biotechnology	Pharmacy/Related Discipline of Pharmacy
2	**Pharmaceutical Chemistry**	Bachelors & Masters Degree in Pharmacy with First Class or equivalent either in Bachelors or Master Degree	Pharmacy	Pharmaceutical Chemistry / Pharmaceutical Analysis / Medicinal Chemistry / Pharmaceutical & Medicinal Chemistry / Chemistry of Natural Products /Quality Assurance/ Quality Assurance Techniques/ Pharmaceutical Biotechnology/ Pharmaceutical Technology/ Pharmaceutics (Drug Regulatory Affairs)	Pharmacy/Related Discipline of Pharmacy
3	**Pharmacology**	Bachelors & Masters Degree in Pharmacy with First Class or equivalent either in Bachelors or Master Degree	Pharmacy	Pharmacology/ Pharmacology & Toxicology/ Clinical Pharmacy/ Biopharmaceutics/ Pharmaceutical Technology/ Pharmaceutical Biotechnology/ Pharmaceutics (Drug Regulatory Affairs)	Pharmacy/Related Discipline of Pharmacy

4	**Pharmacognosy**	Bachelors & Masters Degree in Pharmacy with First Class or equivalent either in Bachelors or Master Degree	Pharmacy	Pharmacognosy/ Pharmacognosy & Phytochemistry/ Medicinal & Natural Products/ Chemistry of Natural Products/ Quality Assurance/ Quality Assurance Techniques/ Pharmaceutical Technology/ Pharmaceutical Biotechnology/ Pharmaceutics (Drug Regulatory Affairs)	Pharmacy/Related Discipline of Pharmacy

17. SPECIAL INSTRUCTIONS, IF ANY.

1. Grant of Terms:

The student who has satisfactorily completed the prescribed requirements of the course and has kept at least 75% attendance at theory classes and practical (if any) separately for each subject will be granted terms.

a. Exemption:

A student who has obtained at least 50% marks in theory paper/s and/or practical/s shall be exempted at his/her option from appearing for the same, The benefit of the exemption so earned will be available for two consecutive years only, since his/her first appearance at that examination.

b. Seminar:

The student will have to give one seminar in First & Second Semester each. In Third Semester students will have to give seminar on research proposal, and in fourth Semester, seminar shall be on colloquium, before submission of the dissertation.

c. Evaluation of Performance in Seminar & Colloquium:

The performance of student in seminar will be evaluated by the Seminar Evaluation Committee.

The grades will be awarded for the performance in each seminar as follows:

A+	**:**	70% or above marks.
A	**:**	65% but less than 70% marks.
B	**:**	60% but less than 65% marks.
C	**:**	55% but less than 60% marks.
D	**:**	50% but less than 60% marks.
F	**:**	Less than 50% marks.

The student will be considered to have passed in the seminar provided he/she obtained at least "D" grade. If a student fails to secure minimum 'D' Grade in the seminar even in the second attempt he/she will be required to give the seminar again in next semester.

The student will be considered to have passed in colloquium provided he/she obtained at least "D" grade. If a student fails to secure minimum 'D' Grade in the colloquium he/she will be required to give the colloquium again in next semester.

The grade awarded to the student in the seminar will be shown separately in his statement of marks of the concerned semester.

d. A.T.K.T.:

A student will be promoted from First Semester to Second Semester and from Second Semester to Third Semester and Fourth Semester irrespective of number subjects in which he/she has failed in the first and second semester examinations.

A candidate will be allowed to continue his/her research work and submit the dissertation. However, the result of the dissertation will not be declared until he/she has cleared the First Semester and the Second Semester Examinations.

A candidate who failed to pass Fourth Semester Examination will be required to keep minimum one fresh Semester and resubmit the revised dissertation, give a colloquium and appear for Viva-voce examination.

e. Award of Class:

A class will be awarded to the student on the basis of aggregate marks obtained by him/her at M. Pharm. First Semester, Second Semester, Third Semester and Fourth Semester.

First Class with Distinction	:	70% and above marks.
First Class	:	60% and above, but less than 70% marks.
Higher Second Class	:	55% and above, but less than 60% marks.
Second Class	:	50% and above, but less than 55% marks.

f. Improvement of Class:

A student will be allowed to improve his/her class at M. Pharm. by reappearing for any two subjects (theory and practical taken together of that examination) of his/her choice of First and Second Semesters of M. Pharm. course.

If a student's application form for reappearing in the examination is accepted, and the candidate appears in the examination, fresh marks will be considered and the candidate forfeits the marks obtained in the previous examinations in that subject head and those marks will not be reconsidered for any purpose again under any circumstances what-so-ever.

g. Dissertation:

Every student before appearing for the M. Pharm. Fourth Semester Examination is required to submit 1 typewritten copy and 1 soft copy (CD) of the Dissertation duly certified by the Guide and through the Principal of the College to the University for Evaluation. The topic for the dissertation shall be assigned to him/her by the Guide.

The student should submit his/her dissertation on or 15th June of every year.

An examinee who fails to submit his/her thesis within the prescribed date or whose thesis has not been accepted or fails to present himself for defense may subject to other provisions of this ordinance be readmitted to the examination at any subsequent examination provided,

- He/she pays the prescribed fees as fixed by the university.

- His/her application is received by the registrar not later than one month before the date of commencement of the examination.
- He/she submits his/her thesis on the same subject on or before examination date.
- Examinee whose thesis has not been accepted shall resubmit his/her work, with such additional work as may be directed, at the next examination.
- However an examinee wishing to submit thesis on a fresh subject, the submitter shall be required to join the department/college as a regular student.

Evaluation of Dissertation:

The Dissertation submitted by a student will be evaluated jointly by:

1) Internal Examiner (Guide).
2) External Examiner (Appointed by the University).

The Dissertation and Viva – Voce examination will carry 150 marks.

The examiners will jointly assign the marks for dissertation and viva-voce on dissertation. This test will be of 100 and 50 marks respectively. The student will have to defend the dissertation. The examiners will jointly assign the mark for dissertation & Viva -voce.

The allotment of marks for the dissertation and viva-voce shall be as under.

Dissertation:

Sr. No.	Type of Work	Marks
1.	Reference work	15
2.	Experimental work	40
3.	Scientific contents	20
4.	Presentation/Communication	15
5.	Result/Conclusion	20
	Total	**100**

Viva-voce:

Sr. No.	Type of Work	Marks
1.	Scientific Contents	10
2.	Presentation / Communication	10
3.	Discussion	10
4.	Report	20
	Total	**50**

REVISED SYLLABUS FOR M. PHARMACY,

COMMON SUBJECTS FOR ALL SPECIALISATIONS

(FIRST YEAR, SEMESTER-I AND SEMESTER-II)

i) Paper : 1 (COMMON) THEORY

ii) Title of Paper : MODERN ANALYTICAL TECHNIQUES MAT

iii) Specific Objectives:

1. To make competent analysts with an ability to handle chemical separations and structure elucidations.
2. To equip graduates with analytical skills essential for practically handling qualitative and quantitative analysis of all substances and materials used and produced in food, drug and cosmetic manufacturing.
3. To provide precise understanding of developments in stereochemical, thermal and biomolecular analysis techniques.

iv) Notes:

1. Basic knowledge of organic and physical chemistry is a prerequisite.

MAT MODERN ANALYTICAL TECHNIQUES Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1.	**Sample Preparation for Analysis:** Different techniques of sample preparation from body fluids, tissue extracts, cell culture extracts and phyto-chemical extracts. Preparation, types, storage, record keeping and validation of reference standards.	3	8-10
2.	**Ultra violet and visible spectroscopy:** Energy levels and selection rules, Woodward-Fieser and Fieser-Kuhn rules. Influence of substituent, ring size and strain on spectral characteristics; Solvent effect; Stereochemical effect; Non-conjugated interactions; Spectral correlation with structure.	6	10-13
3.	**Infrared spectroscopy (IR):** Characteristic regions of the spectrum. Influence of substituents, ring size, hydrogen bonding, vibrational coupling and field effect on frequency, determination of stereochemistry. Spectral interpretation with examples.	6	10-13
4.	**Nuclear magnetic resonance spectrometry (NMR):** Magnetic nuclei, chemical shift and shielding, relaxation processes, chemical and magnetic non-equivalence, local diamagnetic shielding and magnetic anisotropy, spin-spin splitting, Pascal's triangle, coupling constant, mechanism of coupling, quadrupole broadening and decoupling, effect	6	14-16

	of conformations and stereochemistry on the spectrum, diastereomeric protons, virtual coupling, long range coupling-epi, peri, bay effects. Shift reagents-mechanism of action, spin decoupling, double resonance, relative significance and applications of PMR and C^{13} NMR for structure elucidation.		
5.	**Mass spectrometry (MS):** Molecular ion and metastable peak, fragmentation patterns, nitrogen and ring rules, McLafferty rearrangement, electron and chemical ionization modes, applications.	4	10-13
6.	**Separation Techniques:** Separation mechanisms and retention parameters in chromatography. Principle and applications of Short-column chromatography and flash chromatography, vacuum liquid chromatography (VLC), medium pressure liquid chromatography, super critical fluid chromatography, over pressure layer chromatography (OPLC), centrifugal chromatography, ion-pair chromatography, Gel Permeation Chromatography (GPC), GC-MS and LC-MS techniques.	5	12-15
7.	**Pharmaceutical applications** of ESR Spectroscopy, Circular Dicorism and ORD, DSC, XRD.	3	8-10
8.	**Immunochemical Techniques:** ELISA, Immuno- precipitation, Radio immuno assays and Radio-labeling.	3	8-10

(vi) Recommended Reading:

a) Basic Reading:

1. Shah, Y. I.; Paradkar, A. R., Shah, Y. I. and Dhayagude, M. G. Introduction to Biostatistics & Computer Science.
2. Kemp, W. Organic Spectroscopy, 3rd edition, Palgrave, New Yark, 1991.
3. Pal, P.K. and Ganesan, M. Bioavailabity and Bioequivalence in Pharmaceutical Technology, 1st edition, CBS Publishers and Distributors, New Delhi. 1999.
4. Sharma, B. K. Instrumental Methods of Chemical Analysis, 20th edition, Krishna Prakashan Media (P) Ltd. Meerut, 2001.
5. Silverstein, R. M. and Webstar, F. X. Spectrometric identification of organic compounds.

b) Additional Reading:

1. D'Agostino, R. B. Pharmaceutical Statistics using SAS: A Practical Guide.
2. Beckett, A. H. and Stenlake, J. B. Text book of Practical Pharmaceutical chemistry, Vol. I & II, CBS publishers and distributors, U.K. 1988.
3. Chatwal, G. R. and Anand, S. K. Instrumental Methods of Chemical Analysis, 5th edition, Himalaya Publishing House, Mumbai, 2003.
4. Snyder, L. R., Kirkland, J. J. and Glajch, J. L. Practical Method Development,

2nd edition, John Wiley and Sons, Inc., Hoboken, 1997.

5. Conners, K.A. A Textbook of Pharmaceutical Analysis, 3rd edition, Wiley-Interscience Publication, John Wiley & Sons, New Yark, 1982.
6. Floray, K. Analytical profiles of Drug Substances, Academic Press, 2005.

c) References:

i) Books:

1. Rees, J. A. Introduction to Pharmaceutical Calculations.
2. Skoog, D. A., Holler, F. J. and Timothy, A. N. Principles of Instrumental Analysis, 5th edition, Saunders College Publishing. Harcourt Brace College Publishers. Sweeden, 2005.
3. Schirmer, R. E. Modern Methods of Pharmaceutical Analysis, 2nd edition, CRC Press, Florida, 1991.
4. Willard, et.al, Instrumental Methods of Analysis, 7th edition, CBS Publishers and Distributors, Delhi, 1986.

ii) Periodicals/Journals:

1. Bari, S.B., Kadam, B. R., Jaiswal, Y. S. and Shirkhedkar A. A. (2007). Impurity profile: significance in active pharmaceutical ingredient. Eur. J. Anal. Chem., 2, 32-52.
2. J. D. Winefordner, Sample Preparation Techniques in Analytical Chemistry, Volume 162, DOI: 10.1002/0471457817.
3. vegyeszkar2005.ch.bme.hu/.../Mintavetel.../0764537431.pdf
4. depa.fquim.unam.mx/amyd/.../preparaciondemuestras_6120.pdf
5. www.dionex.com/.../110956-Bro-IC-Sample-Prep-15Jul2011-LPN29.
6. ddr.nal.usda.gov/bitstream/10113/40852/1/IND44348455.pdf
7. blog.lib.umn.edu/chaynes/8152/Lecture14l_clh_class.pdf
8. http://nsdl.niscair.res.in/bitstream/123456789/772/1/revised+Ultraviolet+and+Visible+Spectrophotometry.pdf
9. www.chem.umn.edu/groups/harned/classes/.../stereochemistry.pdf
10. http://www2.iq.usp.br/docente/majokato/Disciplinas/Metodos%20Espectrometricos/The_development_of_strategies_for_terpenoid_structure.pdf
11. pharmacol.weebly.com/uploads/3/7/8/8/3788687/nmr_2.pdf
12. www.chem.ucla.edu/harding/notes/notes_14C_nmr02.pdf
13. www.alchemyst.co.uk/alchemystry/pdf/Physical/physical_nmr.pdf
14. www.chem.wisc.edu/areas/reich/nmr/notes-6-cmr.pdf
15. science.widener.edu/svb/massspec/massspec.pdf
16. www.cem.msu.edu/~cem333/Week18.pdf
17. http://link.springer.com/content/pdf/bbm%3A978-3-662-03631-0%2F1

18. https://www.uic.edu/orgs/ctrstbio/manuals/kelly.pdf
19. www.niu.edu/analyticallab/cd/handout.pdf - United States
20. ulbld.lf1.cuni.cz/file/650/Immunochemical_methods_theory.pdf

i) Paper : 1 (COMMON) PRACTICAL

ii) Title of Paper : MODERN ANALYTICAL TECHNIQUES MAT

iii) Specific Objectives:

1. To improve skills for precise and accurate qualitative and quantitative analysis of drugs, phytoconstituents, excipients and products containing multiples of these components.
2. To improve skills for performance of biological and biomolecular assays to characterize drug and related products.
3. To update and improve skill sets essential for structure elucidation of drugs and related products from physical, physicochemical and chemical characterization

iv) Note:

1. Basic undrstanding of pharmacopoeial methods of analysis, physical chemistry, sampling and statistics is a prerequisite.

MAT MODERN ANALYTICAL TECHNIQUES Practical (6 hrs/wk)

Unit	Experiments
1.	Chemical Tests for Identification of Alkaloids, Glycosides and steroids in extracts.
2.	Preparation and chemical characterization of cosmetics like talcum powder, lipsticks, deodorant and cream.
3.	To carry out microbiological assay of antibiotics by Cup Plate and turbidimetric method
4.	UV spectroscopic analysis of two component formulation by simultaneous equation and differential spectroscopic method
5.	Visible spectroscopic method development involving transition metal and ion pair complex
6.	Proposing structures of compounds at least three on analysis of UV, IR, NMR and mass spectra
7.	DSC and XRD spectra analysis to study drug-excipient analysis
8.	Particle size analysis by calibrated Nephalo-turbidimetry
9.	ED50 and LD50 Estimation and Probit analysis

(vi) Recommended Reading:

a) Basic Reading:

1. Silverstein, R. M. and Webstar, F. X. Spectrometric identification of organic compounds.
2. Siddiqui, A.A. Natural products Chemistry: Practical Manuals.
3. Wilkinson, J. B.and Moore, R. J. Harry's cosmetology.
4. Kokare, C.R. Textbook of Practical Biotechnology.
5. Sharma, B. K. Instrumental Methods of Chemical Analysis, 20th edition, Krishna Prakashan Media (P) Ltd. Meerut, 2001.
6. Martin, Swarbrick and Commarata Physical Pharmacy.
7. Kemp, W. Organic Spectroscopy, 3rd edition, Palgrave, New Yark, 1991.
8. Vogel, G. H. Drug discovery and evaluation, pharmacological assay, 2nd edition, Springer, 2002.

b) Additional Reading:

1. Beckett, A. H. and Stenlake, J. B. Text book of Practical Pharmaceutical chemistry, Vol. I & II, CBS publishers and distributors, U.K. 1988.
2. Chatwal, G. R. and Anand, S. K. Instrumental Methods of Chemical Analysis, 5th edition, Himalaya Publishing House, Mumbai, 2003.
3. Kokate, C. K.; Purohit, A. P. and Gokhale S. B Textbook of Pharmacognosy.
4. Snyder, L. R., Kirkland, J. J. and Glajch, J. L. Practical Method Development, 2nd edition, John Wiley and Sons, Inc., Hoboken, 1997.
5. Conners, K.A. A Textbook of Pharmaceutical Analysis, 3rd edition, Wiley-Interscience Publication, John Wiley & Sons, New Yark, 1982.
6. Floray, K. Analytical profiles of Drug Substances, Academic Press, 2005.

c) References:

i) Books:

1. Skoog, D. A., Holler, F. J. and Timothy, A. N. Principles of Instrumental Analysis, 5th edition, Saunders College Publishing. Harcourt Brace College Publishers. Sweeden, 2005.
2. Schirmer, R. E. Modern Methods of Pharmaceutical Analysis, 2nd edition, CRC Press, Florida, 1991.
3. Willard, et.al, Instrumental Methods of Analysis, 7th edition, CBS Publishers and Distributors, Delhi, 1986.

ii) Periodicals/Journals:

1. Wang, L. and Asgharnejad, M. (2000). Second-derivative UV spectrometric determination of simvastatin in its tablet dosage form. J. Pharm. Biomed. Anal., 21, 1243- 1248.
2. Alaa El-Gindy , Ahmed Ashour , Laila Abdel-Fattah ,Marwan M. Shabana ,

HPLC and HPTLC-densitometry method for the simultaneous determination of benazepril hydrochloride and hydrochlorothiazide , J. Pharm. Biomed. Anal, 25, 2001, 171–179.

3. Argekar A. P. and Sawant J. G.; 'A gradient reversed phase HPLC method for simultaneous determination of hydrochlorthaizide and losartan potassium from tablet'; Anal. Lett., 2000,33(5),869-880
4. Barman RK, Anwar UL. Simultaneous high-performance liquid chromatographic determination of atenolol and amlodipine in pharmaceutical-dosage form, Pak. J. Pharm. Sci., 2007; 20: 274-279.
5. Basvaiah, K., Chandrashkher, U. and Nagegowda, P., Titrimetric, Spectrophotometric and kinetic methods of atenolol using bromated – bromide and methyl orange. J. Serb. Soci. Chemicals, 2006, 71, 5, 553-563.

i) Paper : 5 (COMMON) THEORY

ii) Title of Paper : RESEARCH METHODLOGY AND BIOSTATISTICS RMB

iii) Specific Objectives:

1. To avail students about concept of research with all pros and cons.
2. To aware students about importance of documentation and referencing in research.
3. To equip graduates of all branches about research methodology and application of biostatistics in same.\
4. To expose students to the basic aspects of NDA, ANDA and INDA

iv) Note:

1. The students should come to know what is research and research methodology.
2. They should understand importance of biostatistics and its applicability in research.
3. They should be able to explore each and every aspect of research.

RMB RESEARCH METHODLOGY AND BIOSTATISTICS Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1.	**Introduction to Research and Statistics:** Defining Research, Scientific Enquiry, Hypothesis, Scientific Method, Types of Research, Applications of research, Research Process and steps in it, deductive and inductive reasoning. Introduction to Statistics: Its role and uses. Collection; Organization; Graphics and pictorial representation of data; Measures of central tendencies and dispersion. Coefficient of variation.	5	10-13
2.	**Probability and sampling:** Basic concepts; Probability distributions related to normal and binomial distribution. Simple random and other sampling procedures. Distribution of sample mean and proportion.	4	8-10
3.	**Research problem:** Sources, considerations, steps in formulation of a problem and formulation of objectives. Definition of variables – Concepts, indicators and variables, types of variables, types of measurement scales. Point and interval estimation including fiducial limits. Concepts of hypothesis testing and types of errors. Student- t and Chi square tests. Sample size and power. Problem Solving – Types, Process and Approaches – Logical, Soft System and Creative; Creative problem solving process, Development of Creativity, Group Problem Solving Techniques for Idea Generation – Brain storming and Delphi Method.	4	10-13
4.	**Research Design:** Objectives and strategies for experimental design and analysis of variance, completely randomized, randomized blocks. Latin	4	10-12

square and factorial designs. Post- hoc procedures.

Experimental design in clinical trials; Parallel and crossover designs. Statistical test for bioequivalence. Dose response studies.

Two sample t-test, P-value, Confidence Intervals and Paired comparisons. Control and noise factors and parameter design, signal to noise ratio, types, parameter design strategy, tolerance design and robust design.

5.	**Correlation and regression:** Graphical presentation of two continuous variables; Pearson's product moment correlation coefficient, its statistical significance. Multiple and partial correlations. Linear regression; Regression line, coefficient of determination, interval estimation and hypothesis testing for population slope. Introduction to multiple linear regression model. Probit and logit transformations.	4	10-12
6.	**Intellectual property and related regulations:** Fundamentals regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR). Concept behind WTO (World Trade Organisation), WIPO (World Intellectual Property Organisation), GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures) and GATS (General Agreement on Trade in Services). OECD guidelines for chemical testing pertaining to use as drug, related substances, excipients, toxicity, etc. WHO guidelines for standardization of raw material and finished products including herbal products.	5	12-15
7.	**Patenting:** Indian Patent Act 1970 and the Product Patent Regime, 2005; WTO and modifications under TRIPS: Filing of a patent application; Precautions before patenting-disclosures/non-disclosures, publication-article / thesis; Prior art search-published patents, internet search patent sites, specialized services-search requests, costs; Patent application-forms and guidelines, fee structure, time frames, jurisdiction aspects; Types of patent applications-provisional, non provisional, PCT and convention patent applications; INDA/NDA/ANDA filing. Patent infringement- meaning and scope.	6	12-15
8.	**Research Report and thesis:** Writing a research report- Developing an outline, Key elements- Objective, Introduction, Design or Rationale of work, Experimental Methods, Procedures, Measurements, Results, Discussion, Conclusion, Referencing and various formats for reference writing of books and research papers, Report Writing- Prewriting considerations, Thesis writing.	4	8-10

(vi) Recommended Reading:

a) Basic Reading:

1. Cooper, H. M., & Cooper, H. M. (1998). Synthesizing research: a guide for literature reviews. (3rd ed.). Thousand Oaks, Calif.: Sage Publications.
2. Creswell, J. W. (1998). Qualitative inquiry and research design: choosing among five traditions. Thousand Oaks, Calif.: Sage Publications.
3. Denzin, N. K., & Lincoln, Y. S. (2003). Collecting and interpreting qualitative materials. (2nd ed.). Thousand Oaks, Calif.: Sage.
4. Edwards, W., & Newman, J. R. (1982). Multiattribute evaluation. Beverly Hills: Sage Publications.
5. Fink, A. (1998). Conducting research literature reviews: from paper to the Internet. Thousand Oaks: Sage Publications.
6. Gliner, J. A., & Morgan, G. A. (2000). Research methods in applied settings: an integrated approach to design and analysis. Mahwah, N.J.: Lawrence Erlbaum.
7. Greenwood, D. J., & Levin, M. (1998). Introduction to action research: social research for social change. Thousand Oaks: Sage Publications.

b) Additional Reading:

1. http://www.limat.org/data/research/Research%20Methodology.pdf
2. http://research.vtu.ac.in/Downloads/materials/Research%20Methodology%20SNS%20(1).pdf
3. http://www.cartercenter.org/resources/pdfs/health/ephti/library/lecture_notes/health_science_students/ln_research_method_final.pdf
4. http://www.ascilite.org.au/ajet/ajet25/cheung.pdf
5. http://rx.osumc.edu/resResearch/biostatistics/biostatisticsHandout.pdf
6. http://www.fmhs.auckland.ac.nz/som/research/_docs/Biostatistics_Review_FMHS_2_April_2008.pdf.
7. http://mmb.bme.wisc.edu/stuff/GeneralInfo/website/Biostatisticsreview.pdf

c) References:

i) Books:

1. B K Mahajan Methods in Biostatistics for medical students and research workers.
2. Manfred Max Bergman Mixxed Methods Research
3. Bernard Beins Successful Research Projects: A Step-by-Step Guide.
4. Martin Lee Abbott, Jennifer Mckinney Understanding and Applying Research Design
5. Anthony M. Graziano, Michael L. Raulin Research Methods: A Process of Inquiry.

6. Joseph Alex Maxwell Qualitative Research Design: An Interactive Approach.
7. Alan Gardiner Statistics For The Biosciences
8. Roland Ennos Statistical and Data Handling Skills in Biology Course
9. Myra Samuels, Jeffrey Witmer, Andrew SchaffnerStatistics for the Life Sciences.
10. Jerrold Zar Biostatistical Analysis

ii) Periodicals/Journals:

1. Douglas Warfield IS/IT research: a research methodologies review Journal of Theoretical and Applied Information Technology
2. Abramson JH. Survey methods in community medicine. 2nd ed. Eidenburgh: Churchill Livingstone, 1979.
3. Zhilin Yang , Xuehua Wang, Chenting Su A review of research methodologies in international business nternational Business Review 15 (2006) 601–617.
4. Lynn Westbrook Qualitative Research Methods: A Review of Major Stages, Data Analysis Techniques, and Quality Controls LISR 16, 241-254 (1994).
5. The Intellectual Property Review Robert L Baechtold Law Business Research.

i) Paper : 2 (COMMON) PRACTICAL

ii) Title of Paper : RESEARCH METHODOLOGY AND BIOSTATISTICS RMB

iii) Specific Objectives:

1. To groom researchers and prepare them to handle Patent search and filings.
2. To equip graduates with critical knowledge and skills to draft experiment design, research proposals and reports.
3. To improve awareness and develop skills for analyzing legal and sociolegal components of patents.

iv) Note:

1. Assessing legal issues pertaining to Intellectual property and organized data handling and analysis is expected to evolve through the drafting and analyzing activities.

RMB RESEARCH METHODOLOGY AND BIOSTATISTICS Practical (3 hrs/wk)

Unit	Experiments
1.	Patent search reports.
2.	INDA/NDA/ANDA filing draft preparations.
3.	Research design experiments.
4.	Research proposal writing.
5.	Research report writing.
6.	Analysis of a filed/granted patent (Indian/US)

vi) Recommended Reading:

a) Basic Reading:

1. Cooper, H. M., & Cooper, H. M. (1998). Synthesizing research: a guide for literature reviews. (3rd ed.). Thousand Oaks, Calif.: Sage Publications.
2. Creswell, J. W. (1998). Qualitative inquiry and research design: choosing among five traditions. Thousand Oaks, Calif.: Sage Publications.
3. Denzin, N. K., & Lincoln, Y. S. (2003). Collecting and interpreting qualitative materials. (2nd ed.). Thousand Oaks, Calif.: Sage.
4. Edwards, W., & Newman, J. R. (1982). Multiattribute evaluation. Beverly Hills: Sage Publications.
5. Fink, A. (1998). Conducting research literature reviews: from paper to the Internet. Thousand Oaks: Sage Publications.

6. Gliner, J. A., & Morgan, G. A. (2000). Research methods in applied settings: an integrated approach to design and analysis. Mahwah, N.J.: Lawrence Erlbaum.
7. Greenwood, D. J., & Levin, M. (1998). Introduction to action research: social research for social change. Thousand Oaks: Sage Publications.

b) Additional Reading:

1. http://www.limat.org/data/research/Research%20Methodology.pdf
2. http://research.vtu.ac.in/Downloads/materials/Research%20Methodology%20SNS%20(1).pdf
3. http://www.cartercenter.org/resources/pdfs/health/ephti/library/lecture_notes/health_science_students/ln_research_method_final.pdf
4. http://www.ascilite.org.au/ajet/ajet25/cheung.pdf
5. http://rx.osumc.edu/resResearch/biostatistics/biostatisticsHandout.pdf
6. http://www.fmhs.auckland.ac.nz/som/research/_docs/Biostatistics_Review_FMHS_2_April_2008.pdf.
7. http://mmb.bme.wisc.edu/stuff/GeneralInfo/website/Biostatisticsreview.pdf

c) References:

i) Books:

1. B K Mahajan Methods In Biostatistics for medical students and research workers.
2. Manfred Max Bergman Mixxed Methods Research
3. Bernard Beins Successful Research Projects: A Step-by-Step Guide.
4. Martin Lee Abbott, Jennifer Mckinney Understanding and Applying Research Design
5. Anthony M. Graziano, Michael L. Raulin Research Methods: A Process of Inquiry.
6. Joseph Alex Maxwell Qualitative Research Design: An Interactive Approach.
7. Alan Gardiner Statistics For The Biosciences
8. Roland Ennos Statistical and Data Handling Skills in Biology Course
9. Myra Samuels, Jeffrey Witmer, Andrew Schaffner Statistics for the Life Sciences.
10. Jerrold Zar Biostatistical Analysis

ii) Periodicals/Journals:

1. Douglas Warfield IS/IT research: a research methodologies review Journal of Theoretical and Applied Information Technology
2. Abramson JH. Survey methods in community medicine. 2nd ed. Eidenburgh: Churchill Livingstone, 1979.
3. Zhilin Yang , Xuehua Wang, Chenting Su A review of research methodologies in international business nternational Business Review 15 (2006) 601–617.

4. Lynn Westbrook Qualitative Research Methods: A Review of Major Stages, Data Analysis Techniques, and Quality Controls LISR 16, 241-254 (1994).
5. The Intellectual Property Review Robert L Baechtold Law Business Research.

SYLLABUS FOR M. PHARM (PHARMACEUTICAL CHEMISTRY)

SPECIALIZATION: PHARMACEUTICAL CHEMISTRY

i) Course objectives:

1. To make competent pharmaceutical chemists and analysts with an ability to apply their knowledge in various aspects of drug design, discovery and analysis.
2. To keep pace with the current level of understanding of the subject inclusive of computational and informatics tools for exploring the basics and depth of drug design, discovery and analysis.
3. To provide candidates advanced training in drug designing, organic synthesis planning and execution, structure elucidation, biological activity prediction and determination, chemical and biomolecular analysis.
4. To equip graduates with the appropriate skills required to fulfill job responsibilities in the above stated domains of operation in the pharmaceutical, chemical, instrumentation and biomedical industries.

ii) Paper : 2

iii) Title of Paper: ADVANCED PHARMACEUTICAL CHEMISTRY–I APC-I

iv) Specific Objectives:

1. To create understanding of the dynamics and energetic of drug-receptor interactions and the relation of these interactions to structural and physicochemical parameters.
2. To develop understanding related to enzyme kinetics and its relation to drug development and also the understanding of factors influencing interactions of drugs with nucleic acids and the biological consequences.
3. Improve the knowledge base related to parameters which constitute drug like properties and the physicochemical, chemical and steriochemical properties of drugs that influence pharmacokinetics and pharmacodynamics.

v) Note:

1. Basic knowledge of life sciences, organic and medicinal chemistry is a prerequisite. Molecular models and interaction simulations in the form of images and videos can be used to improve understanding.

APC-I ADVANCED PHARMACEUTICAL CHEMISTRY– I Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1	**Inter and intramolecular interactions & energetic in drug action:** Weak interactions in drug molecules; Covalent, ion, ion-dipole, hydrogen bonding, C-H hydrogen bonding, dihydrogen bonding, van der	04	08-12

	Waals interactions and the associated energies. First, second and third laws of thermodynamics and the principles derived from these laws which are of significance to drug action; Free energy and relationship between thermodynamics and statistics; Importance of chemical potential in drug action; Thermodynamic cycle.		
2	**Statistical thermodynamics**: in predicting the structure of biomolecules and their interactions with drug molecules; Macromolecular vs. micromolecular correlation using thermodynamics and statistical thermodynamics.	04	07-10
3	**Receptorology:** Drug-receptor interactions, receptor theories and drug action; Occupancy theory, rate theory, induced fit theory, macromolecular perturbation theory, activation-aggregation theory. Topological and stereochemical considerations.	08	15-20
4	**Kinetics, enzyme kinetics in drug action:** Do all molecules of an enzyme have same kinetics? Mechanisms of enzyme catalysis; Electrostatic catalysis and desolvation; Covalent catalysis, acidbase catalysis, strain / distortion in enzyme catalysis; Coenzyme catalysis; Example based on hemoglobin; Theories of enzyme inhibition and inactivation; Enzyme activation of drugs-prodrugs.	04	10-15
5	**Nucleic acids (NA) as targets for drug action:** NA-interactive agents; Classes of drugs that interact with nucleic acids; Intercalation, NA-alkylation, NA-strand breaking and their importance in drug action.	02	08-12
6	**Drug like properties**: Drug like molecules and theories associated with the recognition of drug like properties.	04	07-10
7	**Drug metabolism:** Physical organic chemistry of drug metabolism, drug deactivation and elimination; Phase-I and phase-II transformations; Concept of hard and soft drugs; Chemistry of ADME. Enzymes responsible for bio-transformations, microsomal and non-microsomal mechanisms; Factors effecting drug metabolism; Drug metabolism in fetus and new born; Models to study drug metabolism.	06	15-20
8	**Stereochemistry and Drug Action:** Molecular isomerism: Molecular motion, time scales and energy; Conformation saturated cyclic systems. Chirality and molecular symmetry; Nomenclature and representations; Macromolecular stereochemistry; Dynamic stereochemistry. Realization that stereoselectivity is a pre-requisite for evolution; Role of chirality in selective and specific therapeutic agents; Case studies; Enantioselectivity in drug absorption, metabolism, distribution and elimination.	04	10-15

(vi) Recommended Reading:

a) Basic Reading:

1. Chirality in Drug Design and Development by Reddy K. Reddy, Indra K. Reddy, Publisher: CRC Press
2. IUPAC Compendium of Chemical Terminology (Online ed.). doi:10.1351/goldbook.H02899
3. Textbook of Receptor Pharmacology by Alasdair J. Gibb, John C. Foreman, Torben Johansen, Publisher: CRC Press
4. The Organic Chemistry of Drug Design and Drug Action by Silverman, Publisher: Elesevier
5. Atomic Charges, Bond Properties and Molecular Energies by Sandor Fliszar, Publisher: Wiley-interscience
6. Atomic Charges, Bond Properties and Molecular Energies by Sandor Fliszar, Publisher: Wiley-interscience
7. The Laws of Thermodynamics by Peter Atkins, Publisher: Oxford University Press, USA
8. Lehninger Principles of Biochemistry by Michael M. Cox, David L. Nelson, Publisher: Macmillan
9. Nucleic Acid Targeted Drug Design by Propst Propst, C. L. Propst, Catherin Propst, Publisher: Informa Healthcare
10. Drug Metabolism, By: Corina Ionescu, Mino R. Caira, Publisher: Career Publications
11. Drug Metabolism and Pharmacokinetics: The Journey of a Chemical Through the Body by Glyn Steventon, Stephen Mitchell, Andrew Hutt, Publisher: John Wiley & Sons
12. Stereochemistry of Carbon Compounds by Ernest L. Eliel, Publisher: Tata Mcgraw Hill Education
13. Stereochemistry Conformation and Mechanism by P. S. Kalsi, Publisher: New Age International

b) Additional Reading:

1. Thermodynamics:Kinetic Theory and Statistical Thermodynamics by F. W. Sears, G. L. Salinger, Publisher: Narosa Publishing House
2. Kinetics of Enzyme Action: Essential Principles for Drug Hunters by Ross L. Stein, Publisher:John Wiley & Sons
3. Biochemistry by Pankaja Naik, Publisher: Jaypee
4. Stereochemistry of Organic Compounds by Samuel H. Wilen, Ernest L. Eliel, Publisher: Wiley
5. Stereochemistry by d. g. morris, david g. morris, publisher: royal

6. Synthetic Strategies for Controlling Inter and Intramolecular Interactions by Nicholas R. Conley Publisher: Proquest, Umi Dissertation Publishing
7. Chirality and Molecular Interactions by Thirumoorthy Krishnan, Publisher: Lap Lambert Academic Publishing
8. Problems And Solutions on Thermodynamics and Statistical Mechanics by Lim Yung-kou, Publisher: Sarat Book Distributors
9. Thermodynamics:Statistical Thermodynamics and Kinetics by Thomas Engel, Philip Reid, Publisher: Pearson Education

c) References:

i) Books:

1. Thermodynamic Cycles: Computer-Aided Design and Optimization by Chih Wu, Wu Wu, Publisher: CRC Press
2. Atkins' Physical Chemistry (8th ed) by Atkins, Peter, de Paula, Julio, Publisher: Oxford University Press
3. Statistical Thermodynamics by ErwinSchrodinger, Physics, Publisher: Dover Publications
4. Protein Structure and Function by G. Petsko and D. Ringe, Publisher:New Science Press, London, UK.
5. Biomedical Engineering: Bridging Medicine and Technology (Cambridge Texts in Biomedical Engineering) by W. Mark Saltzman Publisher: Cambridge University Press
6. Introduction to Biomedical Engineering by San Diego, Publisher:Academic press
7. Enzyme by Jesse Russell, Ronald Cohn, Publisher: Book on Demand Ltd.
8. Contemporary Enzyme Kinetics and Mechanism Edited By: Daniel L. Purich, Publisher: Academic Press
9. Biochemistry by Satyanarayan U, Publisher: Books & Allied (p) Ltd.
10. Fundamentals of Biochemistry by A C Deb, Publisher: New Central book agency
11. Society of Chemistry
12. Stereochemistry Conformation and Mechanism by P. S. Kalsi Publisher: New Age International
13. Dynamic Stereochemistry of Chiral Compounds: Principles and Applications by Christian Wolf Publisher: Royal Society of Chemistry
14. Stereoselectivity in Organic Synthesis by Garry Procter Publisher: Oxford University Press, USA

ii) Periodicals/Journals:

1. http://tfy.tkk.fi/kurssit/Tfy-3.363/lectures/lecture1b.pdf

2. http://ww2.chemistry.gatech.edu/~lw26/structure/molecular_interactions/mol_int.html
3. The statistical-thermodynamic basis for computation of binding affinities: a critical review. M K Gilson, J A Given, B L Bush, and J A McCammon, Biophys J. 1997 March; 72(3): 1047–1069.
4. Drug - Receptor Interactions, Review Article, Vol.9, No. 3, Issue 35, Jul-Sep 2011
5. Principles: Receptor theory in pharmacology, Review, TRENDS in Pharmacological Sciences Vol.25 No.4 April 2004
6. http://en.wikipedia.org/wiki/Receptor_theory
7. http://users.rcn.com/jkimball.ma.ultranet/BiologyPages/E/Enzymes.html
8. http://www.bnl.gov/pubweb/alistairrogers/linkable_files/pdf/Rogers_&_Gibon_2009.pdf
9. DNA-interactive agents, Kelland L., IDrugs. 1998 Aug;1(4):397-8.
10. http://en.wikipedia.org/wiki/Drug_metabolism
11. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC353039/
12. Stereochemistry in Drug Action, Jonathan McConathy, Michael J. Owens, Prim Care Companion J Clin Psychiatry. 2003; 5(2): 70–73.

i) Paper : 2

ii) Title of Paper : ADVANCED PHARMACEUTICAL CHEMISTRY- I APC-I

iii) Specific Objectives:

1. To improve skills for competent handling of drug design softwares for modeling, quantitative statistical analysis and study of intermolecular interactions.
2. To improve skills for study of enzyme kinetics and specifically so for enzymes involved in metabolism and stereoselective and stereospecific synthesis.
3. To improve skill sets essential for characterization of drug-protein interactions.

iv) Note:

1. Basic knowledge of organic, physical and bio-chemistry is a prerequisite.
2. Basic knowledge of computers is a prerequisite.

APC-I ADVANCED PHARMACEUTICAL CHEMISTRY- I Practical (6 hrs/wk)

Unit	Experiments
1.	Analysis of drug protein interactions using acidic, basic and neutral drugs along with body fluid proteins.
2.	Determination of difference in rate of reaction and yield with change in catalyst.
3.	Determination of enzyme kinetics using salivary, gastrointestinal and microbial enzymes.
4.	Assessment of drug nucleic acid/protein interactions using any free access drug design software.
5.	Assessment of drug metabolism and biochemical transformations using tissue homogenates from slaughter houses.
6.	Study of microbial whole cell cultures and chemical methods for enantiomer enrichment.

(vi) Recommended Reading:

a) Basic Reading:

1. Vogel textbook of Pratical Organic Chemistry.
2. Pratical Organic Chemistry F. G. Mann, B.C. Saunders
3. Vogel Textbook of Quantitative Chemical Analysis
4. Chirality in Drug Design and Development by Reddy K. Reddy, Indra K.

Reddy, Publisher: CRC Press

5. IUPAC Compendium of Chemical Terminology (Online ed.). doi:10.1351/goldbook.H02899
6. Textbook of Receptor Pharmacology by Alasdair J. Gibb, John C. Foreman, Torben Johansen, Publisher: CRC Press
7. Nucleic Acid Targeted Drug Design by Propst Propst, C. L. Propst, Catherin Propst, Publisher: Informa Healthcare
8. Drug Metabolism, By: Corina Ionescu, Mino R. Caira, Publisher: Career Publications
9. Drug Metabolism and Pharmacokinetics: The Journey of a Chemical Through the Body by Glyn Steventon, Stephen Mitchell, Andrew Hutt, Publisher: John Wiley & Sons
10. Stereochemistry of Carbon Compounds by Ernest L. Eliel, Publisher: Tata Mcgraw Hill Education
11. Stereochemistry Conformation and Mechanism by P. S. Kalsi, Publisher: New Age International

b) Additional Reading:

1. Thermodynamics: Kinetic Theory and Statistical Thermodynamics by F. W. Sears, G. L. Salinger, Publisher: Narosa Publishing House
2. Kinetics of Enzyme Action: Essential Principles for Drug Hunters by Ross L. Stein, Publisher:John Wiley & Sons
3. Stereochemistry by d. g. morris, david g. morris, publisher: royal
4. Synthetic Strategies for Controlling Inter and Intramolecular Interactions by Nicholas R. Conley Publisher: Proquest, Umi Dissertation Publishing
5. Chirality and Molecular Interactions by Thirumoorthy Krishnan, Publisher: Lap Lambert Academic Publishing
6. Problems And Solutions on Thermodynamics and Statistical Mechanics by Lim Yung-kou, Publisher: Sarat Book Distributors
7. Thermodynamics:Statistical Thermodynamics and Kinetics by Thomas Engel, Philip Reid, Publisher: Pearson Education

c) References:

i) Books:

1. Thermodynamic Cycles: Computer-Aided Design and Optimization by Chih Wu, Wu Wu, Publisher: CRC Press
2. Atkins' Physical Chemistry (8th ed) by Atkins, Peter, de Paula, Julio, Publisher: Oxford University Press
3. Statistical Thermodynamics by ErwinSchrodinger, Physics, Publisher: Dover Publications
4. Protein Structure and Function by G. Petsko and D. Ringe,

Publisher:New Science Press, London, UK.

5. Biomedical Engineering: Bridging Medicine and Technology (Cambridge Texts in Biomedical Engineering) by W. Mark Saltzman Publisher: Cambridge University Press
6. Introduction to Biomedical Engineering by San Diego, Publisher:Academic press
7. Enzyme by Jesse Russell, Ronald Cohn, Publisher: Book on Demand Ltd.
8. Contemporary Enzyme Kinetics and Mechanism Edited By: Daniel L. Purich, Publisher: Academic Press
9. Biochemistry by Satyanarayan U, Publisher: Books & Allied (p) Ltd.

ii) Periodicals/Journals:

1. http://tfy.tkk.fi/kurssit/Tfy-3.363/lectures/lecture1b.pdf
2. http://ww2.chemistry.gatech.edu/~lw26/structure/molecular_interactions/mol_int.html
3. The statistical-thermodynamic basis for computation of binding affinities: a critical review. M K Gilson, J A Given, B L Bush, and J A McCammon, Biophys J. 1997 March; 72(3): 1047–1069.
4. Drug - Receptor Interactions, Review Article, Vol.9, No. 3, Issue 35, Jul-Sep 2011

i) Paper : 3

ii) Title of Paper : DRUG DESIGN AND DEVELOPMENT DDD

iii) Specific Objectives:

1. To create understanding of ligand and receptor chemistry with respect to interactions between them and subsequent biological responses.
2. To develop understanding related to qualitative and quantitative methods for assessing and predicting the biological response produced as a result of variations in chemical structure of ligands.
3. Develop understanding of simulations and analysis of molecular structure and interactions between them.
4. Improve the knowledge base related to various virtual and biological methods of screening and the regulations pertaining to the same.

iv) Note:

1. Basic knowledge of life sciences, organic and medicinal chemistry is a prerequisite. Molecular models and interaction simulations in the form of images and videos can be used to improve understanding.

DDD DRUG DESIGN AND DEVELOPMENT Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1	**Structure Activity Relationships in drug design:** Qualitative versus quantitative approaches, advantages and disadvantages; Random screening, non random screening, drug metabolism studies, clinical observations, rational approaches to lead discovery; Homologation, chain branching, ring chain transformations, bioisosterism; Insights into molecular recognition phenomenon; Structure based, Ligand based, Fragment based drug design and other de novo methods.	05	10-15
2	**Pharmacophore:** Concept, pharmacophore mapping, methods of conformational search used in pharmacophore mapping; Comparison between the popular pharmacophore methods like catalyst/HipHop, DiscoTech and GASP with practical examples.	03	05-10
3	**QSAR:** Electronic effects; Hammett equation, Lipophilicity effects; Hansch equation, Steric Effects; Taft Equation; Experimental and theoretical approaches for the determination of physico-chemical parameters, parameter inter-dependence; Case studies; Regression analysis,	06	15-20

extrapolation versus interpolation, linearity versus non-linearity; The importance of biological data in the correct form; 2D – QSAR; 3D-QSAR-examples CoMFA and CoMSIA.

4	**Molecular Modelling:**	04	10-15

Energy minimization, geometry optimization, conformational analysis, global conformational minima determination; Approaches and problems; Bioactive vs. global minimum conformations; Automated methods of conformational search; Advantages and limitations of available software; Molecular graphics; Computer methodologies behind molecular modeling including artificial intelligence methods.

5	**Molecular docking and dynamics:**	04	10-15

Rigid docking, flexible docking, manual docking; Advantages and disadvantages of flex-X, flex-S, autodock and dock softwares with successful examples; Monte Carlo simulations and molecular dynamics in performing conformational search, docking.

6	**Electronic structure methods and quantum chemical methods of drug design:**	05	10-15

Semi-empirical and ab initio methods; Conformational analysis, energy minimization, comparison between global minimum conformation and bioactive conformation; Predicting the mechanism of organic reactions using electronic structure methods; Complete and constrained conformational search methods their advantages and disadvantages; Theoretical aqueous solvation calculations for the design of ligands. Conformational interconversion, transition-state determination and their role in designing rigid analogs.

7	**Informatics in drug design:**	04	10-12

Bioinformatics, cheminformatics, genomics, proteomics, chemogenomics, pharmainformatics; ADME databases, chemical biochemical and pharmaceutical databases; Drug design techniques using these databases.

8	**General principles of bioactivity screening:**	05	10-13

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. Pharmacological screening models for therapeutic areas such as hypertension, pain, epilepsy, depression, diabetes & maleria.

(vi) Recommended Reading:

a) Basic Reading:

1. Design of Drugs: Basic Principles and Applications, Poupaert, J.H. (Ed.) Marcel Dekker, 2002.
2. Structure-Based Drug Design, Veerapandian, P. (Ed.) Marcel Dekker, 1997.
3. The Organic Chemistry of Drug Design and Drug Action Silverman, R. (Ed.) Academic Press, 2004.
4. Pharmacophore Perception, Development, and Use in Drug Design Güner, O.F., (Eds.) International University Line, 2000. Guidebook on Molecular Modeling in Drug Design, Cohen, N. (Ed.) Academic Press, 1996.
5. Virtual Screening for Bioactive Molecules, Böhm, H.-J., Schneider, G., (Eds.) VCH Verlagsgesellschaft mbH, 2000.
6. Essentials of Computational Chemistry: Theories and Models, Cramer, C.J., (Ed.) John Wiley & Sons, 2002.
7. Statistics in Drug Research: Methodologies and Recent Developments, Chow, S.-C.; Shao, J. (Eds.) Marcel Dekker, 2002.
8. Drug Discovery and Evaluation: Safety and Pharmaco Kinetic Assays, Hans G. Vogel, Springer, 2006
9. Drug Discovery and Evaluation: Methods in Clinical Pharmacology, H.Gerhard Vogel, Jochen Maas, Alexander Gebauer, Springer, 2010.

b) Additional Reading:

1. Use of quantitative structure-activity relationships (QSAR) in drug design http://link.springer.com/article/10.1007%2FBF00765654
2. Pharmacophore-based virtual screening: a review of recent applications http://informahealthcare.com/doi/abs/10.1517/17460441003592072
3. QSAR and 3D QSAR in Drug Design, www.cmbi.kun.nl/edu/bioinf4/articles/pdf/qsa_kubinyi_2.pdf
4. Molecular Modeling as a Tool for Drug Discovery
5. http://www.ncbi.nlm.nih.gov/pubmed/19128219
6. Protein-Ligand Docking: A Critical Review of Molecular Dynamics http://biochem218.stanford.edu/Projects%202002/Butler
7. Computational Chemistry Using Modern Electronic Structure Methods science.uwaterloo.ca/~p2goel/JCE_CC.pdf
8. Unifying Bioinformatics and Chemoinformatics for Drug Design http://tainguyenso.vnu.edu.vn/jspui/bitstream/123456789/16746/1/InTech-
9. http://www.molbio.gu.se/courses/drug/bleicher.pdf

c) References:

i) Books:

1. Modern Methods of Drug Discovery, Hillisch, A.; Hilgenfeld, R. (Eds.) Springer Verlag, 2003
2. Drug Design: Cutting Edge Approaches, Flower, D.R., (Ed.) Royal Society of Chemistry, 2003
3. Structure-based Ligand Design, Gubernator, K., Böhm, H.J., (Eds.)VCH Publishing, 1998.
4. Protein-Ligand Interactions : From Molecular Recognition to Drug Design, Böhm, H. J, Schneider, G., (Eds.) John Wiley & Sons, 2003.
5. Pharmacophores and Pharmacophore Searches Langer T, Hoffmann R. D., John Wiley & Sons, 2006.
6. Handbook of Molecular Descriptors, Mannhold, R.; Kubinyi, H.; Timmerman, H. (Eds.) VCH, Verlagsgesellschaft mbH, 2002.
7. Structure-Property Correlations in Drug Research, Van de Waterbeemd, H. (Ed.) Academic Press, 1996.
8. Quantitative Structure-Activity Relationship (QSAR) Models of Mutagens and Carcinogens, Benigni, R. (Ed.) CRC Press, 2003.
9. 3D QSAR in Drug Design: Ligand-Protein Interactions and Molecular Similarity Kubinyi, H.; Martin, Y.C.; Folkers, G. (Eds.) Kluwer Academic Publishers, 1998.
10. Statistics in Drug Research: Methodologies and Recent Developments Chow, S.C., Shao, J. (Eds.) Marcel Dekker, 2002.
11. Neural Networks in Qsar and Drug Design, Devillers, J., Acad. Press 1996.
12. QSAR: Hansch Analysis and Related Approaches, Kubinyi, H., John Wiley & Sons, 2008.
13. Molecular Modeling and Simulation, Schlick, T. (Ed.) Springer Verlag, 2002.
14. Molecular Modelling: Principles and Applications, Leach, A.R., (Ed.) Prentice Hall, 2001.
15. Virtual Screening: An Alternative or Complement to High Throughput Screening?, Klebe, G., (Ed.) Kluwer Academic Publishers, 2000.
16. Introduction to Protein Architecture: The Structural Biology of Proteins, Lesk, A.M., (Ed.) Oxford University Press, 2001.
17. Protein Structure. Determination, Analysis ,and Application for Drug Discovery, Chasman, D., (Ed.) Marcel Dekker, 2003.
18. Protein-Ligand Interactions : From Molecular Recognition to Drug Design Böhm, H.-J., Schneider, G., (Eds.) John Wiley & Sons, 2003.
19. Virtual Screening: Principles, Challenges, and Practical Guidelines, Sotriffer, C., John Wiley & Sons, 2011.

20. Chemoinformatics Approaches to Virtual Screening: An Approach to Virtual Screening, Varnek, A., Tropsha, A., Royal Society of Chemistry 2008.
21. Molecular Interaction Fields, Cruciani, G., Wiley, 2006.
22. Quantum Chemistry: The Development of Ab Initio Methods in Molecular Electronic Structure Theory, Schaefer, H. F., Courier Dover Publications 2004.
23. Progress in quantum chemistry research, Hoffman, E. O., Nova Science Publishers, 2007.
24. Computational Chemistry: Hamiltonian, Molecular Orbital, Energy Level, Perturbation Theory, Molecular Dynamics, Spartan, Implicit Solvation, Constraint Algorithm, List of Important Publications in Chemistry, Chemometrics, Docking, Hartree-Fock Method, Books Llc, 2010.
25. Bioinformatics: From Genomes to Drugs, Lengauer, T., (Ed.) VCH Verlagsgesellschaft mbH, 2001.
26. Chemoinformatics in Drug Discovery, Oprea T., Wiley, 2006.
27. An Introduction to Chemoinformatics, Leach, A. R., Gillet V. J., Springer 2003.
28. Pharmacogenomics: The Search for Individualized Therapies Licinio, J.; Wong, M.-L. (Eds.) VCH Verlagsgesellschaft mbH, 2002.
29. Computer-Assisted Lead Finding and Optimization: Current Tools for Medicinal Chemistry, Van de Waterbeemd, H.; Testa, B.; Folkers, G. (Eds.) John Wiley & Sons, 1997.
30. Drug-Membrane Interactions : Analysis, Drug Distribution, Modeling Seydel, J.K.; Wiese, M. (Eds.) VCH Verlagsgesellschaft mbH, 2002.
31. Pharmacokinetics and Metabolism in Drug Design Smith, D.A.; van de Waterbeemd, H.; Walker, D.K. (Eds.) John Wiley & Sons, 2000.
32. Pharmacokinetic Optimization in Drug Research Testa, B.; van de Waterbeemd, H.; Folkers, G.; Guy, R. (Eds.) VCH Verlagsgesellschaft mbH, 2002
33. Drug Discovery and Evaluation, Vogel, H. (Ed.) Springer Verlag, 2002.
34. Drug Screening Methods, Gupta, S. K., Jaypee, 2009.
35. Drug bioscreening: drug evaluation techniques in pharmacology, Thompson E. B., VCH, 1990.
36. Safety Pharmacology in Pharmaceutical Development and Approval, Gad, S. C., CRC Press, 2004.
37. Safety Evaluation of Pharmaceuticals and Medical Devices: International Regulatory Guidelines, Gad, S. C., Springer, 2011.
38. In Vitro Toxicology, Gad, S. C., Taylor & Francis, 2000
39. In Vitro Methods in Pharmaceutical Research, Castell, J. V. Gmez-Lechn, M. J., Academic Press, 04-Oct-1996.

ii) Periodicals/Journals:

1. Molecular Docking Screens Using Comparative Models of Proteins, Journal of Chemical. Information and Modelling, 10.1021/ci9003706 CCC
2. Protein Flexibility and Mobility in Structure-Based Drug Design, Frontiers in Drug Design & Discovery, 2007, 3, 000-000.
3. Chemical Property Calculation through JavaScript and Applications in QSAR, Molecules 1999, 4, 16–27
4. Quantum-Chemical Descriptors in QSAR/QSPR Studies, Chemical Reviews, 1996, 96, 1027-1043
5. Why Are Some Properties More Difficult To Predict than Others? A Study of QSPR Models of Solubility, Melting Point, and Log P, Journal of Chemical. Information and Modelling. 2008, 48, 220-232.
6. Superaugmented eccentric connectivity indices: new-generation highly discriminating topological descriptors for QSAR/QSPR modeling, Medicinal Chemistry Research, 2007, 16:331–341.
7. Three-Dimensional QSAR Using the k-Nearest Neighbor Method and Its Interpretation, Journal of Chemical. Information and Modelling. 2006, 46, 24-31.
8. Multivariate QSAR, Journal of Brazilian Chemical Society, Vol. 13, No. 6, 742-753, 2002.
9. High-throughput docking for lead generation. Current Opinion in Chemical Biology, 4, 375–382
10. The art and practice of structure-based drug design: A molecular modeling perspective. Medicinal Research Reviews.16, 3–50.
11. Pharmacophoric Pattern Matching in Files of Three-Dimensional Chemical Structures: Implementation of Flexible Searching. Journal of Molecular Graphics, 11, 146–156.
12. In Applied Multivariate Statistical Analysis, Prentice-Hall: Upper Saddle River, NJ.
13. Development and Validation of a Genetic Algorithm for Flexible Docking. Journal of Molecular Biology, 267, 727–748.
14. The Role of Macromolecular Crystallography and Structure for Drug Discovery: Advances and Caveats. Current Opinion in Drug Discovery & Development, 3, 408–422.
15. Molecular Docking: A Problem with Thousands of Degrees of Freedom. In IEEE International Conference on Robotics and Automation, (Seoul, Korea), IEEE Press.
16. LigBuilder: A Multiple-Purpose Program for Structure-Based Drug Design. Journal of Molecular Modeling, 6, 498–516.
17. A New Empirical Method for Estimating the Binding Affinity of a Protein-Ligand Complex. Journal of Molecular Modeling, 4, 379–394.

18. Computer analysis of protein-protein interaction. Journal of Molecular Biology, 124, 323–342.
19. Chemical similarity searching. Journal of Chemical Informatics & Computational Sciences, 38, 983–996

i) Paper : 6 THEORY

ii) Title of Paper : ADVANCED PHARMACEUTICAL CHEMISTRY–II APC-II

iii) Specific Objectives:

1. Developing a precise understanding of biomolecular structure and its interactions with various ligands and various physical and chemical factors influencing such interactions.
2. Develop understanding of simulations and analysis of molecular structure and dynamics of interactions between them.
3. Improve the knowledge base related to enzymes responsible for biotransformation, their induction, factors affecting biotransformation and their relevance to therapy.
4. Develop understanding of the chemistry and biology of the barriers for targeted drug delivery and chemical compositions that can overcome such barriers.

iv) Note:

1. Basic knowledge of life sciences, organic and medicinal chemistry is a prerequisite. Molecular models and interaction simulations in the form of images and videos can be used to improve understanding.

APC-II ADVANCED PHARMACEUTICAL CHEMISTRY–II Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1	**Methods for the determination of structure of biomolecules:** Biological crystallography- crystallization data collection, refinement, identification of active site, phase determination heavy atom derivatives, electron density maps; Differences in the small molecule and biomolecules crystallography; Spectrofluorimetry-basic principles of fluorescence, intensity of fluorescence, fluorescent group, sensitivity of fluorescence to environment and biological applications; Optical activity measurements, ORD/CD applications to nucleic acids and proteins; Differential Scanning Calorimetry (DSC) and theormogravimetric analysis (TA) of biomolecules and other thermodynamics based instrumental methods estimating the structural features of biomolecules.	05	10-15
2	**Protein Structure and Interactions with ligands:** Sequencing of peptides using various chemical and analytical techniques; Application of various structural determination techniques with case studies like LHRH and TRH peptide. Protein structure building block to quaternary structure of proteins; Ramachandran plots; Peptidomimetics; Structure of lipoproteins and glycoproteins in relation to their function, Protein-ligand interactions; Multiple binding modes.	05	10-15

3	**Structure of lipids, polysaccharides and carbohydrates;** Relationship between their physico-chemical properties and their biological function**.**	03	05-10
4	**Detailed structure of nucleic acids and protein-nucleic acid interactions**, Nucleic acid and small bio-molecule interactions, DNA damage and repair**.**	04	10-15
5	**Structure and function of biomolecules pertaining to different thearapeutic areas:** Cancer- tubulinerole in cell proliferation, various binding sites, the chemistry and biology of tubuline inhibitors; farnesyl transferase- X-ray structure, ras protein and its role; Inflammation- COX-1 and COX-2 their structures and physiological role; Hyperlipidimia- HMG-CoA its structure and role in cholesterol manipulation. Aggregation and stabilization of misfolded proteins.	06	15-20
6	**Adverse drug reactions and drug interactions;** Toxic reactions, allergic reactions, idiosy-ncracy, acute poisoning and its treatment.	04	10-15
7	**Basics in drug targeting,** Site specific drugs, barriers for drug targeting, passive and active targeting, physical, chemical and biological methods of drug targeting with example. Polymeric carriers and biomolecules for delivery of therapeutically active substances to disease targets. Drug action on biomembranes- organic chemistry of drug permeability through membranes.	05	10-15
8	**Strategies for site specific, time and rate controlled delivery of drugs, antibody -based and metabolism based targeting. Organ specific drug delivery systems:** Brain, liver, eyes, kidney. Drug targeting for tumor cells.	04	10-15

(vi) Recommended Reading:

a) Basic Reading:

1. Biomolecular Crystallography: Principles, Practice, and Application to Structural Biology, Bernhard Rupp
2. Circular Dichroism and the Conformational Analysis of Biomolecules, G.D. Fasman.
3. Advances in Amino Acid Mimetics and Peptidomimetics, A. Abell, Volume 2, 1999.
4. Peptides: Chemistry and Biology, G.R. Marshall.
5. Chemistry of Natural Products by O. P. Agrawal vol. I and II.
6. Protein-Ligand Interactions: From Molecular Recognition to Drug Design, Hans-Joachim Bhm, Gisbert Schneider.
7. Organic chemistry of natural product by Gurdeep chatwal vol. I and II.
8. Des Higgins, Willie Taylor. Bioinformatics Sequence Structure & Data Banks.

A practical approach. 2000.

9. High-Density Lipoproteins: Structure, Metabolism, Function, and Therapeutics, Anatol Kontush, M. John Chapman.
10. Glycoproteins: Their composition, structure and function, Alfred Gottschalk, Volume 1.
11. Textbook of Medical biochemistry, Dr. Rana Shinde.
12. Outlines of Biochemistry ,E. E. Cohn and P. K. Stumpf
13. Nucleic Acid Structure and Recognition, Stephen Neidle,Oxford University Press, 2002.
14. An Antitubulin Agent BCFMT Inhibits Proliferation of Cancer Cells and Induces Cell Death by Inhibiting Microtubule Dynamics, Ankit Rai, Avadhesha Surolia mail, Dulal Panda
15. The Diagnosis and Treatment of Acute Poisoning, J.D.P. Graham.
16. Adverse drug reactions and drug interactions; An Essential Guide, Tim House, Cambridge University Press, 2009.
17. Wilson and Gisvold, Textbook of Organic Medicinal and Pharmaceutical Chemistry, J. N. Delgado, W.A. Remers, Lipincott-Raven 10th Ed., 1998.
18. Drug Targeting Organ-Specific Strategies by Grietje Molema and Dirk K. F. Meijer. Wiley-VCH. (2002).
19. Advanced Drug Delivery Reviews, Science Direct Journal Articles.

b) Additional Reading:

1. Prediction of Protein Structure and the Principles of Protein Conformation, G.D. Fasman.
2. Peptide-Based Drug Design: Controlling Transport and Metabolism, Michael D. Taylor.
3. Protein-Ligand Interactions: Methods and Applications, Gerd Ulrich Nienhaus, Humana Press, 2010.
4. Biochemistry, Berg J, Tymoczko J, Lubert S, 7th Edition.
5. Glycopeptides and Glycoproteins, Synthesis, Structure and applications, V. Wittmann, 2007.
6. Functional and Structural Proteomics of Glycoproteins, Owens, Raymond J.; Nettleship, Joanne E.
7. Biochemistry, Berg, Jeremy M. New York, 2007.
8. Principles of Medicinal Chemistry, Foye, Lemke and Williams, Indian Ed. B. I.Waverly, Pvt. Ltd. New Delhi 1995.
9. The symptoms and treatment of acute poisoning, George Herbert William Lucas.

c) References:

i) Books:

1. Upadhyay., Upadhyay., Nath, Biophysical Chemistry– Principles and Techniques", Himalaya Publishing House, 2002
2. Keith Wilson., John Walker., Practical Biochemistry, Cambridge Press. 2000
3. Willard and Merrit., Instrumental Methods and Analysis. CBS Publishers & Distributors. 6th Edn., 2005.
4. Glycoproteins II, (New Comprehensive Biochemistry), J. Montreuil, J.F.G. Vliegenthart, H. Schachter. Volume 29.
5. Nucleic Acids in Chemistry and Biology, G Michael Blackburn, Michael J Gait, David Loakes, David M Williams.
6. Drug Delivery and Targeting, A. M. Hillery, CRC Press, 2002**.**

ii) Periodicals/Journals:

1. Ramachandran, G.N.; Sasiskharan, V. (1968). "Conformation of polypeptides and proteins". Advances in Protein Chemistry 23: 283–437.
2. Ramachandran, G.N.; Ramakrishnan, C.; Sasisekharan, V. (1963). "Stereochemistry of polypeptide chain configurations". Journal of Molecular Biology 7: 95–9.
3. Tubulin binding cofactor C (TBCC) suppresses tumor growth and enhances chemosensitivity in human breast cancer cells. Hage-Sleiman R, Herveau S, Matera EL, Laurier JF, Dumontet C. BMC Cancer. 2010 Apr 12;10: 135.
4. Identification of a Class of Novel Tubulin Inhibitors, Xin Yi , Bo Zhong , Kerri M. Smith , Werner J. Geldenhuys , Ye Feng , John J. Pink , Afshin Dowlati, Yan Xu, Aimin Zhou, and Bin Su, J. Med. Chem., 2012, 55 (7), pp 3425–3435.
5. Inhibitors of farnesyltransferase and geranylgeranyltransferase-I for antitumor therapy: substrate-based design, conformational constraint and biological activity. Dinsmore CJ, Bell IM. Curr Top Med Chem. 2003; 3(10):1075-93.
6. Interactions of Ras proteins with the plasma membrane and their roles in signaling.Eisenberg S, Henis YI. Cell Signal. 2008 Jan;20(1):31-9.
7. Cyclooxygenase inhibitors – current status and future prospects, Gerd Dannhardt, Werner Kiefer, Eur. J. Med. Chem. 36 (2001) 109–126.
8. Inhibitors of HMG-CoA Reductase: Current and Future Prospects. Singh N, Tamariz J, Chamorro G, Medina-Franco JL. Mini Rev Med Chem. 2009 Oct;9(11):1272-83.
9. http://www.ias.ac.in/resonance/June2005/pdf/June2005p35-42.pdf
10. http://www.ploscompbiol.org/article/info%3Adoi%2F10.1371%2Fjourna

l.pcbi.0020009

11. http://www.chem.iitkgp.ernet.in/faculty/SDG/Spectroscopy%20CD.pdf
12. http://structure.bu.edu/sites/default/files/guarnieri2006.pdf
13. http://www.els.net/WileyCDA/ElsArticle/refId-a0001340.html
14. http://mcb5068.wustl.edu/MCB/Lecturers/Bose/Articles/Peptide%20Sequencing%20Review.pdf
15. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2515564/
16. http://www.medchem.uni-erlangen.de/msc/msm1/11-31-Gmeiner.pdf
17. http://www.coursenotes.org/Biology/Outlines/Chapter_5_The_Structure_and_Function_of_Macromolecules
18. http://www.ufv.br/dbv/pgfvg/BVE684/htms/pdfs_revisao/expressaogenica/pre_transcricional/DNADAMAGE%20AND%20REPAIR.pdf
19. http://www.dna-repair.nl/DNA_Repair.pdf
20. http://www.microcal.com/functional-application-areas/binding/nucleic-acid-interactions/nucleic-acid-small-molecule.asp
21. http://www.jnsbm.org/article.asp?issn=0976-9668;year=2011;volume=2;issue=3;spage=9;epage=9;aulast=Ahm
22. http://medicina.med.up.pt/im/trabalhos05_06/sites/Turma21/artigos%20-%20WEB/tiburcio%2012.pdf
23. http://www.jhubc.it/facultypages/ejones/Parsons-ISR.pdf
24. https://www.med.illinois.edu/m2/pharmacology/material/tajkhorshid/overheads/ET-tox-allergy-idiosync.pdf
25. Advanced Drug Delivery Reviews, Science Direct Journal Articles. http://www.sciencedirect.com/science/journal/0169409X

i) Paper : 6 PRACTICAL

ii) Title of Paper : ADVANCED PHARMACEUTICAL CHEMISTRY-II APC-II

iii) Specific Objectives:

1. To improve skills for precise handling of chemicals, glassware and equipments in the process of organic synthesis.
2. To improve skills for study of relative kinetics of reactions involving diverse class of chemical reactants.
3. To update and improve skill sets essential for characterization of intermediates and products of chemical reactions.

iv) Note:

1. Basic knowledge of organic chemistry and chemical kinetics is a prerequisite.

APC-II ADVANCED PHARMACEUTICAL CHEMISTRY-II Practical (6 hrs/wk)

Unit	Experiments
1.	Any three multistep synthesis of heterocycles using solution phase organic synthesis.
2.	Synthesis of compounds involving at least one redox reaction.
3.	Synthesis of compounds involving Phosphorous ylides.
4.	Multistep synthesis of compounds involving nucleclophic addition to carbonyl carbon.
5.	Synthesis for study of comparative reactivity of any three different electrophiles
6.	Synthesis for study of comparative reactivity of any three different nucleophiles.

(vi) Recommended Reading:

a) Basic Reading:

1. Organic chemistry, Francis A. Carey, McGraw-Hill, 2000.
2. Organic Chemistry, 6/e Wade, Jr. Leroy G. Pearson Education India, 2008.
3. Organic Chemistry Thomas N. Sorrell University Science Books, 2006
4. Phosphorus Ylides, Oleg I. Kolodiazhnyi John Wiley & Sons, 26-Sep-2008.
5. Ylides and imines of phosphorus Alyn William Johnson J. Wiley, 05-Aug-1993.
6. Protective groups in organic synthesis Theodora W. Greene, Peter G. M. Wuts Wiley, 1991.
7. Science of Synthesis: Houben-Weyl Methods of Molecular Transformation

Georg Thieme Verlag, 19-Dec-2000

8. Hydroboration H. C. Brown Addison-Wesley Pub Co (January 2000)

b) Additional Reading:

1. Polar Rearrangements Opc Laurence M. Harwood Oxford University Press, 1992.
2. Reactive Intermediates Christopher J. Moody, Gordon Harlow Whitham Oxford University Press, 1992
3. Organometallics in Synthesis, L. S. Hegedus, B. H. Lipshutz, J. A. Marshall, E. Nakamura, E. Negishi, M. T. Reetz, M. F. Semmelhack, K. Smith, H. Yamamoto, John Wiley & Sons, 2001.
4. The Organometallic Chemistry of the Transition Metals, Robert H. Crabtree, John Wiley & Sons, 2009.

c) References:

i) Books:

1. Vogel textbook of Pratical Organic Chemistry.
2. Pratical Organic Chemistry F. G. Mann, B.C. Saunders
3. Vogel Textbook of Quantitative Chemical Analysis
4. Organic reaction mechanisms V K Ahluwalia, R K Parashar, Alpha Science International, 2007.
5. Determination of organic reaction mechanisms, Barry Keith Carpenter, Wiley, 1984.
6. Mechanism and theory in organic chemistry, Thomas H. Lowry, Kathleen Schueller Richardson, Harper & Row, 1987.
7. Organic Reactions: Mechanism With Problems, Rajpal Tyagi, Discovery Publishing House, 2005.
8. Reaction Mechanisms in Organic Synthesis, Rakesh Parashar, Wiley, 2008.
9. March's advanced organic chemistry: reactions, mechanisms, and structure, Michael Smith, Jerry March, Wiley, 2001.

ii) Periodicals/Journals:

1. Taber, D. F.; Gunn, B.P; Ching Chiu, I, Organic Syntheses, Coll. Vol. 7, p.249 (1990); Vol. 61, p.59 (1983). Taber. D. F., 1976. 41, 2649-2650.
2. Guo, Z.; Schultz, A. G., J. Org. Chem., 2001, 66, 2154-2157
3. Zimmerman, Howard E (1975). Quantum Mechanics for Organic Chemists. New York: Academic Press. pp. 154–5. ISBN 0-12-781650-X.
4. Zimmerman, H. E. in “Molecular Rearrangements”, De Mayo, P. Ed., Interscience, New York, 1963, p 350-352
5. Paufler, R. M. Ph.D. Thesis, Northwestern University, Evanston, IL.

1960

6. Kuehne, M. E.; Lambert, B. F. (1963), "1,4-Dihydrobenzoic acid", Org. Synth.; Coll. Vol. 5: 400
7. Paquette, L. A.; Barrett, J. H. (1969), "2,7-Dimethyloxepin", Org. Synth.; Coll. Vol. 5: 467
8. Taber, D. F.; Gunn, B. P.; Ching Chiu, I. (1983), "Alkylation of the anion from Birch reduction of o-Anisic acid: 2-Heptyl-2-cyclohexenone", Org. Synth.; Coll. Vol. 7: 249
9. Derrick L. J. Clive and Rajesh Sunasee (2007). "Formation of Benzo-Fused Carbocycles by Formal Radical Cyclization onto an Aromatic Ring". Organic Letters 9 (14): 2677–2680. doi:10.1021/ol070849l. PMID 17559217.
10. Timothy J. Donohoe and David House (2002). "Ammonia Free Partial Reduction of Aromatic Compounds Using Lithium Di-tert-butylbiphenyl (LiDBB)". Journal of Organic Chemistry 67 (14): 5015–5018. doi:10.1021/jo0257593. PMID 12098328.

i) Paper : 7 THEORY

ii) Title of Paper: ADVANCED ORGANIC CHEMISTRY AOC

iii) Specific Objectives:

1. To create understanding of mechanism involved, kinetics, thermodynamics and regulation for organic chemistry reactions and their applications.
2. To develop understanding related to catalysis of reactions at atomic level and reactivities of general chemicals..
3. Improve the knowledge base related to reactivities of carbohydrates and amino acids with reference to their synthesis and applications.

iv) Note:

1. Basic knowledge of life sciences and organic chemistry is a prerequisite. Molecular models and interaction simulations in the form of images and videos can be used to improve understanding.

AOC ADVANCED ORGANIC CHEMISTRY Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1	**Organic reaction mechanisms :** Methods of determining reaction mechanisms (kinetic and non-kinetic methods); Energy profile diagrams, reaction intermediates, crossover experiments and isotopic labelling; Order of reactions, reversible, consecutive and parallel reactions, solvent, ionic strength and salt effects; Acid-base catalysis; Nucleophilic substitution reactions; Uni- and bimolecular reactions, attacking and leaving groups, steric and electronic effects; Neighbouring group participation; Formation and hydrolysis of esters, amides and acyl halides; Different mechanisms. Electrophilic substitution reactions; Aromatic electrophilic substitutions including Friedel-Crafts reactions; Addition and elimination reactions.	04	10-12
2	**Principles of synthetic planning :** Logic-centered molecular synthesis; Dislocation, synthetic tree, synthons, logical imposition of boundary conditions, direct associated approach; Structure-functionality relationships, functionality and unsaturation levels; Polar reactivity analysis; Control elements, consonant and dissonant circuits; Protocol for synthetic design. Umpolung and umpoled sythons: Concept, acyl and glycine cation/anion, homoenolate anion, vicinyl dicarbonian, carbonyl dication equivalence Various approaches for the synthesis of Taxol, Prostaglandins, Spatol, Aphidicolin on the basis of disconnection and direct associative approaches.	04	10-12

3	**Alkylation:** Enolates; Regio- and stereo-selective enolate generation, "O" versus "C"- alkylation, effects of solvent, counter cation and electrophiles; Symbiotic effect; Thermodynamically and kinetically controlled enolate formations; Various transition-state models to explain stereoselective enolate formation; Enamines and metallo-enamines; Regioselectivity in generation, applications in controlling the selectivity of alkylation.	08	10-13
4	**Reaction of ylides:** Phosphorous ylides; Structure and reactivity, stabilized ylides, effects of ligands on reactivity, Wittig, Horner–Wadsworth–Emmons (HWE) reactions- mechanistic realizations; E/Z selectivity for olefin formation, Schlosser modification; Petersons olefin synthesis. Sulphur Ylides; Stabilized and non-stabilized ylides; Thermodynamically and kinetically controlled reactions with carbonyl compounds, regio- and stereo-selective reactions.	04	10-13
5	**Metal/ammonia reduction:** Reduction of mono-, bi- and tri-cyclic aromatic systems and various functional groups, reductive alkylation, regio- and stereo- selectivity; Reduction of alkynes; Complex metal hydrides and selectrides.	02	10-12
6	**Reactions of electron-deficient intermediates:** Carbene-nitrene and free radical-structure, stability and modes of generation; Addition and insertion reactions of carbenoids and nitrenoids - regio- and stereoselectivity, role of the metal catalysts in the transition-metal catalyzed reactions, other types of reaction of carbenoids, e.g., ylide generation, 1,3-dipolar addition, rearrangement etc.; Intramolecular radical trapping process leading to ring annulation - Baldwin's rule.	04	10-13
7	**Organometallics:** Applications of organo-lithium, cadmium and cerium reagents, heteroatom directed lithiation; Oxy- and amido-mercurations; Gilman reagent, mixed and higher order cuprates, uses in nucleophilic substitution, cleavage of epoxides and conjugate addition reactions; Mechanism of action; Spiro-annulation; Wacker oxidation, Wilkinson's catalyst, carbonylation/hydroformylation reactions; Heck arylation; Role of metal- ligands in controlling regio- and stereo-selectivity; Catalytic and stoichiometric oxidation reactions; Homogeneous and heterogenous processes; Chemoselective reactions; Bio-mimicking processes.	06	10-12
8	**Carbohydrates and peptides:** Relative reactivities of the hydroxyl groups in carbohydrates; preparation of carbohydrate derivatives (esters, ethers, acetals etc.); chemical and enzymatic methods for carbohydrate synthesis. Coupling reactions in peptide synthesis, side reactions in peptide synthesis, protection and deprotection of amino acids, principle of solid phase and solution phase peptide synthesis.	04	10-13

(vi) Recommended Reading:

a) Basic Reading:

1. Jens T. Carstensen. Drug stability: Principles and Practices. Marcel Advanced organic chemistry: reactions, mechanisms, and structure, Jerry March, Wiley, 1985.
2. Organic reaction mechanisms V K Ahluwalia, R K Parashar, Alpha Science International, 2007.
3. Determination of organic reaction mechanisms, Barry Keith Carpenter, Wiley, 1984.
4. Mechanism and theory in organic chemistry, Thomas H. Lowry, Kathleen Schueller Richardson, Harper & Row, 1987.
5. Organic Reactions: Mechanism With Problems, Rajpal Tyagi, Discovery Publishing House, 2005.
6. Reaction Mechanisms in Organic Synthesis, Rakesh Parashar, Wiley, 2008.
7. March's advanced organic chemistry: reactions, mechanisms, and structure, Michael Smith, Jerry March, Wiley, 2001.

b) Additional Reading:

1. Organic Reaction Mechanisms, A.C.Knipe and W.E.Watts, University of Ulster, John Wiley & Sons, 1997.
2. Umpolung: Carbonyl Synthons, William D. Shipe, Organic Supergroup Meeting Princeton University, February 4, 2004.
3. Mechanism and theory in organic chemistry, Thomas H. Lowry, Kathleen Schueller Richardson, Harper & Row, 1987.
4. Organic Reactions: Mechanism With Problems, Rajpal Tyagi, Discovery Publishing House, 2005.
5. Reaction Mechanisms in Organic Synthesis, Rakesh Parashar, Wiley, 2008.
6. March's advanced organic chemistry: reactions, mechanisms, and structure, Michael Smith, Jerry March, Wiley, 2001.
7. Organic Reaction Mechanisms, A.C.Knipe and W.E.Watts, University of Ulster, John Wiley & Sons, 1997.
8. Strategic Applications Of Named Reactions In Organic Synthesis: Background And Detailed Mechanics: 250 Named Reactions , László Kürti, Barbara Czakó, Academic Press, 2005
9. Modern Tools for the Synthesis of Complex Bioactive Molecules, Janine Cossy, Stellios Arseniyadis, John Wiley & Sons, 2012.

c) References:

i) Books:

1. Strategic Applications of Named Reactions in Organic Synthesis, Laszlo Kurti, Barbara Czako, Elsevier Academic Press, 2005.
2. Studies toward the synthesis of forskolin and phomactin A using the dihydropyrone Diels-Alder reaction, Bo Wang, ProQuest Dissertations and Theses, 2009.
3. Forskolin synthesis in in vitro cultures ofColeus forskohlii Briq transformed withAgrobacterium tumefaciens, Swapna Mukherjee, Biswajit Ghosh, Sumita Jha, Plant Cell Reports, May 1996, Volume 15, Issue 9, pp 691-694.
4. Gibberellin Biosynthesis in Phaseolus coccineus Suspensor, Nello Ceccarelli, Roberto Lorenzi, Amedeo Alpi, Zeitschrift für Pflanzenphysiologie, Volume 102, Issue 1, May 1981, Pages 37–44
5. Organic Chemistry, 6/e Wade, Jr. Leroy G. Pearson Education India, 2008.
6. Organic Chemistry Thomas N. Sorrell University Science Books, 2006
7. Phosphorus Ylides, Oleg I. Kolodiazhnyi John Wiley & Sons, 26-Sep-2008.
8. Ylides and imines of phosphorus Alyn William Johnson J. Wiley, 05-Aug-1993.
9. Protective groups in organic synthesis Theodora W. Greene, Peter G. M. Wuts Wiley, 1991.
10. Science of Synthesis: Houben-Weyl Methods of Molecular Transformation Georg Thieme Verlag, 19-Dec-2000
11. Hydroboration H. C. Brown Addison-Wesley Pub Co (January 2000)
12. Polar Rearrangements Opc Laurence M. Harwood Oxford University Press, 1992.
13. Reactive Intermediates Christopher J. Moody, Gordon Harlow Whitham Oxford University Press, 1992
14. Organometallics in Synthesis, L. S. Hegedus, B. H. Lipshutz, J. A. Marshall, E. Nakamura, E. Negishi, M. T. Reetz, M. F. Semmelhack, K. Smith, H. Yamamoto, John Wiley & Sons, 2001.
15. The Organometallic Chemistry of the Transition Metals, Robert H. Crabtree, John Wiley & Sons, 2009.
16. Organometallics and Renewables, Meier, A. R Michael, Weckhuysen, M. Bert, Bruijnincx, C. A. Pieter, Springer, 2012.
17. Organic Chemistry, Robert Morrison and Robert Boyd, Pearson Education India, 2009.
18. The Organometallic Chemistry of the Transition Metals, Robert H.

Crabtree, John Wiley & Sons, 2005.

ii) Periodicals/Journals:

1. Taber, D. F.; Gunn, B.P; Ching Chiu, I, Organic Syntheses, Coll. Vol. 7, p.249 (1990); Vol. 61, p.59 (1983). Taber. D. F., 1976. 41, 2649-2650.
2. Guo, Z.; Schultz, A. G., J. Org. Chem., 2001, 66, 2154-2157
3. Zimmerman, Howard E (1975). Quantum Mechanics for Organic Chemists. New York: Academic Press. pp. 154–5. ISBN 0-12-781650-X.
4. Zimmerman, H. E. in "Molecular Rearrangements", De Mayo, P. Ed., Interscience, New York, 1963, p 350-352
5. Paufler, R. M. Ph.D. Thesis, Northwestern University, Evanston, IL. 1960
6. Kuehne, M. E.; Lambert, B. F. (1963), "1,4-Dihydrobenzoic acid", Org. Synth.; Coll. Vol. 5: 400
7. Paquette, L. A.; Barrett, J. H. (1969), "2,7-Dimethyloxepin", Org. Synth.; Coll. Vol. 5: 467
8. Taber, D. F.; Gunn, B. P.; Ching Chiu, I. (1983), "Alkylation of the anion from Birch reduction of o-Anisic acid: 2-Heptyl-2-cyclohexenone", Org. Synth.; Coll. Vol. 7: 249
9. Derrick L. J. Clive and Rajesh Sunasee (2007). "Formation of Benzo-Fused Carbocycles by Formal Radical Cyclization onto an Aromatic Ring". Organic Letters 9 (14): 2677–2680. doi:10.1021/ol070849l. PMID 17559217.
10. Timothy J. Donohoe and David House (2002). "Ammonia Free Partial Reduction of Aromatic Compounds Using Lithium Di-tert-butylbiphenyl (LiDBB)". Journal of Organic Chemistry 67 (14): 5015–5018. doi:10.1021/jo0257593. PMID 12098328.

OTHER FEATURES

1. INTAKE CAPACITY / NUMBER OF STUDENTS

It depends on intake granted by AICTE, New Delhi, up to 24 students.

2. TEACHERS QUALIFICATIONS:

Bachelors & Masters Degree in Pharmacy with First Class or equivalent either in Bachelors or Master Degree

3. REQUIREMENT OF BOOKS, JOURNALS AND EQUIPMENTS

The details of book and journals have been given under respective specialization/subjects.

(a) LIBRARY:

The details have been given under respective subjects.

(b) SPECIFIC EQUIPMENTS:

LCD:1/course. Computer 1:6 students.

Softwares: Windows XP, Microsoft office.

(c) LABORATORY EQUIPMENTS:

In addition to routinely required equipments like melting/boiling point apparatus, pH meter, oven, incubator, computers, etc. the following specific equipments and accessories are necessary.

1. HPLC (shared)
2. Double beam UV-Vis spectrophotometer (shared between two PG courses)
3. IR spectrophotometer (shared)
4. Multi-station reactor – Microwave/automated
5. Drug Designing and Molecular Modelling Software
6. Microplate reader
7. Fume hood
8. Biological activity measuring equipments – minimum two (shared)

4. GENERAL SAFETY RULES FOR LABORATORY WORK

4.1) List of equipments needed for Laboratory Safety:

1. Fire extinguisher
2. First Aid Kit
3. Good earthing and insulated wirings for electrical supply.
4. Emergency exit
5. Apron and goggles wherever necessary
6. Fuming Chambers
7. Masks, glows and shoes while handling hazardous chemicals & gases (Good valves, manometers and regulators for gas supply)
8. Operational manuals for instruments (handling to be made as suggested.)
9. Leakage of gases to be avoided.
10. Cylinders or flow pipes to handle acids.
11. No weighing for sodium hydroxide and hygroscopic substances on electronic balances.
12. Stabilized supply in the laboratory.

4.2) There is no substitute for safety

1. Any injury no matter how small, it must be reported to teacher immediately.

   a) In case any chemical enters your eyes go immediately to eye-wash facility and flush your eyes and face with plenty of water.

   b) For acid or phenol spilt, does not use water instead put some bicarbonate.

2. In case of fire, immediately switch of all gas connections and light connections in the laboratory and pour sand on the source of fire or cover it with asbestos or cement sheet.

3. In case of gas leakage, immediately switch of all gas connections and light connections in the laboratory and open all windows.
4. While leaving laboratory, make sure that gas, water taps and electricity are switched off.
5. Remove your lab coat. Gloves and clean your hands before leaving laboratory.
6. Make your workplace clean before leaving the laboratory.
7. Keep your hands away from your face, while working in laboratory.
8. Each laboratory must have a first aid box.
9. Know what to do in case of emergency - e.g.

   (a) Know the place of fire extinguisher and first aid box.
10. Don't use cell phones in the laboratory.

    (a) Remember important phone numbers.

4.3) DO's

1. Always wear lab coat, shoes in the laboratory. Every student must have their weight box, a napkin etc.
2. Maintain separate record book for each subject. Make entry before and after using instrument in the log book.
3. Keep your belongings at the place allotted for the same.
4. Maintain silence, order, cleanliness and discipline in the laboratory.
5. Work at the place allotted to you or specially used for certain operations.
6. Keep the working table clean.
7. Handle the laboratory equipments, glassware and chemical with great care.
8. Use only required quantities of material and apparatus of essential size.
9. Perform the test in their proper order.
10. Know the location of eye wash fountain and water shower.
11. Minimize your exposure to organic solvents.
12. The Metal like sodium should be kept under kerosene or liquid paraffin layer in a vessel with a cork stopper.
13. Sodium metal should be cut on dry filter paper. The cut off pieces of sodium should be immediately collected in a vessel containing kerosene or liquid paraffin.
14. Always pour acid into water when diluting and stir slightly.
15. All operations involving poisonous flammable gases and vapours should be carried out in the flame chamber (with exhaust facility)
16. Ladies should avoid wearing sarees. If it is there, apron is essential.
17. Follow quality policy guidelines for fulfillment of their objectives.

4.4) DON'T

1. Don't work alone in the laboratory.
2. Don't leave the glasswares unwashed.

3. Don’t take apparatus, chemicals out of lab.
4. Don’t leave any substance in a vessel or bottle without label.
5. Don’t weigh the reagent directly on the balance pan.
6. Don’t throw the cut off pieces of sodium metal in sink or water. Transfer it immediately in its storage container.
7. Don’t take sodium metal with hands. Use forceps.
8. Don’t panic and run in case of fire. Use the fire extinguishers or sand buckets.
9. Don’t breathe the vapours of organic solvents.
10. Don’t pour any unused reagent back in its stock bottle.
11. Don’t eat or drink any food in laboratory.
12. Don’t use inflammable solvents like benzene, ether, chloroform, acetone and alcohol around flame.
13. Don’t distill to dryness.
14. Don’t exchange stoppers of flasks and bottles containing different reagents.
15. Don’t leave reagent bottle lying on the table.
16. Don’t disturb the order of reagent bottles in which they are placed.
17. Don’t bring reagent on your working table from the general shelf.
18. Don’t throw burning matchstick into dustbin.
19. Don’t leave the laboratory without permission.
20. Don’t pipette anything by mouth.

4.5) LAB SAFETY PRECAUTIONS / MEASURES IN LABORATORY

Part I: Personal Precautions

1. All personnel must wear safety Goggles at all times.
2. All must wear the lab aprons/lab jacket and proper shoes.
3. Except in emergency, over-hurried activities are forbidden.
4. Fume cupboard must be used whenever necessary.
5. Eating, Drinking and Smoking in the laboratories strictly forbidden.

Part II: Use of Safety and Emergency Equipments

1. First aid kits
2. Sand bucket
3. Fire extinguishers (dry chemical and carbon dioxide extinguishers)
4. Chemical Storage cabinet with proper ventilation
5. Material Safety Data sheets.
6. Management of exhaust systems and fume hoods.
7. Sign in register if using instruments.
8. Hand gloves while handling concentrated acids and corrosive substances.

4.6) LABORATORY / FIELD WORK CARE AND SAFETY FOR STUDENTS

1. Your concern for safety should begin even before the first activity. Always read and think about each laboratory assignment before starting.
2. Check chemical labels twice to make sure you have the correct substance. Some chemical formulas and names differ by only a letter or number. Pay attention to the hazard classifications shown on the label.
3. Avoid unnecessary movement and talk in the laboratory.
4. If you have long hair or loose clothes, make sure it is tied back or confined.
5. Make sure all chemicals are clearly and currently labeled with the substance name, concentration, date, and name of the individual responsible.
6. Unnecessary wastage of plant material / animals during practicals should be avoided.
7. Never look directly down into a test tube; view the contents from the side. Never point the open end of a test toward yourself or your neighbor.
8. During study tour / personal collection, more emphasis be given on study of plants / animals in nature and collection of wild plants and animals should not be carried out.
9. If at all the collection of the plant material / animals in needed, it should be carried out under supervision of concerned teacher. Collection of poisonous plants / poisonous mushrooms / harmful animals should be avoided.
10. Oral intake of unknown plant material / animal, out of curiosity, during practical or collection tour is strictly prohibited.
11. If there is any allergic reaction while handling the plants / plant parts / pollen grains / fungal specimens / animals it should be immediately brought to the notice of the concerned teacher and reported to the registered medical practioner.
12. Wearing of handgloves (and mask) is essential while handling poisonous plants or animals / herbarium sheets / toxic and hazardous chemicals / reagents / stung acids / stung alkalis during the experiment should be made with vaccupipette / autopipette / burette under the supervision of concerned teacher / lab assistant.
13. Highly inflammable organic solvents (alcohol, acetone etc.) should not be kept in vicinity of spirit lamp or burner.
14. The laboratory safety measures adopted for handling of hazardous chemicals during practicals should be followed.
15. Operational manuals for equipments such as dissolution test apparatus, rotary vacuum evaporator, centrifuge, autoclave, spectrophotometer etc. should be followed.
16. In case of minor injuries, preliminary treatment should be undertaken with the help of first aid kit available in the laboratory. In case of serious injury, concerned teacher should be immediately contacted for consultation to the physician.
17. The instruction report for breeding, experimentation & dissection of animals should be submitted in a week period. (Which are laid down by Ministry of Social Justice & Empowerment and Ministry of Environment and Forests, Govt. of India).
18. When discarding used chemicals, carefully follow the instructions provided.

19. Equipment Failure - If a piece of equipment fails while being used, report it immediately to your lab assistant or teacher. Never try to fix the problem yourself because you could harm yourself and others.
20. If in doubt, ask!

SYLLABUS FOR M. PHARM (BIOPHARMACEUTICS)

SPECIALIZATION: BIOPHARMACEUTICS

i) Course objectives:

1. Be able to communicate effectively the physicochemical properties of the drug product and the relevant physiology leading to the optimization of drug delivery by any route of administration.
2. To impart basic knowledge of biopharmaceutical science and technology applicable to drug discovery and development so that students will become able to handle these projects with reduction in project failures due to poor biopharmaceutical properties.
3. To provide greater understanding of the applicability and implications of progressing specialized drug delivery strategies.
4. To enhance capabilities of students for giving concrete contributions in development of biopharmaceutics research and science.

ii) Paper : 2 THEORY

iii) Title of Paper: ADVANCED BIOPHARMACEUTICS-I ABP-I

iv) Specific Objectives:

1. To understand the concepts of biopharmaceutics and its basic applications in drug discovery and development.
2. To understand the various rate processes through which drug goes in body in order to develop safe and effective dosage forms.
3. To understand the factors influencing the bioavailability and use of this information to optimize the therapeutic efficacy of drugs and dosage forms.
4. To become able to access both qualitatively and quantitatively the process of drug absorption, distribution, and elimination
5. To understand the development of dissolution methodologies, concepts of BCS, BDDCS and IVIVC and their role in drug product development during preclinical and clinical studies.

v) Note:

Students should be able to

1. Describe all concepts & terms in Biopharmaceutics & Pharmacokinetics.
2. Explain mechanisms of drug absorption, distribution, metabolism & excretion.
3. Calculate permeability coefficient, fraction of drug absorbed and absorption rate constant, hepatic clearance, renal clearance, extraction ratio, distribution half life.
4. Explain factors influencing the bioavailability of drugs from dosage forms.
5. Explain significance of BCS, BDDCS, and IVIVC and develop level A in vitro- in vivo correlation

ABP-I **ADVANCED BIOPHARMACEUTICS-I** **Theory (3hrs/week)**

Unit	Contents	Hrs	Marks
1.	**Introduction** Introduction and history of biopharmaceutics, roll of biopharmaceutics in drug research and development: drug candidate selection, preclinical and clinical development, events involved in absorption of drugs,	03	7 – 10
2.	**Absorption** Cell membrane, absorption mechanism, oral drug absorption, pH partition Hypothesis. Factors affecting: physicochemical, dosage form related, patient related. Drug absorption through other routes: Transdermal, nasal, pulmonary, buccal, ocular and sublingual. Mathematical modeling of simultaneous drug release and in vivo absorption	06	15-20
3.	**Models for Gastrointestinal Absorption of Drugs** Effective membrane permeability and fraction of drug absorbed; permeability and absorption rate constant; assessment of oral drug absorption by using in vivo and in vitro data : concept of maximum absorbable dose, Caco -2 cells, in vivo/ in vitro permeability correlations, physicochemical methods, various in vivo , in vitro and in situ models; in silico methods.	04	08-10
4.	**Distribution** Rate of distribution; factors affecting distribution of drugs; Tissue permeability of drugs; barrier to distribution of drugs; permeability & perfusion limitation; extent of distribution; estimation of volume of distributions (One & Multi-compartmental and non-compartmental analysis); relation between volume of distribution, drug binding & elimination; tissue & protein binding; fraction unbound; drugs with small volume of distribution.	04	10– 12
5.	**Metabolism** Drug metabolism, organs and enzymes, chemical pathways, Phase I and Phase II reactions. First pass effect, factors affecting. Site of metabolism, factors affecting drug metabolism (genetic, species and environmental).	04	10– 12
6.	**Excretion** Renal and nonrenal routes of drug excretion; Concept of clearance, organ clearance, extraction ratio; effect of perfusion, protein binding & enzyme activity on hepatic clearance; Renal excretion: principle processes and factors affecting it; Non renal excretion; dependency of half life on clearance and volume of distribution.	04	10– 12
7.	**Biopharmaceutical Drug Disposition classification system (BDDCS)**	05	10-12

Biopharmaceutical Classification System(BCS), Regulatory history, purpose of BCS, BCS classes, determination of solubility and permeability, Limitations of BCS , Extension to BCS : six class BCS, QBCS, Pulmonary BCS, BDDCS classification, difference between BCS and BDDCS, effects of efflux and uptake transporters on absorption, drug-drug interaction predicted by BDDCS, food effects, application of BDDCS in IVIVC and biowaiver of drugs.

8	**Dissolution methodologies and IVIVC**	06	10-12

Mathematical modeling of drug release, In vitro dissolution testing (Compendial and noncompendial methods), various dissolution improvement technologies, different class of dissolution media, IVIVC; Levels of correlation , prediction of IVIVC based on BCS; Development of level A correlation; Convolution & deconvolution approach; evaluation of predictability of correlation ; Bioavailability studies for development of IVIVC; dissolution data analysis with view to IVIVC ; BCS and IVIVC based biowaivers.

vi) Recommended Reading:

a) Basic Reading:

1. D.M. Brahmankar, S.B. Jaiswal. 1997, Biopharmaceutics & Pharmacokinetics - A treatise. CBS Publications, New Delhi.
2. P.L. Madan. Biopharmaceutics & Pharmacokinetics, 2000, Jaypee publications, New Delhi.
3. Swarbrik. Biopharmaceutics. 1987, Lea & Febiger book publication. U. K
4. Leon Shargel. 2003, Applied Biopharmaceutics & Pharmacokinetics, Prentice Hall International, London.
5. Pharmaceutical Dissolution Testing; Ed by Jennifer Dressman and Johannes Kramer; Taylor & Francis.
6. Biotechnology: Pharmaceutical Aspects, Drug Absorption Studies In situ, in vitro, in silico model; Ed by Carsten Ehrhardt, Kwang-Jin Kim; Springer.

b) Additional Reading:

1. Alfonso R Gennaro (2004). Remington : Pharmaceutical Science and practice pharmacy. (20th ed.) Lippincott Williams and Wilkins, New Delhi,
2. Dr. Tapan Kumar Pal, M. Ganeshan. Bioavailability and Bioequivalence in Pharmaceutical Technology. CBS Publishers and Distributors
3. Peter G. Welling, Francis L. S. Tse, Shrikant V. Dighe. Pharmaceutical Bioequivalence. Marcel Dekker Inc.
4. Milo Gibaldi. 1992 Biopharmaceutics & Pharmacokinetics., Lea & Febiger publication

5. Gibaldi, Handbook of clinical pharmacokinetics. 1992, Marcel Dekker,

c) References:

i) Books:

1. Amidon, G.L., 1981. Drug derivatization as a means of solubilization: physical and biochemical strategies. Yalkowsky, S.H. (Ed.), Techniques of Solubilization of Drugs. Marcel Dekker, New York.
2. Malcohm Rowland C., Thomas N. Tozer. Clinical Pharmacokinetics – Concept & Application., 1987, Lea & Febiger Book
3. P. Jenner and B. Testa; Concept in drug metabolism; Marcel Dekker.
4. Rober E. Notary. Bio-pharmaceutics & Pharmacokinetics – An introduction, 1987, Marcel Dekker, New York.

ii) Periodicals/Journals:

1. Clinical Pharmacokinetics
2. Clinical Pharmacology
3. Journal of Pharmacy And Pharmacology
4. European Journal of Pharmaceutics and Biopharmaceutics
5. International Journal of Pharmaceutics
6. Advanced Drug Delivery Reviews

i) Paper : 2 PRACTICAL

ii) Title of Paper: ADVANCED BIOPHARMACEUTICS-I ABP-I

iii) Specific Objectives:

1. To understand the importance of absorption, distribution, metabolism, excretion on the clinical performance of medicinal agents.
2. To study the impact of physicochemical properties of drugs on their in vivo performance.
3. To study various factors affecting drug solubility and its absorption
4. To understand the significance of dissolution in drug absorption, theories of drug dissolution and become able to develop dissolution test as tool for quality control and bioavailability assessment.
5. To understand the use of various excipients as absorption enhancers.
6. To study how to calculate various pharmacokinetic parameters from patient data and become able to predict changes in these parameters in patients with selected diseases. To become able to utilize these knowledge to individualize patient therapy.
7. To understand the general approaches used in bioavailability and bioequivalence studies and methods to evaluate bioavailability and bioequivalence.
8. To understand the process of development of in vitro in vivo correlations

iv) Note:

Students should;

1. Be able to experimentally deduce and prove the effect of various factors like pH, particle size, polymorphism, composition of dissolution media etc. on solubility of drug and should be able to relate this with physiological and biological performance of drug.
2. Be able carry out dissolution tests for various dosage forms to study factors affecting dissolution rate and perform kinetic analysis of dissolution data.
3. Be able to compare dissolution and bioavailability profiles with their significance
4. Have experimental hand on various techniques used to study absorption and permeation of drugs in vitro.
5. Be able to assess experimentally effect of excipients on permeation of drug.
6. Be able to perform in vitro metabolism study.
7. Be able to experimentally prove various factors affecting urinary and salivary excretion of drugs.
8. Be able to perform in vitro protein biding study to understand process protein binding and determine drug binding sites
9. Be able calculate various pharmacokinetic parameters from urine/plasma data after administration of drug by different routes.
10. Able to design bioavailability and bioequivalence study and interpret data from such study
11. Be able develop level A in vitro in vivo correlation as a case study.

ABP-I **ADVANCED BIOPHARMACEUTICS-I** **Practical (6 hrs/wk)**

Unit	Contents
1.	Experiments based on solubility and dissolution studies
2.	Study of absorption and permeation of drug using in situ rat model, cell models , Determination of logP value of drug
3.	Study the metabolism of drug using rat liver slice model
4.	Pharmacokinetic study of drug using plasma and urinary data
5.	Effect of food products on metabolism and bioavailability of drugs
6.	Pharmacokinetic study of drug using salivary data
7.	Calculation of drug dose in case of controlled release formulations
8.	Measurement of bioavailability based on urinary data rugs excreted through urine
9.	Experiments based on estimation of primary and secondary pharmacokinetic parameters after administration of single or multiple dose of the drug by different routes of administration in animals and humans
10.	Study of protein binding of drugs by using in vitro methods
11.	Bioequivalence testing of drug products
12.	Development in vitro in vivo correlation : case studies

(vi) Recommended Reading:

a) Basic Reading:

1. Milo Gibaldi & Donald Perrier. Pharmacokinetics, 1992, Marcel Dekker, New York.
2. D.M. Brahmankar, S.B. Jaiswal. 1997, Biopharmaceutics & Pharmacokinetics - A treatise. CBS Publications, New Delhi.
3. P.L. Madan. Biopharmaceutics & Pharmacokinetics, 2000, Jaypee publications, New Delhi.
4. Gibaldi & Pancot. Handbook of clinical pharmacokinetics. 1992, Marcel Dekker, New York.
5. Swarbrik. Biopharmaceutics. 1987, Lea & Febiger book publication. U. K

b) Additional Reading:

1. Malcohm Rowland C., Thomas N. Tozer. Clinical Pharmacokinetics – Concept & Application., 1987, Lea & Febiger Book
2. Leon Shargel. 2003, Applied Biopharmaceutics & Pharmacokinetics, Prentice Hall International, London.
3. Milo Gibaldi. Biopharmaceutics & Pharmacokinetics. 1992, Lea & Febiger book publication
4. Rober E. Notary. Bio-pharmaceutics & Pharmacokinetics – An introduction, 1987, Marcel Dekker, New York.

c) References:

i) Books:

1. Swarbrick J and Boylon J.C., Encyclopedia of Pharmaceutical Technology, Vol. 1-20.
2. Grimm, W. Stability Testing of Drug Products. International Publishers Service, Incorporated, 1987.

ii) Periodicals/Journals:

1. Clinical pharmacokinetics
2. Clinical pharmacology
3. Journal of pharmacy and pharmacology

i) Paper : 3 THEORY

ii) Title of Paper: PHARMACOKINETICS PK

iii) Specific Objectives:

1. Discuss the following pharmacokinetic concepts, both in general and as they apply to your program's target drug(s):
   - dose
   - absorption and factors that affect it
   - volume of distribution
   - protein binding
   - steady-state
   - first-order elimination
   - clearance
   - half-life
   - C_{max} T_{max}, AUC, AUMC, MRT
   - desired peak/trough drug concentrations
   - timing of sample collection
2. Apply this knowledge to the interpretation of serum drug concentrations and pharmaceutical care of specific patients.
3. To understand how drugs can be utilized optimally in the treatment of diseases through design and development of new drugs and dosage forms.
4. To understand design of dosage regimen & individualization of drug therapy.
5. Application of pharmacokinetic principles in clinical situations
6. To understand importance of Therapeutic Drug Monitoring in achieving optimal drug therapy.

iv) Note:

Students should be able to

1. Describe all concepts & terms in Biopharmaceutics & Pharmacokinetics.
2. Explain mechanisms & kinetics of drug absorption, distribution, metabolism & excretion.
3. Give mathematical treatment to various pharmacokinetic data.
4. Calculate pharmacokinetic parameters based on compartmental & non-compartmental analysis.

PK **PHARMACOKINETICS** **Theory (3 hrs/wk)**

Unit	Contents	Hrs	Marks
1.	**Introduction** Introduction to pharmacokinetics, brief history of pharmacokinetics, Different pharmacokinetic parameters, and mathematical fundamentals (exponents, logarithms, slope, rates and derivatives, Pharmacokinetic models, Pharmacokinetics of drug absorption: zero order absorption model, first order absorption model, pharmacokinetic basic of controlled drug delivery system, toxicokinetics.	04	08-10
2.	**Physiological concepts and kinetics** Zero order and first order kinetics, movement of drug through membrane, absorption kinetics (intravascular and extravascular), distribution and elimination kinetics, integration with kinetics.	04	08-10
3.	**Drug design in special population** Variability and it causes variability due to age, weight, sex, diseases (renal, cardio vascular, hepatic, genetics and metabolic disorders) and dose adjustment in above mentioned cases.	04	08-10
4.	**Non compartmental analysis based on pharmacokinetic principle** Statistical moment theory, applications, Assessment of AUC, estimation of half life, estimation of absorption kinetics, Mean residence Time, Blood to plasma ratio, drug accumulation, creatinine clearance, fraction metabolized, predicting time and concentration to reach to steady state.	04	10-15
5.	**Compartment modeling** Applications of Laplace transformation in pharmacokinetics, Pharmacokinetic models: importance and applications. Various types of physiological compartment models, absorption model perfusion and distribution, volume of distribution, One compartment model: Intravenous injection, intravenous infusion, first order absorption (urinary and plasma data), Multi compartment models: Intravenous injection, intravenous infusion, first order absorption, multi dose data. concept of lag time	09	17-20
6.	**Nonlinear pharmacokinetics** Non linear pharmacokinetics of absorption, saturation in transport carriers, dose dependent absorption, drug elimination by capacity limited pharmacokinetics. Capacity limited drug metabolism, relationship between AUC and dose, bioavailability of drugs that follows nonlinear pharmacokinetics. Concepts of linear and non-liner pharmacokinetics, Michaelis-Menton Kinetics characteristics. Basic Kinetic parameters, possible causes of non-induction, non-linear	05	13-15

binding, and nonlinearity of pharmacological responses.

7.	**Kinetics of pharmacological Response** Kinetics of directly reversible, irreversible and indirect pharmacological response.	03	8-10
8.	**Time dependent pharmacokinetics** Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics, chemically induced dependency.	03	8-10

(vi) Recommended Reading:

a) Basic Reading:

1. Milo Gibaldi & Donald Perrier. Pharmacokinetics, 1992, Marcel Dekker, New York.
2. D.M. Brahmankar, S.B. Jaiswal. 1997, Biopharmaceutics & Pharmacokinetics - A treatise. CBS Publications, New Delhi.
3. P.L. Madan. Biopharmaceutics & Pharmacokinetics, 2000, Jaypee publications, New Delhi.
4. Gibaldi & Pancot. Handbook of clinical pharmacokinetics. 1992, Marcel Dekker, New York.
5. Swarbrik. Biopharmaceutics. 1987, Lea & Febiger book publication. U. K

b) Additional Reading:

1. Malcohm Rowland C., Thomas N. Tozer. Clinical Pharmacokinetics – Concept & Application., 1987, Lea & Febiger Book
2. Leon Shargel. 2003, Applied Biopharmaceutics & Pharmacokinetics, Prentice Hall International, London.
3. Milo Gibaldi. Biopharmaceutics & Pharmacokinetics. 1992, Lea & Febiger book publication
4. Rober E. Notary. Bio-pharmaceutics & Pharmacokinetics – An introduction, 1987, Marcel Dekker, New York.

c) References:

i) Books:

1. Swarbrick J and Boylon J.C., Encyclopedia of Pharmaceutical Technology, Vol. 1-20.
2. Grimm, W. Stability Testing of Drug Products. International Publishers Service, Incorporated, 1987.

ii) Periodicals/Journals:

1. Clinical Pharmacokinetics
2. Clinical Pharmacology

3. Journal of Pharmacy and Pharmacology
4. European Journal of Pharmaceutics and Biopharmaceutics

i) Paper: 6 THEORY

ii) Title of Paper : ADVANCED BIOPHARMACEUTICS- II ABP-II

iii) Specific Objectives:

1. The student should have a basic knowledge of the bioavailability. To gain an insight in the bioavailability of dosage forms produced in the pharmaceutical industry.
2. Knowing and being able to implement the regulatory guidelines for the bioavailability and bioequivalence.
3. The student will gain good understanding of application of biopharmaceutics in bioavailability and bioequivalence.
4. Student should able to perform the bioavailability studies of various dosage forms.

iv) Note:

1. The topics must be conveyed through plenty of examples. Lecture classes must be conducted as lecture-cum-power point presentations.
2. Keeping in view the requirements of his students, the teacher may have to prepare some teaching and exercise material.
3. For better understanding, good video and animated clips can be used if the more advanced facilities are available. In fact they can be used very fruitfully.

ABP-II ADVANCED BIOPHARMACEUTICS- II Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1.	**Introduction** Definition of Bioavailability, bioequivalence, generic drugs, types of BA, methods to determine BA, Hatch max-man act 1971. Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals, liquid orals and topical dosage forms.	04	9-12
2.	**Application of Biopharmaceutics in BA/BE** Biopharmaceutical aspects of absorption, distribution, metabolism and elimination, factors influencing bioavailability of dosage forms, methods to determine BA/BE. Bioavailability of highly variable drugs, narrow therapeutic index drugs and poorly soluble drugs. Methods for enhancement of BA. Drug product selection, concept of orange book, need of BE studies, generic drug product selection, study submission and drug review process	06	12-14
3.	**Ethical Issues involved in BA/BE studies** Designing of protocol, rationale of the research, selection of subjects.	04	9-12

Construction, role and responsibilities of IRB/IEC

4.	**Conduct of Study** Design of the study, inclusion and exclusion criteria, sampling point, sampling volume, treatment groups, Approaches to determine bioequivalence (21 CFR 320.24)	05	11-13
5.	**Treatment of the Data** Statistical methods used for the treatment of the data, Statistical software to treat the data obtained from analysis, presentation of results and determination of conclusions.	04	9-12
6.	**Documentation in BA/BE** Formation of investigator's information brochure, Case Record Form (CRF), presentation of Results and conclusion.	04	9-12
7.	**Bioavailability of transdermal and topical dosage forms** types of dosage forms, in vivo animal studies, in vitro diffusion, skin stripping, micro dialysis, near IR, human testing, a two-layer diffusive model for describing the variability of transdermal drug permeation, Mathematical models of skin permeability	06	12-14
8.	**Bioanalytical method development and validation for BA/BA studies** Introduction, sample preparation, column, method validation with ICH guidelines, upgraded technologies like GC-MS, LC-MS	03	9-11

(vi) Recommended Reading:

a) Basic Reading:

1. Milo Gibaldi & Donald Perrier. Pharmacokinetics, 1992, Marcel Dekker, New York.
2. D.M. Brahmankar, S.B. Jaiswal. 1997, Biopharmaceutics & Pharmacokinetics - A treatise. CBS Publications, New Delhi.
3. P.L. Madan. Biopharmaceutics & Pharmacokinetics, 2000, Jaypee publications, New Delhi.
4. Gibaldi & Pancot. Handbook of clinical pharmacokinetics. 1992, Marcel Dekker, New York.
5. Swarbrik. Biopharmaceutics. 1987, Lea & Febiger book publication. U. K.

b) Additional Reading:

1. www.fda.gov/cder/guidance/3618
2. www.fda.gov/cder/guidance/2070DFT
3. www.iuphar.org/pdf/hum_55.pdf
4. www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-Id/bio/bio-a_c

5. www.cdsco.nic.in/thml/BE
6. www.tga.gov.au/docs/html/forms/psbiosum

c) References:

i) Books:

1. Dr. Tapan Kumar Pal, M. Ganeshan. Bioavailability and Bioequivalence in Pharmaceutical Technology. CBS Publishers and Distributors
2. Llyod r. Snyder, J. J. Kirkland, J. L. Glajch. Practical HPLC method development. John Wiley & Sons
3. Peter G. Welling, Francis L. S. Tse, Shrikant V. Dighe. Pharmaceutical Bioequivalence. Marcel Dekker Inc.
4. Jerry L. Hamelink, Peter F. Landrum, Harold L. Bergman, William H. Benson. Bioavailability. Physical, chemical, and biological interactions. Lewis publishers

ii) Periodicals/Journals:

1. AAPS Journal
2. Biomaterials
3. European journal of Pharmaceutical Sciences
4. Pharmaceutical technology (findpharma)
5. Pharmaceutical Research (Springer)
6. Pharmaceutical Technology (Elsevier)

i) Paper : 6 PRACTICAL

ii) Title of Paper: ADVANCED BIOPHARMACEUTICS- II ABP-II

iii) Specific Objectives:

1. The student will gain a good understanding of effect of various processing parameters on bioavailability of dosage forms and concept of in vitro in vivo correlation.
2. To study the impact of physicochemical properties of drugs on their in vivo performance.
3. To understand the general approaches used in bioavailability and bioequivalence studies and methods to evaluate bioavailability and bioequivalence.
4. To understand the process of development of in vitro in vivo correlations
5. To become able to develop bioanalytical methods

iv) Note:

1. Be able carry out dissolution tests for various dosage forms to study factors affecting dissolution rate and perform kinetic analysis of dissolution data.
2. Be able to compare dissolution and bioavailability profiles with their significance.
3. Have knowledge of methods used to determine bioavailability and bioequivalence along with statistical aspects of bioequivalence study.
4. Have knowledge of parameters used to validate bioanalytical methods.
5. Able to design bioavailability and bioequivalence study and interpret data from such study.

ABP-II ADVANCED BIOPHARMACEUTICS- II Practical (6 hrs/wk)

Unit	Contents
1	Dissolution studies of 2 to 3 marketed formulations (immediate, sustain release) determination of drug release kinetics
2	Measurement of bioavailability based on urinary data of rifampicin, pyridoxine, nitrofurantoin and the drugs excreted through urine
3	Practical's based on biopharmaceutical aspects of drug formulations (pharmacotechnical variables)
4	Preparation of model study protocol for BA/BE
5	Determination of absolute bioavailability for any one formulation in animals or humans
6	Determination of Relative bioavailability for any one drug in animals or humans
7	Determination of similarity and dissimilarity factor

8 Development of bioanalytical method and validation of the same

9 Intrinsic dissolution study, dissolution method development

(vi) Recommended Reading:

a) Basic Reading:

1. Milo Gibaldi & Donald Perrier. Pharmacokinetics, 1992, Marcel Dekker, New York.
2. D.M. Brahmankar, S.B. Jaiswal. 1997, Biopharmaceutics & Pharmacokinetics - A treatise. CBS Publications, New Delhi.
3. P.L. Madan. Biopharmaceutics & Pharmacokinetics, 2000, Jaypee publications, New Delhi.
4. Gibaldi & Pancot. Handbook of clinical pharmacokinetics. 1992, Marcel Dekker, New York.
5. Swarbrik. Biopharmaceutics. 1987, Lea & Febiger book publication. U. K
6. Yadav A.V, Yadav V.B, Shete A.S, Experimental biopharmaceutics and pharmacokinetics

b) Additional Reading:

1. www.fda.gov/cder/guidance/3618
2. www.fda.gov/cder/guidance/2070DFT
3. www.iuphar.org/pdf/hum_55.pdf
4. www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-Id/bio/bio-a_c
5. www.cdsco.nic.in/thml/BE
6. www.tga.gov.au/docs/html/forms/psbiosum

c) References:

i) Books:

1. Swarbrick J and Boylon J. C. Encyclopedia of Pharmaceutical Technology. Vol.1-3, Marcel Decker Inc. 2005.
2. Llyod r. Snyder, J. J. Kirkland, J. L. Glajch. Practical HPLC method development. John Wiley & Sons
3. Peter G. Welling, Francis L. S. Tse, Shrikant V. Dighe. Pharmaceutical Bioequivalence. Marcel Dekker Inc.
4. Jerry L. Hamelink, Peter F. Landrum, Harold L. Bergman, William H. Benson. Bioavailability. Physical, chemical, and biological interactions. Lewis publishers

ii) Periodicals/Journals:

1. Pharmaceutical technology (findpharma)

2. Pharmaceutical Research (Springer)
3. Pharmaceutical Technology (Elsevier)

i) Paper: 7 THEORY

ii) Title of Paper: RECENT ADVANCES IN NOVEL DRUG DELIVERY SYSTEM RNDDS

iii) Specific Objectives:

1. The student will gain a good understanding of how the novel dosage forms under review are produced and which parameters have an influence on the manufacturing and better understanding of new carriers for drug delivery.
2. Make the hands of the students in development of new dosage forms

iv) Note:

1. The topics must be conveyed through plenty of examples. Lecture classes must be conducted as lecture-cum-power point presentations.
2. The teacher must not depend on a single or a set of two or three text books. He must choose his materials from diverse sources (reference books, journals and internet).
3. Keeping in view the requirements, the teacher may have to prepare some teaching and exercise material.
4. For better understanding, good video and animated clips can be used if the more advanced facilities are available. In fact they can be used very fruitfully.

RNDDS RECENT ADVANCES IN NOVEL DRUG DELIVERY SYSTEM

Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Introduction** Various types of novel drug delivery, classes, objective, rationale, merits and demerits of NDDS, concept of preformulation	03	06– 08
2.	**Protein and Peptide drug delivery** Need, objective, preformulation and formulation development of protein and peptide molecule, pharmacokinetics and toxicodynamics of protein molecules, Barriers in protein and peptide drug delivery. Different route of drug delivery, strategies to improve the bioavailability,	04	10 –12
3.	**Oral and parental controlled release** Fundamentals of controlled drug delivery systems, use of polymers in controlled drug delivery, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of thefollowing controlled releasing systems	04	10– 12

(a) Controlled release oral drug delivery systems

(b) Parenteral controlled release drug delivery systems

(c) Bioadhesive drug delivery systems

4.	**Drug delivery through external devices** (a) Transdermal delivery systems including iontophoresis, sonophoresis and photophoresis (b) Ocular and intrauterine delivery systems (c) Implantable therapeutic systems	04	10-12
5.	**Site specific drug delivery system** Drug targeting to particular organs: (a) Drug delivery to respiratory systems (b) Problems of drug delivery to the brain and targeting to brain (c) Drug delivery to eye, colon (d Drug targeting in neoplastic diseases	07	14 –18
6.	**New Drug Carrier Systems** General mechanisms consideration, Novel carriers system such as Microsponges, Immunoconjugates, Metal Nanoparticles and Quantum Dots, Vesicular Systems- Phytosome, Transferosomes, Ethosomes, Niosomes, Virosomes, Cochleate, Cubosomes.	07	14-18
7.	**Biochemical and molecular biology approaches to controlled drug delivery of** 1. Micro particulate drug carriers: Liposomes, Niosomes, Microspheres, dendrimers, micelles, reverse micells, Nanoparticle and Resealed erythrocytes. 2. Monoclonal antibodies	04	10-12
8.	**Regulatory consideration in novel drug delivery** Bioavailability studies and USFDA, MCA, ICMR, WHO guidelines for ANDA and NDA of novel dosage forms	03	06 –08

(vi) Recommended Reading:

a) Basic Reading:

1. Siepman Juerjen, Ronald A. Segel and Micheal J. Rathbone. Fundamentals and Applications of New Drug Delivery. Springer, US, 2012.
2. Hong Wen, Kinam Park. Oral Controlled Release Formulation Design and Drug Delivery: Theory to Practice. John Wiley and Sons, 2010.
3. Ashim K. Mitra, Ophthalmic drug delivery systems**.** Marcel Dekker, 2003.

4. Richard guy, Jonathan Hadgraft, Transdermal Drug Delivery Systems: 2nd ed. Marcel Dekker, 2002.
5. Hans Schreier, Drug Targeting Technology: A Physical, Chemical, Biological Methods. Taylor & Francis, 2011.
6. Mohan Babu Boggara. Lipid-based drug delivery system---Molecular dynamics simulations and neutron scattering studies. ProQuest, UMI Dissertation Publishing, 2011.

b) Additional Reading:

1. Bharat Bhushan, Springer handbook of nanotechnology, Volume 1. Springer, 2004.
2. Warren H. Finlay. The Mechanics of Inhaled Pharmaceutical Aerosols: An Introduction. Academic Press, 2001.
3. Anthony J. Hickey. Pharmaceutical Inhalation Aerosol Technology, Second Edition, Marcel Dekker, 2005

c) References:

i) Books:

1. N. K. Jain; Controlled and Novel Drug Delivery; CBS publications, 2008.
2. Swarbrick J and Boylon J.C., Encyclopedia of Pharmaceutical Technology, Vol. 1-20.
3. P. J. Tarcha; Polymers for controlled Drug Delivery; CRC Press, 1991.
4. F. Kydonieus; Controlled Release Technologies: Methods, Theory and Application, Vol-I & II; CRC Press Inc. Academic/Plenum Publishers, NY, 2001.
5. A. V. Kabanov, P. L. Felgner, L. W. Seymour. Self-Assembling Complexes for Gene Delivery. From Laboratory to Clinical Trial. John Wiley & Sons: New York, 1998.

ii) Periodicals/Journals:

1. Current Drug Delivery (Bentham Science)
2. Drug Development and Industrial Pharmacy – (Informa Pharmaceutical Science)
3. APPSPharma sci tech
4. Pharmaceutical research
5. International journal of pharmaceutics
6. PDA J Pharmaceutical Science and Technology - Parenteral Drug Association USA

OTHER FEATURES*

*Except list of LABORATORY EQUIPMENTS (c), all points (1, 2, 3, 4) coming under OTHER FEATURES from Syllabus of M. PHARM., (Pharmaceutical Chemistry) are same.

(c) LABORATORY EQUIPMENTS:

In addition to routine equipments like hot air oven, centrifuge, pH meter etc. following specific equipments are necessary.

1. Rotary vacuum film evaporator (Shared)
2. HPLC (Shared)
3. Dissolution test apparatus
4. Spray Drier (Desirable)
5. Lyophiliser (Desirable)
6. Minipress Tablet machine
7. Brookfield Viscometer (Shared)
8. Stability Chambers (two)
9. UV-Visible spectrophotometer (Shared between two PG courses)
10. Photographic Microscope (Shared)
11. Autoanalyser

SYLLABUS FOR M. PHARM (PHARMACEUTICS)

SPECIALIZATION: PHARMACEUTICS

i) Course objectives:

1. To impart the knowledge and skills about the manufacture of excipients
2. To appraise the students of the problems and methods of design dosage formulations and development.
3. To provide in depth knowledge and skills required in the development, evaluation of conventional and novel drug delivery systems.
4. To inculcate the research attitude and induct them to research methodologies.
5. To appraise them of regulatory affairs.

ii) Paper : 2 THEORY

iii) Title of Paper: ADVANCED PHARMACEUTICS- I AP-I

iv) Specific Objectives:

1. To understand the relationship between physicochemical properties and therapeutic effect
2. To appreciate the contribution of physicochemical properties in the performance of dosage forms.
3. To study and understand the importance of stability of pharmaceuticals and factors that affect stability of pharmaceuticals.
4. To enrich the students with the knowledge of various polymers.
5. To understand the applications of solid dispersion in development of dosage forms

v) Note:

1. Students will be able to understand the relationship between physicochemical properties and therapeutic effect.
2. They will be able to appreciate the contribution of physicochemical properties in the performance of dosage forms.
3. They will be able to understand the importance of stability of pharmaceuticals and factors that affect stability of pharmaceuticals.
4. They will be enriched with knowledge of various polymers.
5. 5. They will be able to understand the applications of solid dispersion in development of dosage forms

AP-I **ADVANCED PHARMACEUTICS- I** **Theory (3 hrs/wk)**

Unit	Contents	Hrs	Marks
1.	**Solids:** Particle characterization by size, shape, and surface of individual particle and for contacted particle. Handling of solids, pharmaceutical granulation, compression and compaction properties of binary mixtures, lubricant sensitivity, characterization of granules and compacts.	08	18-22
2.	**Solubility:** Solubility, partial solubility parameters, Methods of enhancing solubility, Solublization, Solublization in Non-aqueous system, Interaction with polymers and oppositely charged species, Hydrotropy, Cyclodextrin inclusion complexes and co-solvents.	04	10-12
3.	**Dissolution:** Theory of dissolution, concept of drug release. Dissolution test apparatus: different designs, factors affecting dissolution rate. Dissolution of different dosage forms: solids, suspensions, topicals, suppositories and controlled release systems.	04	10-12
4.	**Solid Dispersion:** Types, methods of Preparation, selection of carrier: characterizationand applications,Ion exchange, Microparticles, Nanoparticles. Diffusion: Drug absorption, permeability of membranes	04	10-12
5.	**Surfactant System:** Behavior of surfactant in binary and ternary systems. Factors affecting phase behavior; Micellization; micelle structure, shape, size factors affecting CMC and micelle size, thermodynamics and kinetics of micelle formation.	04	08-12
6.	**Emulsions:** Microemulsions, Multiple emulsions, oral lipoid formulations, Stability of emulsions	04	08-10
7.	**Polymer Science**: Types and applications of polymers, polymerization reactions methods of Polymerization and characterization of polymers, thermodynamics of Polymer solutions.	04	08-10
8.	**Stability studies:** WHO, guidelines of stability testing, Kinetics activation energy calculations, accelerated stability, factors Responsible for destabilization of pharmaceutical products and techniques to improve,	04	08-10

shelf life calculations. Stability and photo stability Physical testing of solution, suspension, Emulsion, aerosol, powder, tablet and sustained release products, Matrix and bracketing design.

(vi) Recommended Reading:

a) Basic Reading:

1. Martin A. Bustamante P. and Chun A.H. Physical Pharmacy; Wavery
2. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
3. Rubinstein M. N.; Pharmaceutical Technology, Drug stability, John Wiley and sons.
4. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.

b) Additional Reading:

1. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
2. Tarcha P. J.; Polymer for Controlled Drug Delivery, CRC Press.
3. List P. H .and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
4. Robinson; Novel Drug Delivery Systems, Marcel Dekker.

c) References:

i) Books:

1. Parikh D.M., Handbook of Pharmaceutical Granulation Technology; Marcel Dekkar
2. Brittain H. G.; Physical Characterization of Pharmaceutical solids;
3. Cartensen J. T.; Drug Stability; Marcel Dekker.
4. Kithard A. and Watanabe A. Electrical phemanomena at interfaces; Marcel Dekkar
5. Martin A. Bustamante P. and Chun A.H. Physical Pharmacy; Wavery
6. Alderborn G and. Nystrom C; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
7. Stanley N. G. – Wooed; Enlargement and compaction of particle solids; Butterworths.

ii) Periodicals/Journals:

1. Indian Journal of Pharmaceutical Education and Research
2. Indian Drugs
3. International Journal Pharmaceutical Sciences
4. Acta Pharmaceutica

i) Paper : 2 PRACTICAL

ii) Title of Paper : ADVANCED PHARMACEUTICS – I AP-I

iii) Specific Objectives:

1. To understand the relationship between physicochemical properties and therapeutic effect
2. To appreciate the contribution of physicochemical properties in the performance of dosage forms.
3. To study and understand the importance of stability of pharmaceuticals and factors that affect stability of pharmaceuticals.
4. To enrich the students with the knowledge of various polymers.
5. To understand the applications of solid dispersion in development of dosage forms

iv) Note:

1. Fundamental understanding of students towards in vitro performance of dosage form should be clear.
2. They should be able to draw some predictions related with in vivo performance of dosage form, which are based on modifications in physical properties of drugs and excipients.

AP-I ADVANCED PHARMACEUTICS - I Practical (6 hrs/wk)

Unit	Contents
1.	Powder characterization: a. Microscopy – Particle size analysis, calculation of shape factors.
2.	Solubilization : a. Effect of dielectric constant on solubility b. Complexation
3.	Dissolution studies of various dosage forms.
4.	Ternary phase diagram.
5.	Solid dispersion
6.	Stability of multiple emulsions
7.	Polymer science: Rheological and thermal characterization of polymers.
8.	Stability studies : Accelerated stability studies of a formulation

(vi) Recommended Reading:

a) Basic Reading:

1. Martin A. Bustamante P. and Chun A.H. Physical Pharmacy; Wavery
2. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
3. Rubinstein M. N.; Pharmaceutical Technology, Drug stability, John Wiley and sons.
4. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.

b) Additional Reading:

1. Tarcha P. J.; Polymer for Controlled Drug Delivery, CRC Press.
2. List P. H .and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
3. Robinson; Novel Drug Delivery Systems, Marcel Dekker.

c) References:

i) Books:

1. Parikh D.M., Handbook of Pharmaceutical Granulation Technology; Marcel Dekkar
2. Brittain H. G.; Physical Characterization of Pharmaceutical solids;
3. Marcel Dekker.
4. Cartensen J. T.; Drug Stability; Marcel Dekker.
5. Martin A. Bustamante P. and Chun A.H. Physical Pharmacy; Wavery
6. Alderborn G and. Nystrom C; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
7. Stanley N. G. – Wooed; Enlargement and compaction of particle solids; Butterworths.

ii) Periodicals/Journals:

1. Indian Journal of Pharmaceutical Education and Research
2. Indian Drugs
3. International Journal Pharmaceutical Sciences
4. Acta Pharmaceutica

i) Paper : 3 THEORY

ii) Title of Paper : DESIGN AND DEVELOPMENT OF DOSAGE FORMS DDDF

iii) Specific Objectives:

1. To understand Design and Development of Dosage Forms by understanding basic concepts like optimization, preformulation, validation, packaging of pharmaceuticals, GMP, technology transfer, technology transfer of dosage forms

iv) Note:

1. The topics must be conveyed through plenty of examples. Lecture classes must be conducted as lecture-cum-power point presentations.
2. It is a course that aims to develop skills. It is therefore "practical" in orientation. Plenty of exercises of various kinds must be done by the students.
3. The teacher must not depend on a single or a set of two or three text books. He must choose his materials from diverse sources.
4. Keeping in view the requirements of his students, the teacher may have to prepare some teaching and exercise material.
5. For better understanding, good video and animated clips can be used if the more advanced facilities are available. In fact they can be used very fruitfully.

DDDF DESIGN AND DEVELOPMENT OF DOSAGE FORMS Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1	**Preformulation studies:** Objectives and applications, Characterisation of fundamental & derived properties of drug molecules. Study of particle morphology, particle size, shape, surface area, solubility, ageing and polymorphism. Particle Characterization by optical and electron microscopy, spectroscopy, chromatography, thermal techniques.Studies on drug-drug and drug-excipient interactions and their characterization.	08	18-22
2	**Design of experiments and optimization:** Design of experiment, Terminologies in experimental design. Product, process and response variables. Optimization methodologies with special reference to factorial design, central composite design and mixture designs. Response surface analysis.	04	10-12

3	**Validation:** Concept and need of validation, types of validation, process validation, equipment validation and cleaning validation, validation master plan.	04	10-12
4	**Packaging of pharmaceuticals:** Types of primary and secondary packaging materials for pharmaceuticals. Studies on types and suitability evaluation of glass, plastic and rubber as a primary packaging for non-sterile and sterile dosage forms. Regulatory requirements for pharmaceutical packaging.	04	10-12
5	**Interpretations of current good manufacturing regulations** i. GMP – CFR 210-211 ii. Schedule M iii. Process validation iv. BMR preparation, selection of equipments. In rief process flow chart for each dosage form v. Process analytical technology	04	8-12
6	**Therapeutic Applications of Polymers:** Polymers for therapeutic applications, biocompatible and biodegradable polymers, biodegradability and biodegradability testing of polymers, applications of biodegradable polymers in parenterals and surgicals, polymer-drug conjugates, self-assembled polymeric carriers (polymeric micelles, polymer-coated liposomes, nanoparticles, microspheres, etc.) Solubility of polymers, methods of polymer characterization in solution (thermodynamics of polymer solutions), Viscosity and viscoelasticity of polymers, polyelectrolytes and polyampholytes, cross-linked polymers and polymer complexes.	04	8-10
7	**Technology transfer**: Scope, role and functions. Technology transfer of new product from bench scale to commercialization of new product. Regulatory issues, NDA, ANDA regulatory requirements. Technology transfer of site transfer product from one site to another site or third party technology transfer.	04	8-10
8	**Technology transfer of Dosage forms**: R & D to pilot scale to plant scale studies for dosage forms like liquid orals, solid dosage forms and sterile dosage forms with equipments and SOPs	04	8-10

(vi) Recommended Reading:

a) Basic Reading:

1. Carstensen, J. T. Pharmaceutical preformulation. Technomic Pub. Co. Lancaster, PA, 1998.
2. Lieberman, Lachmann and Schwartz. Pharmaceutical Dosage Form Tablets. Vol-I, II, III, Marcel Dekker, New York, 2nd ed. – 2008.
3. N. G. Stanley – Wooed; Enlargement and compaction of particle solids; Butterworths.
4. D. M. Parikh; Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
5. H. G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
6. Kitahard A. Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
7. J. T. Cartensen; Drug Stability; Marcel Dekker.
8. G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.

b) Additional Reading:

1. A. Martin, P. Bustamante and A. H. Chun; Physical Pharmacy; Waverly.
2. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
3. M. N. Rubinstein; Pharmaceutical Technology, Drug stability, John Wiley and sons.
4. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.
5. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
6. P. J. Tarcha; Polymer for Controlled Drug Delivery, CRC Press.
7. P. H. List and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
8. Robinson; Novel Drug Delivery Systems, Marcel Dekker.
9. N. K. Jain; Pharmaceutical product development, CBS publishers and distributors

c) References:

i) Books:

1. Parikh D.M., Handbook of Pharmaceutical Granulation Technology; Marcel Dekkar
2. Brittain H. G.; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
3. Cartensen J. T.; Drug Stability; Marcel Dekker.
4. Kithard A. and Watanabe A. Electrical phemanomena at interfaces;

Marcel Dekkar

5. Martin A. Bustamante P. and Chun A.H. Physical Pharmacy; Wavery
6. Alderborn G and. Nystrom C; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
7. Stanley N. G. – Wooed; Enlargement and compaction of particle solids; Butterworths.

ii) Periodicals/Journals:

1. Pharmaceutical technology (findpharma)
2. Pharmaceutical Research (Springer)
3. Pharmaceutical Technology
4. Indian Journal of Pharmaceutical Education and Research
5. Indian Drugs
6. International Journal Pharmaceutical Sciences
7. Acta Pharmaceutica
8. Advances in polymer technology- Wiley Online
9. Polymer Science and Technology – Elsevier
10. Polymers for Advanced Technologies - John Wiley & Sons.

i) Paper : 6 THEORY

ii) Title of Paper : ADVANCED PHARMACEUTICS- II AP-II

iii) Specific Objectives:

1. To understand the fundamental concepts in the development of controlled release drug delivery systems.
2. To appreciate the contribution of physicochemical properties in the design of novel drug delivery systems.
3. To understand the different kinds of novel drug delivery systems.
4. To explore the use of polymers in the development of novel drug delivery systems.
5. To understand the formulation and in vitro evaluation methods of novel drug delivery systems.

iv) Note:

1. Students will be able to understand the fundamental concepts in the development of controlled release drug delivery systems.
2. They will be able to appreciate the contribution of physicochemical properties in the design of novel drug delivery systems.
3. They will be able to understand different kinds of novel drug delivery systems.
4. They will be able to explore the use of polymers in the development of novel drug delivery systems.
5. They will be able to understand formulation and in vitro evaluation methods of novel drug delivery systems.

AP-II ADVANCED PHARMACEUTICS- II Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1.	**Modified release drug delivery systems:** Fundamental concepts of controlled release including Biopharmaceutical consideration of controlled release dosage froms, principles in modified release drug delivery systems, formulation, in vivo evaluation of drug delivery systems, osmotic pumps, membrane permeation, pH, controlled, ion exchange controlled, gel diffusion controlled, hydrodynamically balanced system, modulation of gastrointestinal transit time.Methods of gastro-retention and their evaluation	08	18-22
2.	**Mucosal Drug Delivery:** Mechanism of mucoadhesion, bioadhesive polymers, transmucosal penetration Enhancers. Development of buccal, nasal, pulmonary, rectal	04	8-10

and vaginal drug delivery system. In vitro, ex vivo and in vivo evaluation techniques.

3.	**Ocular drug delivery:**	04	8-10
	Ocular dug delivery mechanism, factors affecting ocular drug absorption and development of ocular drug delivery systems, mucoadhesive polymers, ocular inserts, iontophoresis, delivery of peptides and proteins.		
4.	**Transdermal drug delivery:**	04	8-10
	Permeation through skin, physicochemical factors affecting in drug permeation, Permeation enhancers, iontophoresis drug delivery, approaches and technologies For developing transdermal drug delivery systems and their evaluation.		
5.	**Parenteral drug delivery:**	05	8-12
	Liposomes and niososomes: Methods of preparation, characterization, stability applications and evaluation techniques.Loaded erythrocytes: methods of drug entrapment, characterization of loaded erythrocytes, stability, storage and release from the system. Applications and immunological consideration.		
6.	**Colon specific drug delivery:**	04	10-12
	Advantage of colon specific drug delivery, disease of colon and drug absorption through colon. Factors affecting colonic absorption, absorption enhancers, Approaches to colon specific drug delivery, Coating with pH dependent polymers,Time release dosage forms, Delivery systems based on the metabolic activity of colonic bacteria, in vitro ex vivo and in vivo evaluation of colon specific drug delivery devices.		
7.	**Pulsatile drug delivery:**	03	10-12
	Chronobiology, chronopharmacology and chronotherapeutics, Built in rhythms of human body, disorders showing chronological varaiations. Pulsatile delivery using Multiple unit particulate system (MUPS), Port system, Capsular system, Programmed polymer devices, TDDS, Floating pulsatile drug delivery system (DDS), chronotherapy in cancer treatment.		
8.	**Protein and peptide drug delivery:**	04	10-12
	Structural complexity of protein and peptide drugs, routes for peptide delivery, physiological barriers in bioavailability of such molecules. Formulation considerations, Immunogenecity, stability in drug delivery of insulin, regulatory perspectives for such drugs.		

(vi) Recommended Reading:

a) Basic Reading:

1. Novel and controlled drug delivery systems – N.K. Jain
2. Advances in Novel and Controlled Drug Delivery- N.K. Jain
3. Chien, Y.W.: Novel Drug Delivery Systems, Marcel Dekker, New York and Basel
4. Yie W. Chien. Novel drug delivery system – Marcel Dekker N.Y. Second Edition, Revised and Expanded by Vol- 50.

b) Additional Reading:

1. Controlled drug delivery system – Vicent H.L., Marcel Dekker Second Edition, Revised and Expanded by J. R. Robinson and Vincent H. L. Lee. Vol-29.
2. Remington's pharmaceuticals sciences. 21 st Edition, Lippincott Wiilliams and Willkins- Vol. I & II

c) References:

i) Books:

1. Remington's pharmaceuticals sciences
2. Robinson, J.R. & Lee, V.H.I., Controlled and Novel Drug Delivery Marcel Dekker, New York.
3. E.A. Rawlin -Bentley's textbooks of pharmaceuticals
4. Novel drug delivery system – Marcel Dekker N.Y.
5. Controlled drug delivery system- Vincent H.L, Marcel Dekker
6. Bentley's textbook of pharmaceuticals – E. A. Rawlin
7. Novel and controlled drug delivery systems - N. K. Jain.

ii) Periodicals/Journals:

1. Indian Journal of Pharmaceutical Education and Research
2. Indian Drugs
3. International Journal Pharmaceutical Sciences
4. Acta Pharmaceutica

i) Paper : 6 PRACTICAL

ii) Title of Paper : ADVANCED PHARMACEUTICS- II AP-II

iii) Specific Objectives:

1. To understand the fundamental concepts in the development of controlled release drug delivery systems.
2. To appreciate the contribution of physicochemical properties in the design of novel drug delivery systems.
3. To understand the different kinds of novel drug delivery systems.
4. To explore the use of polymers in the development of novel drug delivery systems.
5. To understand the formulation and in vitro evaluation methods of novel drug delivery systems.

iv) Note:

1. It has been expected to understand the physicochemical and biological properties of actives, which decide formulatuio of modified release dosage forms.
2. Clear understanding of benefits reaped form design of modified release dosage forms is must.

AP-II ADVANCED PHARMACEUTICS - II Practical (6 hrs/wk)

Unit	Contents
1.	Formulation of sustained release tablet formulation.
2.	Study of drug diffusion through various polymer membranes
3.	Preparation and evaluation for occuserts.
4.	Preparation and characterization of Microcapsules/Microspheres.
5.	Preparation and evaluation of Transdermal films.
6.	In-vitro permeation studies across skin and nasal mucosa.
7.	Bioavailability study of nasal mucosa.
8.	Formulation design and evaluation of • Liposomes • Multiple emulsions.
9.	Demonstration of design of targeted drug delivery system

(vi) Recommended Reading:

a) Basic Reading:

1. Novel and controlled drug delivery systems – N.K. Jain
2. Advances in Novel and Controlled Drug Delivery- N.K. Jain
3. Chien, Y.W.: Novel Drug Delivery Systems, Marcel Dekker, New York and Basel
4. Yie W. Chien. Novel drug delivery system – Marcel Dekker N.Y. Second Edition, Revised and Expanded by Vol- 50.

b) Additional Reading:

1. Controlled drug delivery system – Vicent H.L., Marcel Dekker Second Edition, Revised and Expanded by J. R. Robinson and Vincent H. L. Lee. Vol-29.
2. Remington's pharmaceuticals sciences. 21 st Edition, Lippincott Wiilliams and Willkins- Vol. I & II

c) References:

i) Books:

1. Remington's pharmaceuticals sciences
2. Robinson, J.R. & Lee, V.H.I., Controlled and Novel Drug Delivery Marcel Dekker, New York.
3. E.A. Rawlin -Bentley's textbooks of pharmaceuticals
4. Novel drug delivery system – Marcel Dekker N.Y.
5. Controlled drug delivery system- Vincent H.L, Marcel Dekker
6. Bentley's textbook of pharmaceuticals – E. A. Rawlin
7. Novel and controlled drug delivery systems - N. K. Jain.

i) Paper : 7 THEORY

ii) Title of Paper : BIOPHARMACEUTICS AND PHARMACOKINETICS BPK

iii) Specific Objectives:

1. To understand the relationship between pharmacokinetic parameters and physiological variables.
2. To appreciate the contribution of biopharmaceutical aspects of drugs in the performance of dosage forms.
3. To study and understand pharmacokinetics in the drug discovery and development.
4. To study bioavailability and bioequivalence in order to correlate in vivo and in vitro release of drugs.
5. To understand the applications of pharmacokinetics in development of dosage forms

iv) Note:

1. Students will be able to understand the relationship between pharmacokinetic parameters and physiological variables.
2. They will be able to appreciate the contribution of biopharmaceutical aspects of drugs in the performance of dosage forms.
3. They will be able to study and understand pharmacokinetics in the drug discovery and development.
4. They will be to study bioavailability and bioequivalence in order to correlate in vivo and in vitro release of drugs.
5. They will be able to understand the applications of pharmacokinetics in development of dosage forms

BPK BIOPHARMACEUTICS AND PHARMACOKINETICS Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Absorption:** Cell membrane, absorption mechanism, oral drug absorption, pH partition hypothesis. Factors affecting: physicochemical, dosage form related, patient related. Drug absorption through other routes: Transdermal, nasal, buccal, ocular and sublingual. In-vitro, In-situ and In-vivo models for drug absorption studies.	05	10-12
2.	**Distribution:** Tissue permeability of drugs, barrier to distribution of drugs. Factors affecting drug distribution, Physico-chemical properties of drugs, volume of distribution, drug-protein binding, factors affecting drug-	05	08-12

protein binding, significance of drug protein binding.Hydrotropy, Cyclodextrin inclusion complexes and co-solvents.

3.	**Metabolism:**	05	10-12
	Drug metabolism, organs and enzymes, chemical pathways, Phase I and Phase II reactions. First pass effect, factors affecting.		
4.	**Excretion:**	03	08-10
	Renal and non renal routes of drug excretion.		
5.	**Integration of kinetics:**	03	08-10
	Interrelationships between pharmacokinetic parameters and physiological variables.		
6.	**Pharmacokinetics:**	06	18-22
	Pharmacokinetics in drug discovery and development, pharmacokinetic models, Laplace transformations and concept of compartment modeling. • One compartment model: Intravenous injection, intravenous infusion, first order absorption (urinary and plasma data) • Multicompartment models: Intravenous injection, intravenous infusion, first order absorption, multidose data. • Non-linear pharmacokinetics, Michaelis- Menten kinetics, estimation of Km and Vm, AUC, enzyme induction. • Non compartmental analysis- statistical moment theory.		
7.	**Applications of pharmacokinetics:**	04	08-10
	Multiple dosing controlled release dosage form, dose adjustment in renal failure, haemodialysis, individualization, monitoring drug therapy, chronopharmacokinetics.		
8.	**Bioavailabilty and bioequavalence:**	05	10-12
	Study design protocols, regulatory requirements and statistical consideration in data analysis.		

(vi) Recommended Reading:

a) Basic Reading:

1. Biopharmaceutics - Swarbrick, Lea & Febiger book publication
2. Remington's pharmaceutical sciences
3. Biopharmaceutics & Pharmacokinetics. A treatise - D. M. Brahmankar S B. Jasiwal
4. Biopharmaceutics & Pharmacokinetics - P. L. Madan
5. Applied Biopharmaceutics & Pharmacokinetics – Leon Shargel.

b) Additional Reading:

1. Pharmacokinetics - Milo Gibaldi & Donald Perrier
2. Handbook of clinical p'cokinetics- Gibaldi & Pancot
3. Introduction to Biopharmaceutics. - G.P. -Shriwastav
4. B. Testa; Advances in drug research; Vol. 19; Academic Press.
5. Biopharmaceutics & P'cokinetics - an introduction - Robert E. Notary.

c) References:

i) Books:

1. D. M. Bramhankar and S.B. Jaiswal; Biopharmaceutics and Pharmacokinetics A Treatise; Vallabh Prakashan.
2. Jean- Pierre Labaune; Handbook of Pharmacokinetics; John Wiley Sons
3. Malcolm Rowland & Thomas N. Tozer Clinical Pharmacokinetics - concept & application, Lea & Febiger book.
4. Blanchard J. B.,. Sawchul R.J and Brodie B.B.; Principle and perspectives in drug bioavailabilty; K. Karger Publication.
5. Gibaldi M. and Perrier; Pharmacokinetics; Marcel Dekker.
6. Rawland M. and Tozer T.N.; Clinical Pharmacokinetics; Waverly Publications.
7. Jenner P. and Testa B.; Concept in drug metabolism; Marcel Dekker.

ii) Periodicals/Journals:

1. Indian Journal of Pharmaceutical Education and Research
2. Indian Drugs
3. International Journal Pharmaceutical Sciences
4. Acta Pharmaceutica

OTHER FEATURES*

*Except list of LABORATORY EQUIPMENTS (c), all points (1, 2, 3, 4) coming under OTHER FEATURES from Syllabus of M. PHARM., (Pharmaceutical Chemistry) are same.

(c) LABORATORY EQUIPMENTS:

In addition to routine equipments like hot air oven, incubator, pH meter etc. following specific equipments are necessary.

1. Rotary vacuum film evaporator (Shared)
2. HPLC (Shared)
3. Dissolution test apparatus
4. Spray Drier (Desirable)
5. Lyophiliser (Desirable)

6. Minipress Tablet machine
7. KBR Press
8. Brookfield Viscometer (Shared)
9. Stability Chambers (two)
10. Coating Pan
11. UV spectrophotometer (Shared between two PG courses)
12. Photographic Microscope (Shared)
13. Software for experimental designs (01)

SYLLABUS FOR M. PHARM (QUALITY ASSURANCE)

SPECIALIZATION: QUALITY ASSURANCE

i) Course objectives:

1. The primary focus in this regard is the development of an adequate and appropriate healthcare workforce, along with the academic and institutional infrastructure to deliver the required competency-based education and training.
2. To develop a curriculum with global framework for quality assurance of pharmacy education that would incorporate core principles and elements considered essential for an effective approach to quality assurance. Changes in the education of pharmacists and regulation of pharmacy practice are the need of the time. As professionals, pharmacists serve the needs of the society in which they practice – both at an individual patient or consumer level and at the broader population level.

ii) Paper : 2 THEORY

iii) Title of Paper: QUALITY ASSURANCE TECHNIQUES – I QAT-I

iv) Specific Objectives:

1. To gain a perception for compliance as per regulatory authorities in processes of production, formulation research, analytical method development, technology transfer of dosage forms produced in the pharmaceutical industry.
2. Knowing and being able to implement the quality planning, quality control and quality improvement techniques for accessing pharmaceutical products and processes to its different quality attributes. It makes students to gain an insight in pharmacy with regard to quality building in pharmaceutical dosage forms.
3. The student will gain a good understanding of regulatory requirements for improvement of the enterprises competitive position, increased productivity, improved quality management and increased profitability with circumference to mere quality assurance.

v) Note:

1. The student should have a basic knowledge of the rules and regulations of regulatory bodies. For better understanding, animated video clips can be used if the more advanced facilities are available.

QAT-I QUALITY ASSURANCE TECHNIQUES - I Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1	**Introduction :** Basic concepts of Quality control, Quality Assurance and Good Manufacturing Practice as applied to the pharmaceutical Industry.	05	12-15

	Organization & functions of the Federal Food & Drug Administration of USA.		
2	**Documentation related to Pharmaceutical Industry :** Manufacturing documents: BMR, routine records, downtime records, calibration and validation records, Consumer related documents: Product recall, complaint traceability printed packing, preventive maintenance records.	03	12-14
3	**New drug applications:** NDA and ANDA requirements, Data presentation, verification and grant by FDA. Preparation of documents for New Drug Application (NDA) as per requirements of FDA and EUDRA guidelines. GMP requirements for FDA, and ICH.	06	12-15
4	**Quality Assurance documents:** validation and types of validation, protocols methodology and related GMP /ICH guidelines, Internal audits, SOP, and storage related issue.	06	10-13
5	**Store management documents:** Stock reconciliation records for raw material, finished products and packaging materials, Maintenance and Environment control related documents.	02	06-08
6	**Good laboratory Practices (GLP)** Regulations , Scope, Organization, personnel- technical competence, desirable qualities of analyst, analyst validation, responsibilities of key personnel in the QC laboratories, biological evaluation microbiological limit tests, sterility tests for effectiveness of antimicrobial preservative , LD 50, ED 50 teratogenicity, mutagenecity, clinical trials , Bioassays, pyrogens and pyrogen testing safely testing presentation of related data and supporting raw data maintenance.	05	12-15
7	**Related quality systems :** Brief introduction to following regulatory agencies. ISO, WHO, USFDA, TGA, MCC, MHRA, ICH. Introduction to latest ISO Guide lines and I C H Guidelines, Pharmaceutical Quality System (ICH Q10), Stability Studies (A P I and Formulations), WHO Guide lines and their applications in pharmaceutical industry.	05	10-12
8	**Quality by Design and Quality risk management** (ICH Q8 & Q9).	04	06-08

(vi) Recommended Reading:

a) Basic Reading:

1. Drugs and Cosmetics Rules-1945, Schedule-M. India.
2. Quality Assurance of pharmaceuticals: A compendium of guidelines and

related materials: Vol. 2: Good manufacturing Practice, World Health Organisation, Geneva-1999.

3. The rules governing medicinal products in European Union: Vol. 4: Good Manufacturing Practice: Medicinal products for human and veterinary use. 1998 Edition: European commission, Directorate General III-Industry, Pharmaceuticals and Cosmetics.
4. 21 Code of Federal Regulations Parts 210 and 211 of U.S.A.
5. IDMA – APA guidelines on Stability Testing of existing drug substances and products. Technical monograph No.1 Oct. 2002.
6. IDMA – APA guidelines on Test Standards for primary and secondary chemical reference substances. Technical Monograph No.2 Sept. 2004.
7. S. Weinberg, Good laboratory practice Regulations, Marcel and Dekker.
8. J. Swarbrick Boylan, Encyclopedia of pharmaceutical technology, Marcel and Dekker.
9. J.R. Berry and R.A. Nash, Pharmaceutical process validation. Marcel and Dekker.
10. S.H. Will and J.R. Stoker, good manufacturing Practices for Pharmaceutics Marcel Dekker.
11. R.F. Brewer, Design of experiments for process improvement and quality Assurance Narrosa.
12. D.H. Stamatis, Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.
13. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh.
14. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition by Douglas J. Pisano and David S. Mantus.
15. Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug Development Series, Vol 1) by Helene I. Dumitriu
16. Pharmaceutical Patent Law by John R. Thomas.

b) Additional Reading:

1. S.O.P. content, Format and Management By Carol De Sain, Published by Advanstar Communications Cleveland Ohio. U.S.A.
2. Designing the perfect Changes Control System By David M. Stephon, Assistant Director, Compliance and Training, Elan Pharmaceutical Technologies. Journal of GXP compliance Vol. S. No. 4: July 2001.
3. Validation of Manufacturing Process PP 53 to 70. Quality Assurance of Pharmaceuticals Vol.2. W.H.O. Geneva.

c) References:

i) Books:

1. Pharmaceutical Process Validation 2nd Edition By Ira R. Berry and

Robert A. Nash. Marcel Dekkar Inc. 1993.

2. Validation of Pharmaceutical Processes (Sterile Products) 2nd Edition. By Fredrick J. Carletion and James P. Agalloco. Marcel Dekker Inc. 1999.
3. Pharmaceutical Quality Assurance by Prof. M. A. Potdar, Nirali Prakashan, Pune – India 2006.

ii) Periodicals/Journals:

1. Journal of GXP compliance ((Springer)
2. Pharmaceutical technology (findpharma)
3. Pharmaceutical Research (Springer)
4. Pharmaceutical Technology (Elsevier)

i) Paper : 2 PRACTICAL

ii) Title of Paper : QUALITY ASSURANCE TECHNIQUES – I QAT-I

iii) Specific Objectives:

The student will gain knowledge of examination of containers and preparation of various key documents required for quality assurance.

iv) Note: On expected level of study from examination and assessment point of view The student should have a basic knowledge of the documentation, examination of containers and IPQC tests of various types of formulations. For better understanding, animated video clips can be used if the more advanced facilities are available.

QAT-I QUALITY ASSURANCE TECHNIQUES - I Practical (6 hrs/wk)

Unit	Contents
1	Physical and Chemical Examination of plastic containers.
2	Examination of labels, cartons and other printed materials.
3	Designing of following key documents a. Site master file b. SOP on SOP c. MPCR / BPCR (For sterile & non-sterile products) d. Change contract format e. Product complaint document f. Internal audit document g. Product recall document h. IPQC document i. Material receipt, sampling, dispensing & storage document
4	Experiment & documentation of dissolution test
5	IPQC tests for Tablets / Capsules / Injections / Liquid / Ointment

(vi) Recommended Reading:

a) Basic Reading:

1. Drugs and Cosmetics Rules-1945, Schedule-M.India.
2. Quality Assurance of pharmaceuticals: A compendium of guidelines and related materials: Vol. 2: Good manufacturing Practice, World Health Organisation, Geneva-1999.
3. The rules governing medicinal products in European Union: Vol. 4: Good Manufacturing Practice: Medicinal products for human and veterinary use. 1998 Edition: European commission, Directorate General III-Industry, Pharmaceuticals and Cosmetics.
4. 21 Code of Federal Regulations Parts 210 and 211 of U.S.A.
5. IDMA – APA guidelines on Stability Testing of existing drug substances and products. Technical monograph No.1 Oct. 2002.
6. IDMA – APA guidelines on Test Standards for primary and secondary chemical reference substances. Technical Monograph No.2 Sept. 2004.
7. S. Weinberg, Good laboratory practice Regulations, Marcel and Dekker.
8. J. Swarbrick Boylan, Encyclopedia of pharmaceutical technology, Marcel and Dekker.
9. J.R. Berry and R.A. Nash, Pharmaceutical process validation. Marcel and Dekker.
10. S.H. Will and J.R. Stoker, good manufacturing Practices for Pharmaceutics Marcel Dekker.
11. R.F. Brewer, Design of experiments for process improvement and quality Assurance Narrosa.
12. B. Othery. ISO 14000 and ISO 9000 Gower.
13. D.H. Stamatis, Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.
14. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh.
15. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition by Douglas J. Pisano and David S. Mantus.
16. Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug Development Series, Vol 1) by Helene I. Dumitriu.
17. Pharmaceutical Patent Law by John R. Thomas.

b) Additional Reading:

1. S.O.P. content, Format and Management By Carol De Sain, Published by Advanstar Communications Cleveland Ohio. U.S.A.
2. Designing the perfect Changes Control System By David M. Stephon, Assistant Director, Compliance and Training, Elan Pharmaceutical Technologies. Journal

of GXP compliance Vol. S. No. 4: July 2001.

3. Validation of Manufacturing Process PP 53 to 70. Quality Assurance of Pharmaceuticals Vol.2. W.H.O. Geneva.

c) References:

i) Books:

1. Pharmaceutical Process Validation 2nd Edition By Ira R. Berry and Robert A. Nash. Marcel Dekkar Inc. 1993.
2. Validation of Pharmaceutical Processes (Sterile Products) 2nd Edition. By Fredrick J. Carletion and James P. Agalloco. Marcel Dekker Inc. 1999.
3. Pharmaceutical Quality Assurance by Prof. M.A. Potdar, Nirali Prakashan, Pune – India 2006.

ii) Periodicals/Journals:

1. Journal of GXP compliance ((Springer)
2. Pharmaceutical technology (findpharma)
3. Pharmaceutical Research (Springer)
4. Pharmaceutical Technology (Elsevier)

i) Paper : 3

ii) Title of Paper : DRUG REGULATORY AFFAIRS AND INTELLECTUAL PROPERTY RIGHTS **DRIPR**

iii) Specific Objectives:

1. To provide post graduate level education in the important aspects of legal and regulatory issues those are critical to the pharmaceutical industry. The course focuses on key legal concepts such as intellectual property and the range of regulatory affairs with which the pharmaceutical industry must comply and strategies for attaining so.
2. To explore the regulatory provisions with respect to clinical trials, Investigational New Drug Application, New Drug Application, ANDA, market authorization of medicines, inspection of Pharmaceutical manufactures and product registration.

iv) Note:

1. The student should have a basic knowledge of the regulatory authorities, rules and regulations of regulatory bodies, various acts etc. For better understanding, animated video clips can be used if the more advanced facilities are available.

DRIPR DRUG REGULATORY AFFAIRS AND INTELLECTUAL PROPERTY RIGHTS **Theory (2 hrs/wk)** **Tutorial (1 hr/wk)**

Unit	Contents	Hrs	Marks
1	**Introduction :** Legislation to regulate the profession of pharmacy – The Pharmacy Act 1948 & Legislation to regulate, import, manufacture distribution and sales of drugs, cosmetics – The Drugs & Cosmetic Act 1940 & rules 1945 with amendments.	04	10-12
2	**Regulatory authorities and agencies:** Objectives and responsibilities of USFDA, TGA, MHRA, ICH, WHO.	03	06-09
3	**Regulatory Acts:** Legislation to control the advertisements, excise duties & prices of drug. The Drugs and Magic Remedies Act & Rules (Objectionable advertisements). The Medicinal & Toiletry preparations (The Excise Duties Act- 1955 & Rules 1976). Legislation to control the operations relating to dangerous drugs & opium. Narcotic Drugs & Psychotropic Substance Act 1985.	06	12-15
4	**Aims, objects and salient features of following legislations governing Pharmaceutical Industry-** Prevention of Food Adulteration Act 1954 Industrial Development & Regulation Act 1951	04	10-12

5	**Aims, objects and salient features of following legislations governing Pharmaceutical Industry-** Consumer Protection Act Pollution & Environment Control Act Factory Act	05	10-12
6	**Import, manufacture, distribution and sale of drugs:** Legislation to regulate the import, manufacture, distribution, sale, labelling and packing of drugs in India:	04	10-12
7	**Relevant sections of Drugs and Cosmetics Act 1940 and Rules 1945**: latest amendments, Guidelines of Blood Banks and blood products – Part X-B, Drugs Price Control Order, Consumer Protection Act.	04	10-12
8	**Patents and intellectual property rights (IPR):** definition, scope, objectives, source of patient information, patent processing and application. Patents, copyrights, trademarks, silent features, trade related aspects (TRIPS), international and regional agreements, Benefits of IPRs to improve the quality of research work, Strategies for avoiding research duplications, infringement, Indian patent act and its recent amendment with respect to following aspect 1. Patentable and non-patentable inventions. 2. Essential criteria for filing a patent. 3. Filling a patent in India and abroad 4. Drafting of patent application. Introduction to World Intellectual Property Organization. (WIPO)	06	12-16

(vi) Recommended Reading:

a) Basic Reading:

1. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices, Gary Walsh, John J. Tobin, Wiley-VCH Verlag GmbH.
2. Pharmaceutical Competitive Intelligence for the Regulatory Affairs Professional, Raymond A. Huml, Springer
3. Drug regulatory affairs, Sai Kishore, Ikon Books.
4. Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights, D. Lleweyn, T. Aplin, William Cornish, Sweet & Maxwell (2010).
5. International Intellectual Property Rights : Protecting Your Brands, Marks, Copyrights, Patents, Designs and Related Rights Worldwide, Karla C. Shippey, World Trade Press (2009).

6. Pharmaceutical Jurisprudence, Kuchekar, Nirali
7. Law Relating To Intellectual Property Rights, V K Ahuja, LexisNexis India (2007)

b) Additional Reading:

1. Drugs & Cosmetic Act.
2. Patents Act.
3. Consumer Protection Act.
4. Environmental Protection Act.
5. Federal Food, Drug & Cosmetic Act.
6. Bansol, IPR Guidelines for Pharm students and Researchers.
7. Pisano-FDA Regulatory Affairs.
8. Phillip W. Grubb, Patents for Chemicals, Pharmaceuticals and Biotechnology.
9. FDA regulatory Affairs, edited by D. J. Pisano and D. Mantus, CRS Press, Boca Rocan,Florida.
10. New Drug Approval process, 4th Edition, R.A.Guarino, Marcel Dekker, New York.
11. IPR Handbook for Pharma Students and Researchers, Parikshit Bansal, Pharma Book Syndicate, Hyderabad.
12. Patents, N. R. Subbaram, Pharma Book Syndicate, Hyderabad.
13. Relevant articles from journals.
14. www.mohfw.nic.in
15. www.usfda.gov
16. www.mhra.gov.uk
17. www.ich.org/cache/compo/363-272-1.html
18. apps.who.int/prequal/info_general/documents/TRS823/WHO_TRS_823-Annex2.pdf
19. www.pat2pdf.org
20. www.patentstorm.us
21. www.freepatentsonline.com
22. http://www.wipo.int/pctdb/en/
23. www.espacenet.com

c) References:

i) Books:

1. Assurance of Quality Pharmaceutical Total Quality approach by MSP Khan, Chittagong, Bangladesh, Signet Press – 1990.
2. Quality Assurance of Pharmaceutics Vol I & II of WHO publications, 1999.
3. GMPs by Mehra

4. The Drugs and Cosmetic Act, 1940 by Vijay Mallik
5. ISO 9000 and Total Quality Management by S.K.Ghosh
6. How to Practice GMP by P.P.Sharma
7. GMP of Pharmaceuticals by Willing and Stoker.
8. Practicals based on instrumental methods of analysis. A sufficient training will be given through exercises using different kinds of spectral analysis.
9. Willing, S.W., & Stoker, Good Manufacturing Practices for Pharmaceuticals, Marcel Dekker, New York.
10. Guarino, R.A., New Drug Approval Process, Marcel Dekker, New York.

ii) Periodicals/Journals:

1. Drug Development and Industrial Pharmacy – (Informa Pharmaceutical Science)

i) Paper : 6 THEORY

ii) Title of Paper : QUALITY ASSURANCE TECHNIQUES –II QAT-II

iii) Specific Objectives:

1. The student should gain an understanding of validation processes and its role in quality assurance. This will serve in the development, design and quality assurance of pharmaceuticals in an effort to improve the quality of patient health care.

iv) Note:

1. The topics must be conveyed through plenty of examples. Lecture classes must be conducted as lecture-cum-power point presentations.
2. Keeping in view the requirements of students, the teacher may have to prepare some teaching and exercise material.
3. For better understanding, good video and animated clips can be used if the more advanced facilities are available. In fact they can be used very fruitfully.

QAT-II QUALITY ASSURANCE TECHNIQUES -II Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1	**Introduction to Pharmaceutical Validation:** Definition, Government regulation, scope of Validation, Advantage of Validation, Organisation for Validation, Validation Master plan, URS, D.Q., IQ, OQ & P.Q. of facilities.	03	08-10
2	**Process validation:** Differences and similarities between process qualification and process validation, protocols, methodology and interpretation of data. Manufacturing Process Model, Validation of process like mixing, granulation, drying, compression filling and water process system.	05	12-15
3	**Equipment Validation:** Concept of URS, Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification, , Validation of following equipment - HPLC, UV and IR spectrophotometer, dissolution test apparatus Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression Machine, Dry Heat Sterilization, Autoclaves and Capsule filling machines.Installation qualification and operational qualification for sterilization equipments like autoclave, oven and membrane filter.	06	12-15
4	**Cleaning validation and validation of vendor, service and electronic data processing:** Validation of effective cleaning, Vendor audit, sample testing and trend	06	12-14

analysis, Training, maintenance and packing, Software validation methodology, Validation of Pharmaceutical Water System & pure steam, Validation of HAVC system, Validation of Compressed air.

5	**Validation of instruments:** HPLC, UV and IR spectrophotometer and dissolution test apparatus.	04	10-12
6	**Validation of Analytical Method:** Validation parameters, accuracy, precision, ruggedness, statistical design and statistical consideration.	04	12-14
7	**Computer System Validation:** Regulatory background, Computer system development and validation process, Stages in the computers system validation.	04	08-10
8	**Guidelines and technique for experiments on animals.**	04	06-10

(vi) Recommended Reading:

a) Basic Reading:

1. Guidelines on General Principles of Process Validation, Division of Manufacturing and Product Quality, CDER, FDA, Rockville, Maryland (May1987).
2. Current Good Manufacturing Practices in Manufacture, Processing, Packingand Holding of Human and Veterinary Drugs, Federal Register 43(190), 45085 and 45086, September 1978.
3. Good drug manufacturing practice, audit check list, Govt. of Brazil, Ministry of Health, 1983.
4. Good Manufacturing Practices for Pharmaceuticals, Willig, S.H. and Stoker, J.R., Marcel Dekker, New York (1997).

b) Additional Reading:

1. Nash, R.A., The essentials of pharmaceutical validation in Pharmaceutical Dosage Forms: Tablets, Vol.3, 2nd ed., Lieberman, H.A., Lachman, L. and Schwartz,J. B.,eds., Marcel Dekker, NewYork (1990).
2. Nash, R.A., Product formulation, CHEMTECH,(April1976)

c) References:

i) Books:

1. Pharmaceutical Process Validation, Berry, I.R. and Nash, R.A.,eds., Marcel Dekker, New York (1993).
2. Nash, R. A., Making the Paper Match the Work, Pharmaceutical Formulation & Quality (Oct/Nov2000)
3. Guidance for Industry, Scale Up & Postapproval Changes, CDER,

FDA(Nov 1995).

ii) Periodicals/Journals:

1. Journal of GXP compliance ((Springer)
2. Pharmaceutical technology (findpharma)
3. Pharmaceutical Research (Springer)
4. Pharmaceutical Technology (Elsevier) Commentary, Pre-approval Inspections/Investigations, FDA, J. Parent. Sci. & Tech.
5. Chapman, K. G.,A history of validation in the United States, Part I, Pharm. Tech., (November 1991).

i) Paper : 6 PRACTICAL

ii) Title of Paper : QUALITY ASSURANCE TECHNIQUES –II QAT-II

iii) Specific Objectives:

1. The student will gain knowledge of validation of instruments, processes and methods with reference to the parameters that influence the process of production, analysis and working of equipments.

iv) Note: On expected level of study from examination and assessment point of view

1. The student should gain a basic understanding and knowledge of the monitoring and performing validation of methods, instruments and processes and should improve learning potential and ability in decision making on validation aspects. For better understanding, animated video clips can be used if the more advanced facilities are available.

QAT-II QUALITY ASSURANCE TECHNIQUES -II Practical (6 hrs/wk)

Unit	Experiments
1.	Validation of analytical method (minimum four exercises)
	Validation of following equipment
	a. Autoclave
2.	b. Hot air oven
	c. Powder Mixer (Dry)
	d. Tablet Compression Machine
3.	Validation of a processing area.
4.	Validation of at least two analytical instruments.
5.	Cleaning validation of one equipment.

(vi) Recommended Reading:

a) Basic Reading:

1. Quality Assurance of pharmaceuticals: A compendium of guidelines and related materials: Vol. 2: Good manufacturing Practice, World Health Organisation, Geneva-1999.
2. The rules governing medicinal products in European Union: Vol. 4: Good Manufacturing Practice: Medicinal products for human and veterinary use. 1998 Edition: European commission, Directorate General III-Industry,

Pharmaceuticals and Cosmetics.

3. Shikawa, K., What is Total Quality Control? The Japanese Way, Prentice-Hall, Engle wood Cliffs, NJ(1985)
4. Bolton, S., Pharmaceutical Statistics: Practical and Clinical Applications, 3rd ed., Marcel Dekker, New York (1997).
5. Kahan, J.S., Validating computer systems, MD & DI (March1987).

b) Additional Reading:

1. Agalloco, J. P., Practical considerationsin retrospective validation, Pharm. Tech. (June 1983).
2. Designing the perfect Changes Control System By David M. Stephon, Assistant Director, Compliance and Training, Elan Pharmaceutical Technologies. Journal of GXP compliance Vol. S. No. 4: July 2001.
3. Validation of Manufacturing Process PP 53 to 70. Quality Assurance of Pharmaceuticals Vol.2. W.H.O. Geneva.

c) References:

i) Books:

1. Swarbrick J and Boylon J. C. Encyclopedia of Pharmaceutical Technology. Vol.1-3, Marcel Decker Inc. 2005.
2. Pharmaceutical Quality Assurance by Prof. M.A. Potdar, Nirali Prakashan, Pune – India 2006.

ii) Periodicals/Journals:

4. Pharmaceutical Technology (Elsevier)
5. Journal of Pharmaceutical sciences
3. Journal of GXP compliance ((Springer)
4. Pharmaceutical technology (findpharma)
5. Pharmaceutical Research (Springer)

i) Paper : 7 THEORY

ii) Title of Paper : QUALITY MANAGEMENT AND AUDIT QMA

iii) Specific Objectives:

1. To provide the student with understanding of the role of quality management and its implementation within the pharmaceutical industry.
2. To understand the quality management system, inprocess quality control that contributes to the control, quality and validity of a product and/or service. The student will also acquire the information regarding the pharmaceutical plant and design operation.

iv) Note:

1. The topics must be conveyed through plenty of examples. Lecture classes must be conducted as lecture-cum-power point presentations.
2. It is a course that aims to develop skills. It is therefore "practical" in orientation. Plenty of exercises of various kinds must be done by the students.
3. The teacher must not depend on a single or a set of two or three text books. He must choose his materials from diverse sources.
4. Keeping in view the requirements of his students, the teacher may have to prepare some teaching and exercise material.
5. For better understanding, good video and animated clips can be used if the more advanced facilities are available. In fact they can be used very fruitfully.

QMA QUALITY MANAGEMENT AND AUDIT Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1	**Quality Management:** Introduction, Quality Assurance, Components of Q.A., Good Manufacturing Practice, Quality Control, Concept of Total Quality Management, Philosophy of GMP'S, cGMP and ISO9000.	06	15-18
2	**Organization and personnel:** Introduction, Qualification, Experience Responsibilities and Key Personnel, training, hygiene and clothing, personnel records, Legal Aspects, Consultants.	04	10-12
3	**Premises:** Surrounding, Building And Facilities: Introduction, Principal Area, Location, design, plant layout, construction Plumbing and Drainage system, Lighting, Sewage, Refuge and Disposal of Water, Washing and Toilet Facilities, Sanitation, maintenance of sterilite areas, control of contamination.	05	12-15

4	**Materials Management:** Introduction, Purchasing, Raw Materials, Packaging Materials, Intermediate and Bulk Products, Finished Products, Rejected and Recovered Materials, Recalled Products, Returned goods, Reagents and Culture Media, Waste Materials, Reference standards, Miscellaneous Materials	05	10-12
5	**Manufacturing Operations And Control:** Introduction, Sanitation of Manufacturing Premises, Mix-ups and Cross Contamination, Processing of Intermediates and Bulk product, Packaging Operations, I.P.Q.C., Release of Finished Product, Process Deviations, Charge-in of Components, Time Limitations on Production, Drug product Inspection, Expiration Dating, Calculation of Yields, Production Record Review, Distribution and distribution records. Handling of returned goods, Recovered materials and reprocessing Complaints and recalls, evaluation of complaints, recall procedures, related records and documents, Distribution and distribution records. Handling of returned goods, Recovered materials and reprocessing Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.	06	12-14
6	**Outsourcing:** Introduction, Manufacturing and Packaging Outsourcing, Analytical Outsourcing, Other Services- Outsourcing	03	06-08
7	**Pharmaceutical Quality Audits**: Plant Level documentation, Plant Level Department wise Quaternaries, Principle of Quality Audit. Finished product release, Quality review, Quality audit. Batch release documents, Loan license (contract manufacture).	04	10-13
8	**Pharmaceutical plant design:** Regulatory requirements of Pharma facilities with reference to cGMP, Design of Q.C. Laboratory, Design of effluent treatment plant	03	05-08

(vi) Recommended Reading:

a) Basic Reading:

1. Loftus, B. T., Nash, R. A., ed. Pharmaceutical Process Validation. vol.57. New York: Marcel Dekker(1993).
2. U. S. Food and Drug Administration. Compliance Program no. 7356.002.
3. U. S. Food and Drug Administration. Guideline on General Principles of Process Validation.Rockville,MD:FDA,1987.
4. Federal Food Drug and Cosmetic Act, Title 21 U.S.Code, Section 501(a)(2)(B)WHO.
5. U. S. Code, Federal Food Drug and Cosmetic Act, Title 21, Section 510(h).
6. Code of Federal Regulations ,Title 21, Parts 21 & 211, Proposed Revisions,

Fed Reg (May3,1996)

b) Additional Reading:

1. Pharmaceutical Process Validation 2nd Edition By Ira R. Berry and Robert A. Nash. Marcel Dekkar Inc. 1993.
2. Assurance of Quality Pharmaceutical Total Quality approach by MSP Khan, Chittagong, Bangladesh, Signet Press – 1990.
3. FDA. Guidelines on General Principles of Process Validation. Rockville, MD: Division of Manufacturing and Product Quality (HFN-320) Center for Drugs and Biologics (May1987).

c) References:

i) Books:

1. Total Quality Management- Guiding Principle for Application, J. P. Peker, ASTM manual series, Philadelphia.
2. Total Quality Management – The Key to Business Improvemetn, Champman & Hall, Londan.
3. Quality Assurance Guide by Organisation of Pharmaceutical products of India.
4. A guide to Total Quality Management – Kaushik Maitra and Sedhan K.Ghosh.
5. ISO 9000 and Total Quality Management – Sadhank. G. Ghosh.
6. Project Management, Clifford F. Gray and Erik W., Larson Publisher: McGraw Hill Company.
7. Pharmaceutical Production facilities: Design and applications, Graham Cole, Publisher: Taylor & Francis.
8. Production/Operations Management, El wood Bufa, Wiley Eastern Limited, New Delhi.
9. Planning and control, Samuel Eilon, Universal book corporation, Mumbai.
10. Relevant articles from journals.
11. Good Laboratory Practice Regulations, Sandy Weinberg, Vol. 124, Marcel Dekker Inc., New York.
12. Good laboratory Practice, Jurg Seiler, Springer New York.
13. Good Laboratory Practice and Regulatory Issues, P. V. Mohanan, Educational book centre, Mumbai.
14. How to Practice GLP, P. P. Sharma, Vandana Publication, New Delhi.
15. Quality Assurance of Pharmaceuticals, Volume I& II, (A Compendium guidelines & Related Materials), Pharmabook Syndicate, WHO, Geneva.
16. Pharmaceutical Quality Assurance, MA Potdar, Nirali Prakashan,

Pune.

17. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
18. Relevant articles from journals.
19. Pharmaceutical Facilities: Design, Layouts And Validation, Potdar Manohar A, PharmaMed Press/BSP Books (2010)
20. Planning and Control of Manufacturing Operations, John Kenworthy, Kenworthy, John Wiley & Sons
21. Logistics and Manufacturing Outsourcing: Harness Your Core Competencies, James A. Tompkins, Steven W. Simonson, Bruce W. Tompkins, Tompkins Press
22. Outsourcing of R&D in the Pharmaceutical Industry: From Conceptualization to Implementation of the Strategic Sourcing Process, Bianca Piachaud, Palgrave MacMillan
23. Pharmaceutical Quality Assurance and Management, K P Bhusari, PharmaMed Press/BSP Books (2011)
24. Quality Assurance and Quality Management, Y. Anjaneyulu, PharmaMed Press/BSP Books (2009)
25. Good Manufacturing Practices and Inspection: Quality assurance of pharmaceuticals (Volume 1 & 2), WHO, PharmaMed Press Quality systems and controls for Pharmaceuticals, Deepak K. Sarkar, Wiley publications.
26. Six Sigma In The Pharmaceutical Industry: Understanding, Reducing And Controlling Variation In Pharmaceuticals And Biologicals, Brian K. Nunnally and John S. Macconell, CRC publications.
27. Design of Experiments For Process Improvement and Quality Assurance R.F.Brewer, Narrosa publications.

ii) Periodicals/Journals:

1. Applications of Statistics to Industrial Experiments. NewYork: Wiley Pharmaceutical Technology
2. Drug Development and Industrial Pharmacy – (Informa Healthcare)
3. Journal of GXP compliance ((Springer)
4. Pharmaceutical technology (findpharma)
5. Pharmaceutical Research (Springer)
6. Pharmaceutical Technology (Elsevier)

OTHER FEATURES*

*Except list of LABORATORY EQUIPMENTS (c), all points (1, 2, 3, 4) coming under OTHER FEATURES from Syllabus of M. PHARM., (Pharmaceutical Chemistry) are same.

(c) LABORATORY EQUIPMENTS:

In addition to routine equipments like pH meter, disintegration test apparatus, friability test apparatus, incubator, magnetic stirrer, mechanical stirrer etc. following equipments are necessary.

1. High Performance Liquid Chromatography (Shared)
2. Infrared Spectrophotometer (Shared)
3. UV-Visible Spectrophotometer (Shared between two PG Courses)
4. Stability Chamber (Shared)
5. Dissolution Test Apparatus
6. Ultrasonicator
7. Rotary film vacuum evaporator
8. Penetrometer
9. Tensile strength tester
10. KBr Press

SYLLABUS FOR M. PHARM (PHARMACOLOGY)

Specialization: PHARMACOLOGY

(i) Course objectives:

1. To familiarize the students with the methods, planning and documentation related to the preclinical, clinical, toxicological and safety pharmacological evaluations of drugs.
2. To provide them with the opportunities to undertake preclinical, toxicological and safety pharmacological evaluations of known drugs through theory and practical classes so that they develop competence to undertake similar activities individually or as a group member during their professional career.
3. To train the students to collect, correlate and systematically present information on the scientific developments in the field of preclinical pharmacology, clinical pharmacology, safety Pharmacology and toxicology.
4. To create awareness amongst the students regarding the ethical conduct in the pharmacological research along with alternatives being developed and validated to replace conventional animal based models in drug discovery.
5. To train the students to analyze, evaluate and criticize the scientific publications in the peer reviewed journals so that they acquire skills related to scientific writing and presentation.

ii) Paper : 2 THEORY

iii) Title of Paper : ADVANCED PHARMACOLOGY – I ACOL-I

iv) Specific Objectives:

1. The students should be introduced to the overall process of preclinical and clinical screening of drugs.
2. The students should get knowledge about how the Pharmacological screening (both preclinical and clinical) has evolved and what are recent developments in this field.
3. The students should know preclinical screening of certain classes of drugs.
4. The students should know the modern techniques used in preclinical screening of drugs with advantages and applications of such techniques.
5. The students should get thorough understanding about the ethical handling of experimental animals and develop ability to individually plan screening of pharmacological activity of drugs in the whole animals for different categories of drugs.

v) Note:

1. The student should have a basic knowledge of anatomy, physiology, pathophysiology and pharmacology.
2. The use of softwares, animated clips and video series is encouraged for better understanding of the subject.

ACOL-I **ADVANCED PHARMACOLOGY – I** **Theory (3 hrs/wk)**

Unit	Contents	Hrs	Marks
1.	**Recent trends on different classes of receptors and drugs acting on them.** **a.** Cholinergic receptors **b.** Dopamine receptors **c.** Serotonin receptors **d.** GABA receptors **e.** Opioid receptors	06	15-20
	Detailed preclinical screening of the drugs of following categories		
2	Drugs acting on the gastrointestinal tract	03	05-10
3	Drugs acting on autacoids. Anti-inflammatory and analgesic compounds	03	05-10
4	Drugs acting on immune system, Fc-receptors on T and B lymphocytes, Antibody dependent and cellular cytotoxicity	04	10-15
5	Drugs acting on endocrine system- antidiabetics, Anti-thyroid agents, Diuretics and drugs acting on the reproductive system	06	15-20
6	Chemotherapeutic agents and anticancer drugs, drugs acting on apoptosis	04	10-15
7	Drugs acting on the hematopoietic system	03	05-10
8	In vitro drug screening methods, High throughput screening of drugs, alternatives to animal testing in drug discovery, In silico drug screening**.**	07	15-20

(vi) Recommended Reading:

a) Basic Reading:

1. Evans CL, Principles of Human Physiology, J & A Churchill Ltd. London
2. Guyton LC,Text Book of Medical physiology, Saunders Co., London
3. Best CH and Taylor NB, The Physiological basis of Medical Practice, The Williams and Wilkines Co., Baltimore
4. Jensen D, The Principles of Physiology, Appletto- Century-Crofts, New York
5. Vander A , Sherman JH and Luciano D., Human Physiology The Mechanisms of Body Functions, Tata Mc Graw Hill Publishing Co., New Delhi.
6. Turner RA, Screening Methods in Pharmacology, Academic Press, London.

7. Crossland J, Lewis's Pharmacology, Churchill Livingstone, Edinburgh.
8. Katzung BG, Basic and Clinical Pharmacology, Lange Medical Publication, California

b) Additional Reading:

1. Bacq ZM, Capek, Fundamentals of Biochemical Pharmacology
2. Lawrence DR, Bennett PN, Brown MJ, Clinical Pharmacology, Churchill Livingstone, New York.
3. Lawrence DR and Bacharach AL, Evaluation of Drug Activities: Pharmacometrics, Academic Press, London.
4. Rothstein MA, Pharmacogenomics, Wiley-Liss, New Jersy.
5. Lesk AM., Introduction to Bioinformatics, Oxford University Press, Oxford.
6. Khan IA. and Khanum A., Recent advances in Bioinformatics, Ukaaz Publications, Hydrabad.

c) References:

i) Books:

1. Lawrence DR and Bacharach AL, Evaluation of Drug Activities: Pharmacometrics, Academic Press, London
2. Goodman and Gilman : Pharmacological Basis of Therapeutics, Pregamon Press, New York.
3. Nodine Siegler, Animal and Clinical Pharmacological Techniques in Drug Evaluation.
4. Turner RA, Screening Methods in Pharmacology, Academic Press, London
5. Goldsteine, Principles of Drug Action, Jhon Wiley and Sons, New York
6. Vogel HG, Drug Discovery and Evaluation, Springer, Germany

ii) Periodicals/Journals:

1. Indian Journal of Pharmacology
2. Indian Journal of Physiology & Pharmacology
3. Journal of Experimental Pharmacology and Therapeutics
4. Indian Journal of Experimental Biology
5. Annual Reviews in Pharmacology and Toxicology
6. Pharmacological Review

i) Paper : 2 PRACTICAL

ii) Title of Paper : ADVANCED PHARMACOLOGY-I ACOL-I

iii) Specific Objectives:

1. The student will know various regulations required to be followed for animal experimentation.
2. The student will develop the skills required for handling of animals and performing the animal experimentation.

iv) Note:

1. The use of softwares, video clips, and simulations should be encouraged wherever possible.

ACOL-I ADVANCED PHARMACOLOGY – I Practical (6 hrs/wk)

Unit	Contents
1.	CPCSEA regulations, Maintenance of experimental animals, Animal house facility as per regulations
2.	Handling of experimental animals and drug administration by different routes
3.	Screening of drugs acting on CNS: Neurobehavioral screening as per Irwin's method, Elevated plus maze, Water maze, Zero maze, Chemically and electrically induced convulsions, actophotometer, analgesiometer, Acetic acid induced writhings, Clonidine induced twitches
4.	Introduction to use of physiographs in experimental Pharmacology, Demonstration of invasive Rat blood pressure experiment, ECG, EEG etc
5.	EP-DOG (simulation of dog blood pressure experiment)
6.	Use of anesthetics and cannulation of veins, arteries and trachea of rat
7.	Identification of phases of estrous cycle in rats
8.	Recording of different physiological responses in experimental animals and their modifications by drugs 1. Blood pressure 2. ECG 3. Urine output

(vi) Recommended Reading:

a) Basic Reading:

1. Goodman & Gilman. The pharmacological Basis Of Therapeutics. Editors: Joel G. Hardman, Lee E. Limbird Consulting Editors: Alfred Goodman Gilman 10th Edition Mcgraw Hill Medical Publishing Division.
2. H Gerhard Vogel (Ed.) Drug Discovery & Evaluation ,Pharmacological Assay Coeditors: Wolfgang H. Vogel, Bernward A. Scholkens, Jurgen Sandaw , Gunter Muller , Wolfgang F. Vogel 2nd edition. Springer –Verlog Berlin Heidelberg 2002.

b) Additional Reading:

1. Laurence DR Bacharach AL, editors. Evaluation of drug activities: Pharmacometrics. London and New York: Academic Press; 1965.

c) References:

i) Books:

1. Goodman & Gilman. The pharmacological Basis Of Therapeutics. Editors: Joel G. Hardman, Lee E. Limbird Consulting Editors: Alfred Goodman Gilman 10th Edition Mcgraw Hill Medical Publishing Division.
2. JH Nodine and PE Siegler, Editors, Animal and Clinical Pharmacological Techniques in Drug Evaluation, Year Book Medical Publishers (1964).
3. Screening Methods in Pharmacology Vol I & II By Robert A. Turner & Peter Hebborn, New York, Academic Press ,1965 -71,IInd Edition.
4. Goldstein, A., Aronow, L., Kalman, SM: In Principles of drug action. The basis of pharmacology. New York: John Wiley and Sons 1974.
5. H Gerhard Vogel (Ed.) Drug Discovery & Evaluation ,Pharmacological Assay Coeditors: Wolfgang H. Vogel, Bernward A. Scholkens, Jurgen Sandaw , Gunter Muller , Wolfgang F. Vogel 2nd edition. Springer – Verlog Berlin Heidelberg 2002.

ii) Periodicals/Journals:

1. Indian Journal of Pharmacology
2. Indian Journal of Physiology & Pharmacology
3. Journal of Experimental Pharmacology and Therapeutics
4. Indian Journal of Experimental Biology
5. Annual Reviews in Pharmacology and Toxicology
6. Pharmacological Review

i) Paper : 3 THEORY

ii) Title of Paper : NEW DRUG DEVELOPMENT PROCESS NDDP

iii) Specific Objectives:

1. The students should be introduced to the overall process of drug development including regulatory aspects of new drug development.
2. The students know the ethical issues involved in conduct of clinical trials.
3. The student should be well versed with clinical trial design, protocol development and good clinical practices involved in conducting clinical trials.
4. The students should be well acquainted with the process of pharmacovigilance.

iv) Note:

1. The student is expected to visit the pharmacovigilance centre or the clinical study site so as to get the first hand information of the process.

NDDP NEW DRUG DEVELOPMENT PROCESS Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	Process of identifying novel drug targets and overall steps in new drug development including regulatory aspects (NDA, IND, ANDA etc).	06	15-20
2.	**Ethical issues in clinical trials:** Principal, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing), Protection of participants, The Nuremberg Code, The Declaration of Helsinki, The Belmont Report	03	08-15
3.	**Clinical trial design:** Designs used in clinical trials with their advantages and disadvantages, hypothesis, risks and benefits, subject selection, inclusion and exclusion criteria, randomization, blinding and controls	04	15-20
4.	**Clinical trial protocol Development:** Required Documentation including Investigator's Brochure, Case Report Forms, Serious Adverse Event (SAE) Reports, Laboratory Certification, data collection and quality control of data, closing out of clinical trial	03	10-15
5.	**Good Clinical Practice:** Concepts and importance GCP guidelines in the clinical research	04	08-10
6.	**Pharmacovigilance**: Definition, collection of data, reporting, assessment of Post marketing surveillance, periodic safety update reports, Risk-benefit assessment	04	08-15

7.	**Therapeutic drug monitoring**: Definition, Indication for TDM & clinical applications, Monitoring plasma drug levels, Techniques used in TDM, General Guidelines for TDM.	03	08-15
8.	**Drugs utilization evaluation:** Definition, Importance of Drug utilization evaluation, Steps involved in conducting Drug utilization evaluation & Guidelines.	03	08-10

(vi) Recommended Reading:

a) Basic Reading:

1. Turner, J.R., New drug development : design, methodology, and analysis. 2007, Hoboken, N.J.: Wiley-Interscience. xxi, 270 p.
2. Smith, C.G. and J. O'Donnell, The process of new drug discovery and development. 2nd ed. 2006, New York: Informa Healthcare. 668 p.
3. Mann, R.D. and E.B. Andrews, Pharmacovigilance. 2nd ed. 2007, Chichester, England ; Hoboken, NJ: John Wiley & Sons. xviii, 686 p.
4. Machin D, Day S, Green S. Textbook of Clinical Trials. 2nd Edition, Wiley Interscience.

b) Additional Reading:

1. Cobert, B.L. and P. Biron, Pharmacovigilance from A to Z : adverse drug event surveillance. 2002, Malden, MA: Blackwell Science. xiii, 235 p.
2. Gupta S. K. Drug Discovery & Clinical Research. Jaypee, New Delhi.

c) References:

i) Books:

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

Therapeutics (Macmillan New York)

9. Carig C. R. and Stizel B. E. Modern Pharmacology (Little Brown & Co. Boston)
10. Grollman Pharmacology & Therapeutics (Lea and Febiger Philadelphia)

ii) Periodicals/Journals:

1. Indian Journal of Pharmacology
2. Indian Journal of Physiology & Pharmacology
3. Journal of Experimental Pharmacology and Therapeutics
4. Indian Journal of Experimental Biology
5. Annual Reviews in Pharmacology and Toxicology
6. Pharmacological Review

i) Paper : 6 THEORY

ii) Title of Paper : ADVANCED PHARMACOLOGY – II ACOL- II

iii) Specific Objectives:

1. The students should become well versed with recent developments in the understanding of receptors.
2. The students should get knowledge about the recent advancements in the field more specifically of the drugs used in ANS, CNS, CVS & Respiratory system.
3. Student should know the modern techniques used in pharmacological evaluations.
4. The students should develop thorough understanding about the pharmacokinetic studies in preclinical & clinical stages.
5. The students should understand various genetic disorders & advancements in gene therapy & genome mapping.

iv) Note:

1. The student should be well versed with the detailed anatomy and physiology of the experimental animals and human beings.
2. They should have thorough understanding of the Pharmacology and therapeutics of different categories of drugs.

ACOL- II ADVANCED PHARMACOLOGY – II Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1.	**Recent trends on different classes of receptors and drugs acting on them.** **a.** NF-kB **b**. TNF-α **c.** Purinergic receptors **d.** Glutamate receptors **e.** PPAR-γ	05	05-10
2.	Drugs acting on the autonomic nervous system.	03	05-10
3.	Drugs acting on the central nervous system- Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotics, analgesics, antipyretics, anticonvulsants, memory enhancers	07	15-20
4.	Drugs acting on the cardiovascular system- Cardiac glycosides, Anti-arrhythmic, Anti-hypertensives	06	10-15
5.	Drugs acting on the respiratory system- anti-asthmatics, bronchodilators, anti-tussives	03	10-15
6.	Knowledge of Modern Methods of Pharmacological evaluations including radioligand binding assay, patch clamp, ELISA, and other sophisticated methods like microarray techniques, Chemiluminiscence,	06	10-15

	Flow cytometry, Immunohistochemistry, different blotting techniques and their applications		
7.	Pharmacokinetic studies in Preclinical and clinical phase of drug development	02	10-15
8.	Pharmacogenetic disorders, Concept of gene therapy and recent development in the treatment of various hereditary diseases, Human genome mapping and its potential in drug research, transgenic animals and their uses in drug discovery	04	15-20

(vi) Recommended Reading:

a) Basic Reading:

1. Goodman & Gilman. The pharmacological Basis Of Therapeutics. Editors: Joel G. Hardman, Lee E. Limbird Consulting Editors: Alfred Goodman Gilman 10th Edition Mcgraw Hill Medical Publishing Division.
2. H Gerhard Vogel (Ed.) Drug Discovery & Evaluation ,Pharmacological Assay Coeditors: Wolfgang H. Vogel, Bernward A. Scholkens, Jurgen Sandaw , Gunter Muller , Wolfgang F. Vogel 2nd edition. Springer –Verlog Berlin Heidelberg 2002.

b) Additional Reading:

1. JH Nodine and PE Siegler, Editors, Animal and Clinical Pharmacological Techniques in Drug Evaluation, Year Book Medical Publishers (1964).
2. Goldstein, A., Aronow, L., Kalman, SM: In Principles of drug action. The basis of pharmacology. New York: John Wiley and Sons 1974.

c) References:

i) Books:

1. Laurence DR Bacharach AL, editors. Evaluation of drug activities: Pharmacometrics. London and New York: Academic Press; 1965.
2. Goodman & Gilman. The pharmacological Basis Of Therapeutics. Editors: Joel G. Hardman, Lee E. Limbird Consulting Editors: Alfred Goodman Gilman 10th Edition Mcgraw Hill Medical Publishing Division.
3. JH Nodine and PE Siegler, Editors, Animal and Clinical Pharmacological Techniques in Drug Evaluation, Year Book Medical Publishers (1964).
4. Screening Methods in Pharmacology Vol I & II By Robert A. Turner & Peter Hebborn, New York, Academic Press ,1965 -71,IInd Edition.
5. Goldstein, A., Aronow, L., Kalman, SM: In Principles of drug action. The basis of pharmacology. New York: John Wiley and Sons 1974.
6. H Gerhard Vogel (Ed.) Drug Discovery & Evaluation ,Pharmacological Assay Coeditors: Wolfgang H. Vogel, Bernward A. Scholkens, Jurgen

Sandaw , Gunter Muller , Wolfgang F. Vogel 2nd edition. Springer –Verlog Berlin Heidelberg 2002.

ii) Periodicals/Journals:

1. Indian Journal of Pharmacology
2. Indian Journal of Physiology & Pharmacology
3. Journal of Experimental Pharmacology and Therapeutics
4. Indian Journal of Experimental Biology
5. Annual Reviews in Pharmacology and Toxicology
6. Pharmacological Review

i) Paper : 6 **PRACTICAL**

ii) Title of Paper : ADVANCED PHARMACOLOGY-II **ACOL- II**

iii) Specific Objectives:

1. The students should be able to perform the bioassay of various drugs on various tissues.
2. The students should be able to plan & perform the toxicological screening of drugs on animals.
3. Students should get knowledge about the planning, execution and documentation related to Toxicology and safety pharmacology testing.
4. The students should be able to monitor drug levels in biological fluid.

iv) Note:

1. The use of softwares, video clips, and simulations should be encouraged wherever possible.

ACOL- II **ADVANCED PHARMACOLOGY-II** **Practical (6 hrs/wk)**

Unit	Contents
1.	Determination of PA2, PD2 values of different drugs. Bioassays of drugs on different isolated tissue preparations like rat ileum, guinea pig ileum, rat stomach strip, rat anococcygeus muscle, guinea pig trachea and other suitable preparations. e.g. **Agonists:** Ach, Histamine, oxytocin, nor-adrenaline **Antagonists:** Atropine, Prazosin, phentolamine, cyproheptidine
2.	Determination of effect of different drugs on rat blood pressure experiments.
3.	Electrophoresis.
4.	Isolation of DNA and RNA using commercially available kits
5.	Drug mutagenicity study using mice bone-marrow micronucleus test.
6.	Restriction digestion of DNA using commercially available kits.
7.	Isolation of plasmids using commercially available kits.
8.	Monitoring of any one marketed drug in biological fluids.

(vi) Recommended Reading:

a) Basic Reading:

1. Fundamentals of Experimental Pharmacology by M.N. Ghosh
2. Screening Methods in Pharmacology, Vol I & II, edited by Robert A. Turner and

Peter Hebborn

3. Textbook of invitro Practical Pharmacology by Ian Kitchen

b) Additional Reading:

1. Evaluation of Drug Activities : Pharmacometrics, Vol I & II, edited by D.R. Laurence and A.L. Bacharah

c) References:

i) Books:

1. Selected Topics in Experimental Pharmacology by U.K. Sheth, N.K. Dadkar and Usha G. Kamat
2. Pharmacological Experiments of Isolated preparations by Edinburgh University Pharmacology Staff, 1968
3. Analytical procedures for Therapeutics Drug Monitoring and Emergency Toxicology by Randall C. Baselt
4. Drug-Bioscreening Drug Evaluation Techniques in Pharmacology in Emmanuel B. Thompson
5. "Laboratory Manual of Biopharmaceutics and Pharmacokinetics" Bhise SB, Dias RJ, Dhawale SC, Mali KK. Trinity Publishing House; 2010

ii) Periodicals/Journals:

1. Indian Journal of Pharmacology
2. Indian Journal of Physiology & Pharmacology
3. Journal of Experimental Pharmacology and Therapeutics
4. Indian Journal of Experimental Biology
5. Annual Reviews in Pharmacology and Toxicology
6. Pharmacological Review

i) Paper : 7 THEORY

ii) Title of Paper : SAFETY PHARMACOLOGY AND TOXICOLOGY SPT

iii) Specific Objectives:

1. The students should get the knowledge regarding recent methods of toxicity testing and safety testing of chemicals.
2. The students should get knowledge about the planning, execution and documentation related to Toxicology and safety pharmacology testing.
3. The students should know the modern techniques used in determination of biological parameters.
4. The students develop thorough understanding about the OECD & ICH guidelines for safety & toxicological studies.
5. The students should know various alternatives to minimizing the usage of animals in safety pharmacology & toxicity testing.

iv) Note:

1. The student should have basic knowledge of safety pharmacology & toxicology studies.

SPT SAFETY PHARMACOLOGY AND TOXICOLOGY Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	Safety Pharmacology studies as per ICH guidelines	10	20-25
2.	Documentation and protocol preparation, knowledge of planning, performing, analyzing, reporting and monitoring of safety pharmacology studies.	02	10-15
3.	Alternatives to animals in toxicity testing, Methods to minimize the use of animals in safety Pharmacology and toxicology.	02	10-15
4.	Novel techniques for determination of biological parameters from experimental animals- Microarray techniques, Telemetry	02	10-15
5	LD50 determination and its significance in pharmacological research (comparison of conventional methods with OECD methods for LD50 determination)	01	05-10
6	OECD guidelines for toxicity testing- subacute and chronic toxicity testing, genetic toxicity testing, phototoxicity, immunotoxicity, teratogenicity	10	15-20
7	Validated non-animal (in-vitro) toxicity testing methods as per OECD	02	05-10

guidelines

8	Documentation and protocol preparation, knowledge of planning, performing, analyzing, reporting and monitoring of above toxicity studies.	01	05-10

(vi) Recommended Reading:

a) Basic Reading:

1. Sogliero-Gilbert, G., Drug safety assessment in clinical trials. Statistics, textbooks and monographs. 1993, New York: Dekker. x,
2. Marx, U. and V. Sandig, Drug testing in vitro : breakthroughs and trends in cell culture technology. 2007, Weinheim: Wiley-VCH. xix,.
3. Gad, S.C., Safety assessment for pharmaceuticals. 1995, New York: Van Nostrand Reinhold. xv, 496 p.

b) Additional Reading:

1. Bénichou, C., Adverse drug reactions : a practical guide to diagnosis and management.1994, Chichester, West Sussex, England; New York: Wiley. xviii, 302p.

c) References:

i) Books:

1. Niesink R. J. M. de Vries J and Hollingers M.A. toxicology, Principles and applications, CRC Press 1996
2. Amdur M.O. Doul J. and Klassen C.D. casarettand doull's toxicology
3. Gupta P.K. and salunkhe D.K. Modern toxicology vol – I, II, and III (metropolitan, New Delhi)
4. OECD guidelines
5. ICH guidelines

ii) Periodicals/Journals:

1. Indian Journal of Pharmacology
2. Indian Journal of Physiology & Pharmacology
3. Journal of Experimental Pharmacology and Therapeutics
4. Indian Journal of Experimental Biology
5. Annual Reviews in Pharmacology and Toxicology
6. Pharmacological Review

OTHER FEATURES*

*Except list of LABORATORY EQUIPMENTS (c), all points (1, 2, 3, 4) coming under OTHER FEATURES from Syllabus of M. PHARM., (Pharmaceutical Chemistry) are same.

(c) LIST OF LABORATORY EQUIPMENTS:

In addition to routine equipments like Sherringtons revolving drum machine, student organ bath, centrifuge, etc. following specific equipments are necessary.

1. Physiograph
2. HPLC (Shared)
3. Eddy's Hot Plate Analgesiometer
4. Analgesiometer (Tail Flick)
5. Electroconvulsometer
6. Rota Rod Apparatus
7. Pole Climbing Apparatus
8. Actophotometer
9. Histamine Chamber
10. Plethysmometer
11. Elevated / Y / Radial Plus Maize
12. Autoanalyser
13. Spectrophotometer

SYLLABUS FOR M. PHARM (PHARMACOGNOSY)

SPECIALIZATION: PHARMACOGNOSY

(i) Course objectives:

1. To make competent pharmacognocists and phytochemists with an ability to apply their knowledge and skills in various aspects of drug design, discovery and analysis and application in industry.
2. To keep pace with the current level of understanding of the subject inclusive of modern techniques of cultivation, post harvest treatment, isolation of phytoconstituents, herbal formulation development and informatics tools for exploring the basics and depth of drug discovery and analysis.
3. To provide candidates advanced training in isolation, purification, characterization planning and execution, structure elucidation, biological and pharmaceutical activity prediction and determination, chemical and biomolecular analysis.
4. To equip graduates with the appropriate skills required to fulfill job responsibilities in the above stated area of operation in the pharmaceutical, herbal, ayurvedic, clinical research, biotechnology and biomedical industries.

ii) Paper : 2 THEORY

iii) Title of Paper: ADVANCED PHARMACOGNOSY – I ACOG-I

iv) Specific Objectives:

1. To gain an insight in the phytopharmaceuticals, neutraceuticals and cosmeceuticals
2. To understand the role and adventages of phyto-based excepients used in Pharma related industries.
3. The student will gain a good understanding of herbal drug industries.
4. Students will be acquainted with information retrieval system and regulatory affairs for herbal drugs.

v) Note:

1. The student should have a basic knowledge of the extraction and purification techniques of phytoconstituents and their physicochemical properties.
2. Students should have knowledge of pharmaceutical and Ayurvedic dosage forms.

ACOG-I ADVANCED PHARMACOGNOSY – I Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1.	**General Research Methodology for Herbal drugs:** History, Herbal research concept, methods of herbal drugs research.	04	08-10

2.	**Herbal drug Industry:** History, World wide sinario, Basics requirements, future prospectives	04	08-10
3.	**Herbal drug Regulatory affairs:** Different guidelines for herbal drugs, ICH, WHO, FDA, ICMR	03	06-08
4.	**Information Retrieval systems of Herbal Drugs:** Data bases NARLEP, EMBDE, Planta Filae, USDA,	04	08-10
5.	**Literature survey of following therapeutic groups:** Literature on activity models and plant information	08	22-26

i. Immunomodulators

- Withania somnifera
- Centella asiatica
- Embelica officinalis
- Ocimum sanctum

ii. Antipeptic ulcer

- Glyceriza root
- Azadirachta indica
- Gingiber officinalis

iii. Hepatoprotectives

- Silibum marianum
- Phyllanthus niruri
- Picrorrhiza kurroa
- Andrographis paniculata

iv. Anticancer

- Taxus species
- Camptotheca acuminate

v. Antifertility

- Embelica ribes
- Azadirachta indica
- Gossypium species

vi. Nervine Tonic

- Centella asiatica
- Acorus calamus

vii. Valeriana wallichi Anti-AIDS

- Areca catechu
- Thea sinensis

6.	**Volatile oil of commercial significance:** Drugs and oils used in cosmetic, food , perfume and pharma industries	06	14-18
7.	**Review of Natural sweeteners: History, physic-chemical properties, pharma applications**	03	06-08
8.	**Natural Preservatives and colorants:** Physico chemical properties, Characters, FDA Guidelines	04	08-10

(vi) Recommended Reading:

a) Basic Reading:

1. WHO, Quality Control methods for medicinal plant material
2. Chemistry of Natural Products, P.S Kalsi
3. Chaudhari R D, Herbal Drug Industry, Eastern publication
4. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons
5. E. Ramstad, Modern Pharmacognosy, Mc-graw hill Book Company
6. Wagner, Plant Drug Analysis
7. PDR for Herbal Medicines, Second Ed., Medicinal Economic Company, New Jersey
8. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
9. Standardisation of Botanicals by V.Rajpal, Vol.1, Eastern Publishers, New Delhi, 2002.
10. Plant data bases, Wikipedia encyclopedia
11. Pharmaceutical excepients
12. Regulatory affairs for herbal drugs

b) Additional Reading:

1. Agrawal O.P., Chemistry of Organic Natural Product, Goel Publication House, UP.
2. Pharmacognosy: Kokate, Puruhit, Gokhale, Nirali Prakashan, Pune, 15th edtn.
3. Cultivation and utilization of aromatic plants Atal and Kapoor, CSIR Publication.
4. WHO guidelines for standardization of medicinal plants Geneva 2002.
5. Chopra, Indigenous drugs of India.

c) References:

i) Books:

1. Plant drug analysis Peach and Tracy Narosa Publishing house Delhi
2. H.G.Brittain, Physical Characterization of Pharmaceutical solids, Marcel Dekker

3. Tarcha, P. J. Polymers for controlled Drug Delivery; CRC Press. 1991.
4. Remington's Pharmaceutical Sciences. 21-st editions, Vol. I-II Lippincott Williams and Wilkins.
5. Phytochemical methods : J. B. Harborne
6. Ayurvedic Pharmacopoeia.
7. Indian Pharmacopoeia.
8. British Herbal Pharmacopoeia
9. Quality Standards of Indian Medicinal Plants, Vol -I, ICMR, New Delhi.

ii) Periodicals/Journals:

1. Journals published by NISCAIR
2. Pharmaceutical Research Journals (Springer, Elsewere)
3. Pharmacognosy and natural products journal

i) Paper : 2 PRACTICAL

ii) Title of Paper : ADVANCED PHARMACOGNOSY – I ACOG-I

iii) Specific Objectives:

1. To gain an insight in the phytopharmaceuticals, neutraceuticals and cosmeceuticals
2. To understand the methods of extraction in detail.
3. The student will gain a good understanding of chromatographic techniques.

iv) Note:

1. The student should have a basic knowledge of the extraction and purification techniques of phytoconstituents and their physicochemical properties.
2. Students should have knowledge of advanced methods of phytochemical investigation.

ACOG-I ADVANCED PHARMACOGNOSY – I Practical (6 hrs/wk)

Unit	Contents
1	Evaluation and standardization of a given herbal drug by physical, chemical and biological methods.
2	Isolation of total oleo-resin from ginger
3	Isolation of pectin
4	Isolation of papain
5	Isolation of glycyrrhizin form Glycyrrhiza glabra
6	Isolation and estimation of total phenolics
7	Isolation of Eugenol from clove oil.
8	Isolation of sennosides from senna leaves.
9	Extraction of volatile oil and its formulation into perfume
10	Isolation of lycopene from Tomatoes
11	Isolation of α,β Glucosamine from crab shells

(vi) Recommended Reading:

a) Basic Reading:

1. WHO, Quality Control methods for medicinal plant material
2. Chemistry of Natural Products, P.S Kalsi

3. Chaudhari R D, Herbal Drug Industry, Eastern publication
4. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons
5. E. Ramstad, Modern Pharmacognosy, Mc-graw hill Book Company
6. Wagner, Plant Drug Analysis
7. PDR for Herbal Medicines, Second Ed., Medicinal Economic Company, New Jersey
8. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
9. Standardisation of Botanicals by V.Rajpal, Vol.1, Eastern Publishers, New Delhi, 2002.
10. Plant data bases, Wikipedia encyclopedia
11. Pharmaceutical excepients
12. Regulatory affairs for herbal drugs

b) Additional Reading:

1. Agrawal O.P., Chemistry of Organic Natural Product, Goel Publication House, UP.
2. Pharmacognosy: Kokate, Puruhit, Gokhale, Nirali Prakashan, Pune, 15th edtn.
3. Cultivation and utilization of aromatic plants Atal and Kapoor, CSIR Publication.
4. WHO guidelines for standardization of medicinal plants Geneva 2002.
5. Chopra, Indigenous drugs of India.

c) References:

i) Books:

1. Various pharmacopoeias
2. Practical Pharmacognosy: Kokate C.K.,Vallabh prakashan, New Delhi.
3. Practical Pharmacognosy: Khandelwal K.R. Nirali Prakashan, Pune.
4. Phytochemical methods : J.B.Harborne
5. Thin layer chromatography: Stahl.
6. Plant drug analysis Peach and Tracy Narosa Publishing house Delhi
7. Journal of Phytochemistry
8. Journal of chromatography

ii) Periodicals/Journals:

1. Journals published by NISCAIR
2. Pharmaceutical Research Journals (Springer, Elsewere)
3. Pharmacognosy and natural products journal

i) Paper : 3 THEORY

ii) Title of Paper: HERBAL DRUG FORMULATIONS HDF

iii) Specific Objectives:

1. To gain an insight in the phytopharmaceuticals, neutraceuticals and cosmeceuticals
2. To understand the extraction and standardization of phytoconstituents
3. The student will gain a good understanding of ayurvedic formulations.
4. Students will be acquainted with information on modern techniques of drug analysis

iv) Note:

1. The student should have a basic knowledge of the extraction and purification techniques of phytoconstituents and their physicochemical properties.
2. Students should have knowledge of pharmaceutical and Ayurvedic dosage forms.

HDF HERBAL DRUG FORMULATIONS Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Plant Extracts, Preparation and standardization** Tinospora cardifolia, Curcuma longa, Solanum xanthocarpum, Ocimum santum, Adhatoda vasica, Emblica officinalis, Centella asiatica, Melia Azadirachta, withania somnifera..	08	20-24
2.	**Traditional drug formulations** Ayurveda (Asava, Arista, Bhasma, Kwatha, Ghruta, Avalcha), Homoeopathy, Siddha, Unani, Aromatherapy	05	12-15
3.	**Herbal drug formulations** Therapeutic drugs used Cosmetics: Skin, Hair.	04	08-10
4.	**Agroproducts of economic significance** – Corn oil, Soybean, Spirulina, Pectin, Papain.	04	08-10
5.	**Standardization of phyto-pharmaceuticals by HPTLC technique.** Bacoside.Andrographolide, Solasodine, Glycerrhetinic acid, Vasicine, Sennosides	04	08-10
6.	**Standardization of phyto-pharmaceuticals by HPLC technique:** Amarogention Asiaticoside	05	12-15

Cardifoloside

Lupeol

Solasodine

7.	**Standardization of Ayurvedic formulations**	03	06-08
8.	**Group estimation of phytoconstituents**	03	06-08

(vi) Recommended Reading:

a) Basic Reading:

1. Shah and Quadri Text Book of Pharmacognosy.
2. Chopra, Indigenous drug of India.
3. Rangari V.D., Pharmacognosy & Phytochemistry, Vol I, II, Career Publication, Nashik
4. Wealth of India. The Raw Materials. CSIR, New Delhi (Related Volumes)
5. K. M. Nadkarni, Material Medica. Vol.I-II
6. The Practical Evaluation of Phytopharmaceuticals.by Brain & Turner.
7. WHO, Quality Control methods for medicinal plant material
8. Chemistry of Natural Products, P.S Kalsi
9. Chaudhari R D, Herbal Drug Industry, Eastern publication
10. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons
11. E. Ramstad, Modern Pharmacognosy, Mc-graw hill Book Company
12. Wagner, Plant Drug Analysis
13. PDR for Herbal Medicines, Second Ed., Medicinal Economic Company, New Jersey
14. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
15. Standardisation of Botanicals by V. Rajpal, Vol.1, Eastern Publishers, New Delhi, 2002.
16. Plant data bases, Wikipedia encyclopedia
17. Pharmaceutical excepients
18. Regulatory affairs for herbal drugs

b) Additional Reading:

1. Agrawal O.P., Chemistry of Organic Natural Product, Goel Publication House, UP.
2. Pharmacognosy: Kokate, Puruhit, Gokhale, Nirali Prakashan, Pune, 15th edtn.
3. Cultivation and utilization of aromatic plants Atal and Kapoor, CSIR Publication.
4. WHO guidelines for standardization of medicinal plants Geneva: 2002.

c) References:

i) Books:

1. Plant drug analysis Peach and Tracy Narosa Publishing house Delhi
2. H.G.Brittain, Physical Characterization of Pharmaceutical solids, Marcel Dekker
3. Tarcha, P. J. Polymers for controlled Drug Delivery; CRC Press. 1991.
4. Remington's Pharmaceutical Sciences. 21-st editions, Vol. I-II Lippincott Williams and Wilkins.
5. Phytochemical methods : J. B. Harborne
6. Ayurvedic Pharmacopoeia.
7. Indian Pharmacopoeia.
8. British Herbal Pharmacopoeia
9. Quality Standards of Indian Medicinal Plants, Vol -I, ICMR, New Delhi.

ii) Periodicals/Journals:

1. Journals published by NISCAIR
2. Pharmaceutical Research Journals (Springer, Elsewere)
3. Pharmacognosy and natural products journals

i) Paper : 6 THEORY

ii) Title of Paper: ADVANCED PHARMACOGNOSY-II ACOG-II

iii) Specific Objectives:

1. To gain an insight in the phytopharmaceuticals, neutraceuticals and cosmeceuticals
2. To understand the role and adventages of cultivation and post harvesting technology.
3. The student will gain a good understanding of how to obtain phytoconstituents in pure form and their structural elucidation.
4. To understand the marine source of crude drugs

iv) Note:

1. The student should have a basic knowledge of the extraction and purification techniques of phytoconstituents.
2. Students should have knowledge of methods of spectral analysis.

ACOG-II ADVANCED PHARMACOGNOSY-II Theory (3 hrs/wk)

Unit	Contents		Hrs	Marks
1.	**Cultivation and post harvest technology of** Opium, Ashwagandha, Senna, Solanum Kharsium and Aloe		06	12-16
2.	**Isolation and Estimation of**		08	20-22
	Clove oil	Atropine		
	Curcumin	Vinca alkaloids		
	Quinidine	Taxol		
	Emetine	Sennoside		
	Glycerrhizin	Starch		
	Microcrystalline cellulose			
3.	**Structural Elucidation of**		04	08-10
	Citral	Nicotine		
	Atropine	Amygdaline		
	Caffeine	Morphine		
4.	**Chemotaxonomy of Flavonoids and Terpenoids.**		02	04-06

5.	**Marine drug** General methods of extraction and isolation of phytoconstituents and study of cytotoxic, anti-inflammatory, cardiovascular, antibiotics and antimicrobials from marine source.	06	12-16
6.	**Pest control** Issues related to use of pesticides, natural and synthetic pesticides, organic farming.	04	08-10
7.	**Herbal based nutraceuticals**	03	08-10
8.	**Herbal based cosmeceuticals**	03	08-10

(vi) Recommended Reading:

a) Basic Reading:

1. Shah and Quadri Text Book of Pharmacognosy.
2. Chopra, Indigenous drug of India.
3. Rangari V.D., Pharmacognosy & Phytochemistry, Vol I, II, Career Publication, Nashik
4. Wealth of India. The Raw Materials. CSIR, New Delhi (Related Volumes)
5. K. M. Nadkarni, Material Medica. Vol.I-II
6. The Practical Evaluation of Phytopharmaceuticals.by Brain & Turner.
7. WHO, Quality Control methods for medicinal plant material
8. Chemistry of Natural Products, P.S Kalsi
9. Chaudhari R D, Herbal Drug Industry, Eastern publication
10. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons
11. E. Ramstad, Modern Pharmacognosy, Mc-graw hill Book Company
12. Wagner, Plant Drug Analysis
13. PDR for Herbal Medicines, Second Ed., Medicinal Economic Company, New Jersey
14. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
15. Standardisation of Botanicals by V.Rajpal, Vol.1, Eastern Publishers, New Delhi, 2002.
16. Plant data bases, Wikipedia encyclopedia
17. Pharmaceutical excepients: B. M. Mithal
18. Regulatory affairs for herbal drugs

b) Additional Reading:

1. Agrawal O.P., Chemistry of Organic Natural Product, Goel Publication House, UP.

2. Pharmacognosy: Kokate, Puruhit, Gokhale, Nirali Prakashan, Pune, 15th edtn.
3. Cultivation and utilization of aromatic plants Atal and Kapoor, CSIR Publication.
4. WHO guidelines for standardization of medicinal plants: Geneva 2002.

c) References:

i) Books:

1. Plant drug analysis Peach and Tracy Narosa Publishing house Delhi
2. H.G.Brittain, Physical Characterization of Pharmaceutical solids, Marcel Dekker
3. Cultivation of medicinal plants: Kokate, Purohit, Gokhale, , Nirali Prakashan . Pune
4. Remington's Pharmaceutical Sciences. 21-st editions, Vol. I-II Lippincott Williams and Wilkins.
5. Phytochemical methods : J. B. Harborne
6. Ayurvedic Pharmacopoeia.
7. Indian Pharmacopoeia.
8. British Herbal Pharmacopoeia
9. Cultivation and Utilization of medicinal plants: Atal & Kapoor, RRL, Jammu
10. Cultivation and Utilization of aromatic plants : Atal & Kapoor, RRL, Jammu

ii) Periodicals/Journals:

1. Journals published by NISCAIR
2. Pharmaceutical Research Journals (Springer, Elsewere)
3. Pharmacognosy and natural products journals

i) Paper : 6 PRACTICAL

ii) Title of Paper : ADVANCED PHARMACOGNOSY – II ACOG-II

iii) Specific Objectives:

1. To gain an insight in the phytopharmaceuticals, neutraceuticals and cosmeceuticals
2. To understand the methods of extraction in detail.
3. The student will gain a good understanding of chromatographic techniques.

iv) Note:

1. The student should have a basic knowledge of the extraction and purification techniques of phytoconstituents and their physicochemical properties.
2. Students should have knowledge of advanced methods of phytochemical investigation.
3. Student should have basic knowledge of analytical methods and traditional formulations.

ACOG-II ADVANCED PHARMACOGNOSY – II Practical (6 hrs/wk)

Unit	Contents
1.	Selection, Authentication, Herbarium preparation, Macroscopy, Microscopy and powder characteristics study of official herbal drugs.
2.	Estimation of following phytopharmaceuticals Total Triterpene acids in Boswellia serrata Total phenolic acids as Benzoic acid from Benzoin Total Tropane alkaloids from Datura/ Hyoscyamus tinctures Estimation of Andrographolide from Andrographis paniculata Column chromatographic isolation of Psolaren from Psolarea corylifolea seed extracts
4.	Study of UV and Visible spectra data of some natural products.
5.	Study of IR spectra of some natural products.
6.	Preparation of Traditional drug formulation mentioned in the Advanced Pharmacognosy theory and their standardization.

(vi) Recommended Reading:

a) 1. Practical Pharmacognosy, Khandelwal, K.R. 7th. Ed. Nirali Prakashan, Pune, 2000.

2. Pharmacopoia of India, Ministry of Health, Govt. of India.1966.

3. Practical Pharmacognosy, Kokate C.K. Vallabh Prakashan, New Delhi.
4. Indian Herbal Pharmacopoia, Vol.-III IDMA. Mumbai.
5. Thin Layer Chromatography- E.Stahl, 2nd Edition.1969.
6. Ayurvedic Pharmacopoeia of India: Govt. of India.
7. Spectroscopic Identification of Organic compounds, Silverstain R.M. Bassler G.C. and Morril T.C. 5th Ed., John Wiley and Sons Inc. 1991.

b) Additional Reading:

1. Agrawal O.P., Chemistry of Organic Natural Product, Goel Publication House, UP.
2. Pharmacognosy: Kokate, Puruhit, Gokhale, Nirali Prakashan, Pune, 15th edtn.
3. Practical Pharmacognosy by C.K.Kokate.
4. WHO guidelines for standardization of medicinal plants: Geneva 2002.

c) References:

i) Books:

1. Plant drug analysis Peach and Tracy Narosa Publishing house Delhi
2. H.G.Brittain, Physical Characterization of Pharmaceutical solids, Marcel Dekker
3. Remington's Pharmaceutical Sciences. 21-st editions, Vol. I-II Lippincott Williams and Wilkins.
4. Phytochemical methods : J. B. Harborne
5. Ayurvedic Pharmacopoeia.
6. Indian Pharmacopoeia.
7. British Herbal Pharmacopoeia

ii) Periodicals/Journals:

1. Journals published by NISCAIR
2. Pharmaceutical Research Journals (Springer, Elsewere)
3. Pharmacognosy and natural products journals

i) Paper : 7 THEORY

ii) Title of Paper: RECENT ADVANCES IN PHARMACOGNOSY RCOG

iii) Specific Objectives:

1. To gain an insight in the phytopharmaceuticals, neutraceuticals and cosmeceuticals
2. To understand the role and adventages of phyto-based excepients used in Pharma related industries.
3. The student will gain a good understanding of herbal drug industries.
4. Students will be acquainted with information retrieval system and regulatory affairs for herbal drugs.

iv) Note:

1. The student should have a basic knowledge of the extraction and purification techniques of phytoconstituents and their physicochemical properties.
2. Students should have knowledge of pharmaceutical and Ayurvedic dosage forms.

RCOG RECENT ADVANCES IN PHARMACOGNOSY Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	Immunity, Immunomodulatory drugs of plant origin.	04	08-10
2.	Ethnopharmacognosy / Ethnomedicine, its concept, scope and importance.	04	08-10
3.	Aromatic plant resources in India. Screening: Chemical screening procedures of vegetable drugs of medicinal importance.	03	06-08
4.	Antibacterial, antiviral, hypolipidemic, anti-inflammatory, anti-malarial, hepatoprotective, antidiabetics and anticancer drugs from natural origin, Their recent advances as reported in literature. Biological allergens and hallucinogens.	08	20-24
5.	Comparative phytochemistry, its history, concepts, applications and methods, DNA finger printing.	06	16-20
6.	WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants.	03	06-08
7.	Problems and recent trends in pest management, scope of biological control and use of environment friendly pesticides especially plant derived products, Pyrethroids, pheromones and juvenile hormones	04	08-10
8.	Clinical Pharmacognosy	04	08-10

(vi) Recommended Reading:

a) Basic Reading:

1. Shah and Quadri Text Book of Pharmacognosy.
2. Chopra, Indigenous drug of India.
3. Rangari V.D., Pharmacognosy & Phytochemistry, Vol I, II, Career Publication, Nashik
4. Wealth of India. The Raw Materials. CSIR, New Delhi (Related Volumes)
5. K. M. Nadkarni, Material Medica. Vol.I-II
6. The Practical Evaluation of Phytopharmaceuticals.by Brain & Turner.
7. WHO, Quality Control methods for medicinal plant material
8. Chemistry of Natural Products, P.S Kalsi
9. Chaudhari R D, Herbal Drug Industry, Eastern publication
10. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons
11. E. Ramstad, Modern Pharmacognosy, Mc-graw hill Book Company
12. Wagner, Plant Drug Analysis
13. PDR for Herbal Medicines, Second Ed., Medicinal Economic Company, New Jersey
14. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
15. Standardisation of Botanicals by V.Rajpal, Vol.1, Eastern Publishers, New Delhi, 2002.
16. Plant data bases, Wikipedia encyclopedia
17. Pharmaceutical excepients
18. Regulatory affairs for herbal drugs

b) Additional Reading:

1. Agrawal O.P., Chemistry of Organic Natural Product, Goel Publication House, UP.
2. Pharmacognosy: Kokate, Puruhit, Gokhale, Nirali Prakashan, Pune, 15th edtn.
3. Cultivation and utilization of aromatic plants Atal and Kapoor, CSIR Publication.
4. WHO guidelines for standardization of medicinal plants: Geneva 2002.

c) References:

i) Books:

1. Plant drug analysis Peach and Tracy Narosa Publishing house Delhi
2. H.G.Brittain, Physical Characterization of Pharmaceutical solids, Marcel Dekker
3. Tarcha, P. J. Polymers for controlled Drug Delivery; CRC Press. 1991.

4. Remington's Pharmaceutical Sciences. 21-st editions, Vol. I-II Lippincott Williams and Wilkins.
5. Phytochemical methods : J. B. Harborne
6. Ayurvedic Pharmacopoeia.
7. Indian Pharmacopoeia.
8. British Herbal Pharmacopoeia
9. Quality Standards of Indian Medicinal Plants, Vol -I, ICMR, New Delhi.

ii) Periodicals/Journals:

1. Journals published by NISCAIR
2. Pharmaceutical Research Journals (Springer, Elsewere)
3. Pharmacognosy and natural products journals

OTHER FEATURES*

*Except list of LABORATORY EQUIPMENTS (c), all points (1, 2, 3, 4) coming under OTHER FEATURES from Syllabus of M. PHARM., (Pharmaceutical Chemistry) are same.

(c) LABORATORY SAFETY EQUIPMENTS:

In addition to routine equipments like TLC Kit, hot air oven, Vacuum pump, centrifuge, percolators, grinding mill, pH meter, thermostatic water bath, cleavangers apparatus etc following equipments are necessary

1. Photographic microscope (Shared)
2. Muffle furnace with platinum crucible
3. Rotary film vacuum evaporator
4. Vacuum dryer
5. Orbital shaker (Shared)
6. Stability chamber (Shared)
7. Soxhlet extraction battery
8. Tray dryer
9. IR (Shared)
10. IR moisture balance (Shared)
11. Freeze dryer (Shared)
12. Micro wave extractor (Shared)
13. HPLC (Shared)
14. UV-visible spectrophotometer (Shared)

SYLLABUS FOR M. PHARM (PHARMACEUTICAL TECHNOLOGY)

SPECIALIZATION: PHARMACEUTICAL TECHNOLOGY

(i) Course objectives:

1. To address the needs of pharmaceutical industry particularly in technology transfer, research and development, process development and optimization and product development that ultimately serves to uplift the economy of industry and human society in health care.
2. To provide knowledge intensive specialized, highly skilled human resource to conduct research, ensure its application and generate commercial enterprises.
3. To understand the newer areas like proteomics/genomics, molecular genetics, industrial biotechnology, drug designing, IPR and patenting in technology.
4. To cover areas of designing of unit operations for formulation development of new drug delivery systems, biopharmaceutical aspects, biochemical engineering, advanced protein engineering, preservation technologies, pharmaceutical biotechnology, IPR and other official guidelines.
5. To meet challenges in pharma and biotech industries, while at the same time preparing them for research in frontier areas of pharmaceuticals, biotechnology and chemical industries.chemical, instrumentation and biomedical industries.

i) Paper : 2 THEORY

ii) Title of Paper: ADVANCED PHARMACEUTICAL TECHNOLOGY – I APT-I

iii) Specific Objectives:

1. To gain an insight in the production process and bioavailability of dosage forms produced in the pharmaceutical industry.
2. Knowing and being able to implement the techniques for the analysis of biotechnological drugs. It makes students to gain an insight in pharmacy questions with regard to the delivery of drugs.
3. The student will gain a good understanding of how the dosage forms under review are produced and which parameters have an influence on the production, storage and bioavailability of these dosage forms.

iv) Note:

1. The student should have a basic knowledge of the pharmaceutical dosage forms.
2. For better understanding, good video and animated clips can be used if the more advanced facilities are available. In fact they can be used very fruitfully.

APT-I ADVANCED PHARMACEUTICAL TECHNOLOGY – I Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1.	**Pre-Formulation Technology:** Objectives and applications, physical, chemical and biological properties of drugs and excipients. Studies on drug-drug and drug-excipient interactions and their characterization.	04	10-15
2.	**Optimization Techniques in Product Development Technology:** Identifying formulation and process variables, by quality by design (QbD), experimental designs like Factorial and Artificial neural network (ANN), Response surface methodology. In-vitro test systems to evaluate and monitor the performance of different types of dosage forms.	04	08-12
3.	**Tablet Technology:** Systematic and modern approach to tablet components and production designs. Press design and layout, press control (off line and online) and automization, trouble shooting, recent tablet technologies. Techniques of tablet coating, mechanism of coat formation (aqueous and nonaqueous coat), .coating compositions, physico–mechanical properties of polymer f.ilms. Industrial coaters, process atomization and optimization, c.oating problems and troubleshooting.	08	20-30
4.	**Polymer Technology:** Introduction, classification, solid and solution state properties of polymers. Biodegradable polymers and their applications.	04	08-12
5.	**Pelletisation Technology:** Techniques of pelletisation. Extrusion spheronisation process, process controls and formulation variables. Hot melt extrusion: On line, in line and off line process controls and applications.	02	08-12
6.	**Dissolution Technology and IVIVC:** Compendial and non-compendial dissolution techniques; USFDA Guidelines; Techniques of dissolution enhancement; In vitro drug release kinetics. Introduction to BCS & IVIVC; prediction of IVIVC based on BCS; Development of level A correlation and dissolution testing methods ; Convolution & deconvolution approach; bio-relevant media; evaluation of predictability of correlation; Bioavailability studies for development of IVIVC; dissolution data analysis with view to IVIVC; BCS and IVIVC based biowaivers.	04	08-12
7.	**Stability Testing:** Destabilization modes and techniques of stabilization of pharmaceuticals. Importance of accelerated stability study, stress test method, Freeze thaw methods, centrifugal methods. Accelerated stability testing of new drug substances and new dosage forms. Evaluation of stability data. Predicting shelf life of pharmaceutical formulations.	06	10-15
8.	**Process Analytical Technology (PAT):** Introduction and applications to	04	08-12

pharmaceutical industry; regulatory aspects of PAT; Impact of PAT on industry organization & process; identification and control of critical quality & performance parameters; PAT tools; Chemometric techniques; Implementation of PAT; Limitations for its implementation.

(vi) Recommended Reading:

a) Basic Reading:

1. Carstensen, J. T. Pharmaceutical preformulation. Technomic Pub. Co. Lancaster, PA, 1998.
2. Lieberman, Lachmann and Schwartz. Pharmaceutical Dosage Form Tablets. Vol-I, II, III, Marcel Dekker, New York, 2nd ed. – 2008.
3. Yoshioka and Stella. Stability of Drugs and Dosage Form. Kluwer Academic/Plenum publisher, NY, USA, 2000.
4. Theory and Practice of Industrial Pharmacy, Lachmann and Lieberman, Varghese, Publishing House, Bombay, 3rd Ed. – 1991.
5. Hajare Ashok, Physical Pharmacy, New Central Book Agency, Kolkata, 2012.
6. Jens T. Carstensen. Drug stability: Principles and Practices. Marcel Dekker, 2000.

b) Additional Reading:

1. Gupta, S. C. and Kapoor, V. K. Fundamentals of Applied Statistics. S. Chand and Sons, 2008.
2. Henry L. Alder and Edward B. Roessler. Introduction to probability and Statistics. W. H. Freeman & Co Ltd; 5th ed. 1972.
3. Saunders and Flemming. Mathematics and Statistics for use in Pharmacy, Biology, Chemistry, Pharmaceutical Press, 1966.
4. B. K. Mahajan. Methods in Biostatistics (for Medical students and Research worker), 6th Ed, 1997, Jaypee Brothers Medical publishers (P) Ltd., New Delhi.

c) References:

i) Books:

1. Swarbrick J and Boylon J.C., Encyclopedia of Pharmaceutical Technology, Vol. 1-20.
2. Grimm, W. Stability Testing of Drug Products. International Publishers Service, Incorporated, 1987.
3. Tarcha, P. J. Polymers for controlled Drug Delivery; CRC Press. 1991.
4. Watt, P. R.: Tablet Machine Instrumentation in Pharmaceutics: Principles and Practice, Ellis Horwood Limited, England, 1988.

ii) Periodicals/Journals:

1. Pharmaceutical Technology (Findpharma)
2. Pharmaceutical Research (Springer)
3. Pharmaceutical Technology (Elsevier)

i) Paper : 2 PRACTICAL

ii) Title of Paper : ADVANCED PHARMACEUTICAL TECHNOLOGY – I APT-1

iii) Specific Objectives:

1. To gain a good understanding of how the dosage forms under review are produced.
2. To know which parameters have an influence on the production, storage and bioavailability of different dosage forms.

iv) Note:

1. The experiments must be conducted in group of two students.
2. Keeping in view the requirements of students, the teacher may have to personaly work with them.
3. For better understanding, good video and animated clips can be used.

APT-I ADVANCED PHARMACEUTICAL TECHNOLOGY – I Practical (6 hrs/wk)

Unit	Contents
1.	To study of effect of particle size, moisture content and lubricants on flowability and compressibility of powders
2.	To study of effect of binding agents on the properties of tablets.
3.	To evaluate drug-excipient compatibility in a formulation.
4.	To demonstrate product development protocols from preformulation data.
5.	To formulate matrix tablets using polymers and study their release behaviors
6.	To formulate and evaluate sugar/non-enteric/enteric coated tablets.
7.	To study the effect of diameter of balls, number of balls, volume of balls, amount of feed on the particle size reduction using ball mill.
8.	To study rate of sedimentation and the effect of suspending agents on the rate of sedimentation of the given sample.
9.	To study sedimentation volume of suspensions prepared by using various suspending agents.
10.	Study the effect of temperature, surface area and viscosity of the liquid on the rate of evaporation.
11.	To study the effect of surface area, material bed thickness, temperature and moisture content on the rate of drying.
12.	To study phase behavior of three component system and construct ternary phase diagram

13. Preparation and evaluation of pellets using certain techniques like extrusion spheronisation, etc.

(vi) Recommended Reading:

a) Basic Reading:

1. Munira Momin, Tejal A. Mehta. Practical Manual of Pharmaceutical Engineering. B. S. Shah Prakashan, Ahmedabad. 2nd ed: 2009
2. Sudhakara Reddy Pondugula, M. Gopal Rao, R. Vamsi Krishna. Pharmaceutical Engineering: Practical Manual, 2010.
3. H. N. More and A. A. Hajare. Practical Physical Pharmacy, Third Edition, Career Publications, Nashik, 2011.
4. Gaud and Gupta. Practical Physical Pharmacy. Vallabh Prakashan, Delhi
5. Dermatological Formulation – Percutaneous Absorption. Srian W. Berry, Marcel Dekker Inc. New York.
6. Controlled Drug Delivery, Second Edition, Lee and Robinson, Marcel Decker Inc.

b) Additional Reading:

1. Novel Drug Delivery Systems, Y. W. Chein, Marcel Dekker, Inc
2. Microencapsulation, Simon Benita, Pub. Marcel Dekker Inc.
3. Specialized Drug Delivery Systems, Praveen Tyle, Pub. Marcel Dekker Inc.

c) References:

i) Books:

1. Controlled and Novel Drug delivery, N. K. Jain, 1st Ed. CBS Publisher and Distributor.
2. Controlled release of drugs; Morton Rosoff; VCH Publishers.
3. Topical drug delivery formulations; Osborne, and Amann; Marcel Dekker.

ii) Periodicals/Journals:

1. Current Drug Delivery (Bentham Science)
2. Drug Development and Industrial Pharmacy – (Informa Pharmaceutical Science)
3. PDA J Pharmaceutical Science and Technology - Parenteral Drug Association USA

i) Paper : 3 THEORY

ii) Title of Paper : TECHNOLOGY TRANSFER TT

iii) Specific Objectives:

1. Based on the cited theoretical knowledge, the acquisition of analytical research skills for the scale up and control of bulk products and of finished preparations will be focused at, aiming at the development of the student's most critical sense so as to deal with future product scaling and quality control challenges of medicaments and related preparations.
2. Students will be able to learn and to be able to apply the principles of scale up of process and products at various levels.
3. The student, when finishing the course, should be capable of exerting an executive position in the area of technology transfer, in its most wide sense. They will acquire the required visions and skills for leading specialized tech transfer officer at pilot plant scale, laboratory scale and large scale and their control, regulatory and related departments.

iv) Note:

1. The topics must be conveyed through plenty of examples. Lecture classes must be conducted as lecture-cum-power point presentations.
2. It is a course that aims to develop skills. It is therefore "practical" in orientation. Plenty of exercises of various kinds must be done by the students.
3. The teacher must not depend on a single or a set of two or three text books. He must choose his materials from diverse sources.
4. Keeping in view the requirements of his students, the teacher may have to prepare some teaching and exercise material.
5. For better understanding, good video and animated clips can be used if the more advanced facilities are available. In fact they can be used very fruitfully.

TT TECHNOLOGY TRANSFER Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Pharmaceutical industry**: Status at national and international level, Pharmaceutical factory planning and layout, personnel requirement and reporting, input specifications and finished product specifications.	04	10-15
2.	**Supply chain management (SCM) and Enterprise Resource Planning (ERP):** The Basics of SCM. Features, selection criteria, merits, issues and challenges in Implementation. SCM modules. ERP objectives, concepts of	03	10-15

integration and tailorability, and the new ERP systems.

3.	**Technology transfer**: Scope, role and functions. Technology transfer of new product from bench scale to commercialization of new product. Regulatory issues, NDA, ANDA regulatory requirements. Technology transfer of site transfer product from one site to another site or third party technology transfer.	06	12-15
4.	**Process optimization and automation in Pharma manufacturing**: Overview of Pharmaceutical process engineering e. g. HVAC, New product launch, trouble shooting in production and shop floor.	06	12-20
5.	**Technology transfer of Dosage forms**: R & D to pilot scale to plant scale studies for dosage forms like liquid orals, solid dosage forms and sterile dosage forms with equipments and SOPs,	04	08-15
6.	**Production planning, control**: Documentation, Inventory management, material management & maintenance management, GMP and cGMP.	04	08-10
7.	**Documentation**: Flow diagrams, material balance sheets, technical data sheets, material and inventory control, Master formula generation and maintenance, SOPs for different dosage forms and activities.	04	10-15
8.	**Environmental Issues:** Industrial hazards, safety, pollution and effluent treatment, Hazard Analysis & and Critical Control Process, prevention measures in pharma industries. Monitoring systems Case studies of pharma industrial accidents. Environment, pollution regulations.	05	10-15

(v) Recommended Reading:

a) Basic Reading:

1. Kate McCormick and D. Wylie, Jr. Mcvay (Authors). Pharmaceutical Process Design and Management.
2. Anurag S. Rathore (Editor), Gail Sofer (Editor). Process Validation in Manufacturing of Biopharmaceuticals, Third Edition (Biotechnology and Bioprocessing). CRC Press.
3. Brandrup, J. , Immergur, E. H. Polymer Handbook; 4th ed., John Wiley and Sons, 2003.
4. Thomas M. Jacobsen, Albert I. Wertheimer. Modern Pharmaceutical Industry: A Primer, Jones and Bartlett, 2010.
5. Wiggins Stevan. The pharmaceutical industry, Center for Education and Research in Free Enterprise, Texas A&M University, 1985
6. Chopra Sunil. Supply Chain Management, strategy, planning and operation, Dorling Kindersley (India) Pvt. Ltd,2010.
7. William Y. C. Wang, Michael S. H. Heng, Patrick Y. K. Chau. Supply chain

management: issues in the new era of collaboration and competition, Idea group publishing, 2007.

8. Tanford, C. Physical Chemistry of Macromolecules, John Wiley, NY, 1961.
9. Neil F. Sullivan. Technology transfer: making the most of your intellectual property, Cambridge University press, 1995.
10. Schroeer Dietsich, Elena Micro, Technology transfer, Ashgate, 2000
11. Fraade David J. Automation of pharmaceutical operations, Pharmaceutical Technology Publications, 1983
12. Brian R.T. Frost. Jamshidi Mohammad, Advances in materials and automation, American Society of Mechanical Engineers, 1990

b) Additional Reading:

1. Charles G. Gebelein, T.C. Chin and V. C. Yang; Cosmetic and Pharmaceutical Applications of Polymers; Plenum Press, New work.
2. David J. am Ende. Chemical Engineering in the Pharmaceutical Industry: R&D to Manufacturing. John Wiley and sons, 2011.
3. Michael Levin. Pharmaceutical Process Scale-Up. Marcel Dekker Inc. 2001.
4. William Boltan. Production planning and control. Longman Scientific & Technical, 24-Jan-1994
5. Chapman Stefan. Fundamentals of Production Planning and Control. Pearson Education Inc.2009

c) References:

i) Books:

1. N. K. Jain; Controlled and Novel Drug Delivery; CBS publications, 2008.
2. Ronald E., Briet Suzanne. What is documentation?. Scarecrow Press, 28-Mar-2006.
3. Pharmaceutical documentation monograph. Institute of Quality Assurance, 1995.
4. Ron Fridel. Environmental Issues, Volume 10. Linda syekes Picture research 2006.
5. Susan Buckingham, Mike Turne. Understanding Environmental Issues. Susan Buckinghamand Mike Turner 2008.

ii) Periodicals/Journals:

1. Advances in polymer technology- Wiley Online
2. Polymer Science and Technology – Elsevier
3. Polymers for Advanced Technologies - John Wiley & Sons.

i) Paper : 6 THEORY

ii) Title of Paper : ADVANCED PHARMACEUTICAL TECHNOLOGY- II APT-II

iii) Specific Objectives:

1. The student should have a basic knowledge of the pharmaceutical dosage forms. To gain an insight in the production process and bioavailability of dosage forms produced in the pharmaceutical industry.
2. Knowing and being able to implement the techniques for the analysis of biotechnological drugs. It makes students to gain an insight in pharmacy questions with regard to the delivery of drugs.
3. The student will gain a good understanding of how the dosage forms under review are produced and which parameters have an influence on the production, storage and bioavailability of these dosage forms.

iv) Note:

1. The topics must be conveyed through plenty of examples. Lecture classes must be conducted as lecture-cum-power point presentations.
2. Keeping in view the requirements of his students, the teacher may have to prepare some teaching and exercise material.
3. For better understanding, good video and animated clips can be used if the more advanced facilities are available. In fact they can be used very fruitfully.

APT-II ADVANCED PHARMACEUTICAL TECHNOLOGY- II Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1.	**Fundamentals of sustained, controlled and targeted drug delivery:** Basics, design of sustained release dosage forms. Biopharmaceutics of sustained and controlled drug delivery systems. Need and fundamentals, techniques of targeting, design of targeting compounds and devices.	04	10-15
2.	**Oral controlled drug delivery system:** Therapeutic needs of OCDDS. Design parameters/characteristics and their ranges for OCDDS. Properties of drugs suitable/unsuitable for OCDDS. Types of OCDDS, design and evaluation of gastro retentive and colon specific drug delivery systems. In vitro, ex vivo and in vivo evaluation of OCDDS.	04	10-15
3.	**Ocular Drug Delivery Systems:** Drug absorption in eye, formulation consideration and evaluation of ophthalmic products, contact lenses, occuserts, container and closures, safety.	04	08-15
4.	**Transdermal drug delivery systems:** Theory, design, formulation and evaluation including iontophoresis, sonophoresis and other latest developments in skin delivery systems. Development and evaluation of	04	10-15

transdermal devices and osmotic pumps.

5.	**Drug Targeting Technologies:** Need, fundamentals and techniques of targeting. (i) Physical Targeting Approaches: Enteric/colonic Targeting Through Coating, Lipid-Based Formulations for Oral Administration (ii) Chemical Targeting Approaches: Drug Targeting by Retrometabolic Design: Soft Drugs and Chemical Delivery Systems, Neoglyco- and Neopeptide Albumins for Cell- Specific Delivery of Drugs and prodrugs, (iii) Biological Targeting Approaches- Gene Delivery with Artificial Viral Envelopes, Evolution of Viral Liposomes: Improvements and Applications, Targeting of Viral Vectors	06	10-15
6.	**Lipid vesicle based drug delivery systems:** Liposomes: Structure, classification, methods of preparation, mechanism of formation, composition, chemical and physicochemical characterization, stability and applications in drug delivery, drug targeting, Composition, methods of preparation and applications of nanostructured lipid carriers (NLCs), lipid drug conjugates; niosome, pharmacosomes and ethosomes.	04	10-15
7.	**Micro and nano technology:** Design and evaluation of microcapsules. Release kinetics, applications, and recent advances. Nanotechnology and nanomedicine, merits and demerits. Techniques of nanonisation. Nano-technological products: nano-devices, nano-robotics for surgery, cancer detection and diagnosis, gold nanoparticles. Nanomaterials: dendrimers, nanotubes, nanofibres, nanowires and quantum dots.	06	12-15
8.	**Aerosols:** Advances in metered dose inhaler designs and dry powder inhalers. Respules for inhalation. Particle engineering techniques to improve inhalable fraction and evaluation thereof.	04	10-15

(vi) Recommended Reading:

a) Basic Reading:

1. Siepman Juerjen, Ronald A. Segel and Micheal J. Rathbone. Fundamentals and Applications of New Drug Delivery. Springer, US, 2012.
2. Hong Wen, Kinam Park. Oral Controlled Release Formulation Design and Drug Delivery: Theory to Practice. John Wiley and Sons, 2010.
3. Ashim K. Mitra, Ophthalmic drug delivery systems**.** Marcel Dekker, 2003.
4. Richard guy, Jonathan Hadgraft, Transdermal Drug Delivery Systems: 2nd ed. Marcel Dekker, 2002.
5. Hans Schreier, Drug Targeting Technology: A Physical, Chemical, Biological Methods. Taylor and Francis, 2011.
6. Mohan Babu Boggara. Lipid-based drug delivery system: Molecular dynamics simulations and neutron scattering studies. ProQuest, UMI Dissertation Publishing, 2011.

b) Additional Reading:

1. Bharat Bhushan, Springer handbook of nanotechnology, Volume 1. Springer, 2004.
2. Warren H. Finlay. The Mechanics of Inhaled Pharmaceutical Aerosols: An Introduction. Academic Press, 2001.
3. Anthony J. Hickey. Pharmaceutical Inhalation Aerosol Technology, Second Edition, Marcel Dekker, 2005

c) References:

i) Books:

1. N. K. Jain; Controlled and Novel Drug Delivery; CBS publications, 2008.
2. Swarbrick J and Boylon J.C., Encyclopedia of Pharmaceutical Technology, Vol. 1-20.
3. P. J. Tarcha; Polymers for controlled Drug Delivery; CRC Press, 1991.
4. A. F. Kydonieus; Controlled Release Technologies: Methods, Theory and Application, Vol-I and II; CRC Press Inc. Academic/Plenum Publishers, NY, 2001.
5. A. V. Kabanov, P. L. Felgner, L. W. Seymour. Self-Assembling Complexes for Gene Delivery. From Laboratory to Clinical Trial. John Wiley and Sons: New York, 1998.

ii) Periodicals/Journals:

1. Current Drug Delivery (Bentham Science)
2. Drug Development and Industrial Pharmacy – (Informa Pharmaceutical Science)
3. PDA J Pharmaceutical Science and Technology - Parenteral Drug Association USA

i) Paper : 6 PRACTICAL

ii) Title of Paper : ADVANCED PHARMACEUTICAL TECHNOLOGY- II APT-II

iii) Specific Objectives:

1. To gain a good understanding of how the dosage forms under review are produced.
2. To know which parameters have an influence on the production, storage and bioavailability of different dosage forms.

iv) Note:

1. The experiments must be conducted in group of two students.
2. Keeping in view the requirements of students, the teacher may have to personaly work with them.
3. For better understanding, good video and animated clips can be used.

APT-II ADVANCED PHARMACEUTICAL TECHNOLOGY- II Practical (6 hrs/wk)

Unit	Contents
1.	Study of drug diffusion study through various polymer membranes.
2.	Preparation and evaluation of wax embedded microspheres.
3.	Preparation and study on invitro evaluation of mucoadhesive systems and hydrogels.
4.	Study of Mier's super solubility curve for the given samples.
5.	Determine the effect of various factors on the rate of filtration.
6.	To determine overall heat transfer coefficient of drying process.
7.	Determine moisture content in a given sample by Karl Fischer Titrator/ moisture balance.
8.	To study effect of filter aid concentration on rate of filtration.
9.	Preparation of polymer films containing different drugs and study of film characteristics and release patterns.
10.	Preparation and study on invitro evaluation of mucoadhesive system.
11.	Preparation and evaluation for occuserts.
12.	Formulation and characterization of liposomes.
13.	Preparation of nanoparticles using some solvent based techniques
14.	Use of spray drying technique to generate DPI.

(vi) Recommended Reading:

a) Basic Reading:

1. Munira Momin, Tejal A. Mehta. Practical Manual of Pharmaceutical Engineering. B. S. Shah Prakashan, Ahmedabad. Second Edition: 2009
2. Sudhakara Reddy Pondugula, M. Gopal Rao, Govinda Rajan Gudala, R. Vamsi Krishna. Pharmaceutical Engineering: Practical Manual, 2010.
3. H. N. More and A. A. Hajare. Practical Physical Pharmacy, Third Edition, Career Publications, Nashik, 2011.
4. Gaud and Gupta. Practical Physical Pharmacy. Vallabh Prakashan, Delhi, 2009.
5. Dermatological Formulation – Percutaneous Absorption. Srian W. Berry, Marcel Dekker Inc. New York. 2005
6. Controlled Drug Delivery, Second Edition, Lee and Robinson, Marcel Decker Inc. 2002

b) Additional Reading:

1. Novel Drug Delivery Systems, Y. W. Chein, Marcel Dekker, Inc. 2005
2. Microencapsulation, Simon Benita, Pub. Marcel Dekker Inc. 2005
3. Specialized Drug Delivery Systems, Praveen Tyle, Pub. Marcel Dekker Inc. 2007

c) References:

i) Books:

1. Swarbrick J and Boylon J. C. Encyclopedia of Pharmaceutical Technology. Vol.1-3, Marcel Decker Inc. 2005.
2. Jain, N. K. Controlled and Novel Drug delivery, 1st ed. CBS Publisher and Distributor. 2007.
3. Microcapsules and Microencapsulation Techniques. M. I. Gutcho, Noyes Data, Corporation, 1976.
4. Osborne and Amann. Topical drug delivery formulations; Marcel Dekker.2008.

ii) Periodicals/Journals:

1. Pharmaceutical technology (findpharma)
2. Pharmaceutical Research (Springer)
3. Pharmaceutical Technology (Elsevier)

i) Paper : 7 **THEORY**

ii) Title of Paper : BIOPHARMACEUTICS AND BIOMEDICAL ENGINEERING **BPBME**

iii) Specific Objectives:

1. To provide the student with a critical attitude and knowledge about the use of pharma/biotechnology in the biomedical sciences.
2. To make students master in pharmaceutical care or master in drug development. Understanding the process of production of pharma/biotechnological drugs. Knowledge of problems related to the administration of drugs and the current status of pharmaceutical research.
3. To know the mechanisms involved in biopharmaceutical processes and the factors affecting them.

iv) Note:

1. Students must learn how to define and interpret pharmacokinetic models and to calculate parameters. This knowledge must allow him to understand and design dose regimens e.g. in the individual patient with varying pharmacokinetics.
2. The topics must be conveyed through plenty of examples. Lecture classes must be conducted as lecture-cum-power point presentations.
3. It is a course that aims to develop skills. It is therefore "practical" in orientation. Plenty of exercises of various kinds must be done by the students.
4. The teacher must not depend on a single or a set of two or three text books. He must choose his materials from diverse sources.
5. Keeping in view the requirements of his students, the teacher may have to prepare some teaching and exercise material.
6. For better understanding, good video and animated clips can be used if the more advanced facilities are available. In fact they can be used very fruitfully.

BPBME **BIOPHARMACEUTICS AND BIOMEDICAL ENGINEERING** **Theory (2 hrs/wk)**
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Concepts of Compartment models**: Compartmental models: One and two compartmental approaches to Pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine various pharmacokinetic parameters under the conditions of Intravenous bolus injection and Intravenous infusion. Determination of mean residence time (MRT), statistical moment theory (SMT), means absorption time (MAT) and means dissolution time (MDT). Applications of pharmacokinetics (clinical applications and Design & development of	05	12-15

	novel drug delivery systems)		
2.	**Bioavailability and bioequivalence:** Bioavailability, bioequivalence, generic drugs; parameters of bioavailability, criteria for BE; Statistical aspects; study design of BE studies; validation parameters for bioanalytical methodology; bioequivalence requirements for IND/NDA/ANDA products; BE studies of highly variable drugs, narrow therapeutic index drugs, modified release dosage forms and biotechnology products.	06	12-15
3.	**Bioprocess Technology:** Introduction to bioprocess technology, Fermenter design, types of Fermentation, downstream processing.	04	10-15
4.	**Formulation of Biologicals:** Formulation of erythropoietin, interferons, insulin, growth hormones, follicle stimulating hormone (FSH). Stabilization aspect of biologicals. Drying techniques: spray, freeze, and supercritical fluid drying.	06	12-20
5.	**Biomedical applications in Drug Delivery:** Introduction to molecular electronics- field emission and shielding microelectromechanical systems, molecular and supramolecular switches for intracellular drug delivery, bionsensors, microfabricated nanochannels, plasma assisted immobilization of bioactive molecules for biomedical and biotechnological applications.	06	10-15
6.	**Informatics and database management:** Fundamentals and applications of predictive pharmaceutics, chemicopharmaceutics, cheminformatics, bioinformatics and data mining.	02	08-15
7.	**Blood products & Plasma substitutes**: Whole human blood, Dried human plasma, human gamma globulins, clinical dextran and absorbable hemostats. Labeling and storage conditions. FDA Guidelines for preparation, storage and use of blood and its products.	03	08-15
8.	**Regulation of product development and marketing:** Pharmaceutical, medical and health-related government and regulatory bodies at national and international level. Bodies like International Conference on Harmonisation (ICH), World Health Organization (WHO), European Medicines Agency (EMEA), Department of Health (South Africa), Association of the British Pharmaceutical Industry (ABPI), Medicines and Healthcare Products Regulatory Agency (MHRA), The Food and Drug Administration (FDA), Therapeutic Goods Administration (TGA).	04	08-10

(vi) Recommended Reading:

a) Basic Reading:

1. Shein-Chung Chow and Jen-Pei Liu. Biostatistics: Design and Analysis of Bioavailability and Bioequivalence studies, New York, Marcel Dekker, 2000.
2. William Hoyle, Pilot plant & scale up of chemical process , Royal society of chemistry , information services , 1997.
3. Elaine Whitmore , Development of FDA – Regulated Medical Products, ASQ (American society for quality) 2003
4. Bramhankar D. M. and Jaiswal S. B. Biopharmaceutics and Pharmacokinetics A Treatise; Vallabh Prakashan..
5. Jean- Pierre Labaune. Handbook of Pharmacokinetics; John Wiley Sons.
6. WHO Model Formulary 2008 by Mark C. Stuart , Moria Kouimtzi , WHO organization , Suzanne R. Hill.
7. Safe Blood and Blood Product distance learning material by WHO 2002.

b) Additional Reading:

1. Introduction: Process Analytical Technology, http://www.fda.gov/der/OPS/PAT.htm.
2. Moser Anton, Bioprocess technology kinetics and reactors, Springer-Verlag, 1988.
3. Enfors Seven-olof; Haggstorm Lena, Bioprocess technology fundamentals and applications, Royal Institute of technology, 2000.
4. Gad Shane Cox, Handbook of pharmaceutical biotechnology, A John Wiley and sons Inc. 2007.

c) References:

i) Books:

1. Patient Package Insert as a Source of Drug Information Edited by M. Bogaert, R. v. d. Stichele, J. -M. Kaufman, R. Lefebvre, Excerpta Medica.
2. Remington, the science and practice of pharmacy, Lippincott Williams & Wilkins, 2000.
3. Gertz Michael, Bertram Ludascher (Eds.), Scientific & statistical database management, Springer publication.
4. Sandro fiore, Giovanni Aloisio Editors, Grid & Cloud Database Management, Springer publication 2011.
5. Marko Zlokarnik, Scale up in chemical engineering, Wiley, VCH Verlag GmbH and Company. 2005.

ii) Periodicals/Journals:

1. Indian Journal of Pharmaceutical Sciences

2. Pharmaceutical Technology
3. Indian Journal of Biotechnology

OTHER FEATURES*

*Except list of LABORATORY EQUIPMENTS (c), all points (1, 2, 3, 4) coming under OTHER FEATURES from Syllabus of M. PHARM., (Pharmaceutical Chemistry) are same.

(c) LABORATORY EQUIPMENTS:

In addition to routine equipments like hot air oven, incubator, pH meter, etc. following specific equipments are necessary.

1. Tablet mini press (Shared)
2. Tablet Coating Pan (Shared)
3. Dissolution Test Apparatus
4. Stability Chamber (shared)
5. Sonicator (shared)
6. High Speed Homogenizer
7. Particle Size Analyzer – Melvern (desirable)
8. Microscope with Computer Interface (shared)
9. Gel Permeation Chromatograph (desirable)
10. Freeze Dryer (desirable)
11. Spray Dryer (shared)
12. Deep Freezer (shared)
13. Brookfield Viscometer (shared)
14. Karl Fisher Titrator
15. UV-Visible Spectrophotometer (shared)
16. FTIR (shared)
17. HPLC (shared)

SYLLABUS FOR M. PHARM (PHARMACEUTICAL ANALYSIS)

SPECIALIZATION: PHARMACEUTICAL ANALYSIS

(i) Course objectives:

1. To develop competent analysts with an ability to provide knowledge and skill based analytical solutions for food, drug and cosmetic analysis.
2. To equip graduates with analytical skills essential for practically handling qualitative and quantitative analysis of all substances and materials used and produced in food, drug and cosmetic manufacturing.
3. To provide graduates advanced training in analytical instrumentation and related trouble shooting.
4. To facilitate updation of understanding of various regulatory guidelines concerned with assessment and assurance of quality of food, drug and cosmetics.

ii) Paper : 2 THEORY

iii) Title of Paper : ADVANCED PHARMACEUTICAL ANALYSIS-I APA-I

iv) Specific Objectives:

1. To improve the awareness about the methodology and significance of calibration and validation of analytical instruments.
2. To enhance the understanding about various applications of spectroscopic, thermal and chemical analysis.
3. To familiarize the graduates about the interdisciplinary nature of pharmaceutical analysis with specific reference to the chemistry involved in physical and physicochemical methods of analysis.

v) Note:

1. Basic knowledge of organic and physical chemistry is a prerequisite. Molecular interaction simulations in the form of images and videos can be used to improve understanding of the separation phenomenon.
2. Students should understand significance of calibration in minimization of analytical errors.
3. They should be able to explore importance of validation in getting correct results from analytical instruments.

APA-I ADVANCED PHARMACEUTICAL ANALYSIS-I Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1.	**UV-Visible Spectroscopy:** Introduction, calibration, validation and applications in qualitative and	05	12-14

quantitative analysis (in brief), Woodward-Fisher rule.

2.	**IR-Spectroscopy:** Introduction, calibration, validation and application (in brief) of IR and FT-IR spectroscopy.	06	12-14
3.	**NMR Spectroscopy:** Introduction, calibration, validation and application (in brief) of P-NMR and C-NMR.	05	12-12
4.	**Mass Spectroscopy:** Introduction, calibration, validation and application (in brief).	04	10-12
5.	**Atomic Absorption and Atomic Emission spectroscopy:** Introduction, calibration, validation and application.	04	08-12
6.	**Thermal Analysis:** Theory and applications of Thermo gravimetric Analysis, Differential Thermal Analysis, Differential Scanning Calorimeter.	06	10-12
7.	**Named Reactions, their mechanism and application in drug analysis:** Grignard, Perkin, Darzen, Mannich and Merrifield solid phase synthesis.	03	08-12
8.	**Karl- Fischer Titration:** Introduction, reagents instrumentation, calibration, validation and application (in brief) of Karl- Fischer Titration.	03	08-12

(vi) Recommended Reading:

a) Basic Reading:

1. Beckett, A. H. and Stenlake, J. B. Text book of Practical Pharmaceutical chemistry, Vol. I & II, CBS publishers and distributors, U.K. 1988.
2. Chatwal, G. R. and Anand, S. K. Instrumental Methods of Chemical Analysis, 5th edition, Himalaya Publishing House, Mumbai, 2003.
3. Kemp, W. Organic Spectroscopy, 3rd edition, Palgrave, New Yark, 1991.
4. Pal, P.K. and Ganesan, M. Bioavailabity and Bioequivalence in Pharmaceutical Technology, 1st edition, CBS Publishers and Distributors, New Delhi. 1999.
5. Sharma, B. K. Instrumental Methods of Chemical Analysis, 20th edition, Krishna Prakashan Media (P) Ltd. Meerut, 2001.
6. Silverstein, R. M. and Webstar, F. X. Spectrometric identification of organic compounds.
7. Ministry of Health and Family Welfare, Indian Pharmacopoeia, 4th edition, Government of India, CBS Publishing House, New Delhi, 1996.

b) Additional Reading:

1. Snyder, L. R., Kirkland, J. J. and Glajch, J. L. Practical Method Development, 2nd edition, John Wiley and Sons, Inc., Hoboken, 1997.
2. Conners, K.A. A Textbook of Pharmaceutical Analysis, 3rd edition, Wiley-Interscience Publication, John Wiley & Sons, New Yark, 1982.
3. Floray, K. Analytical profiles of Drug Substances, Academic Press, 2005.

c) References:

i) Books:

1. Skoog, D. A., Holler, F. J. and Timothy, A. N. Principles of Instrumental Analysis, 5th edition, Saunders College Publishing. Harcourt Brace College Publishers. Sweeden, 2005.
2. Schirmer, R. E. Modern Methods of Pharmaceutical Analysis, 2nd edition, CRC Press, Florida, 1991.
3. Willard, et.al, Instrumental Methods of Analysis, 7th edition, CBS Publishers and Distributors, Delhi, 1986.

ii) Periodicals/Journals:

1. Tony Owen Fundamentals of modern UV-visible spectroscopy
2. Savitzky, A.; Golay, M. Anal. Chem., 1964, 36, 1627–1639.
3. Macadam, D.L. Colour Measurement, Springer: Berlin, 1981.
4. Chamberlain, G.J.; Chamberlain, D.G. Colour; its measurement, computation and application, Heyden: London, 1980.
5. Levine, R.L.; Federici, M.M. "Quantification of aromatic residues in proteins; model compounds for second derivative spectroscopy"; Biochemistry, 1982, 21, 2600– 2606.
6. Kisner, H.J.; Brown, W.B.; Kavarnos, G.J. "Multiple analytical frequencies and standards for the least-squares analysis of serum lipids"; Anal. Chem. 1983, 55, 1703.
7. Maris M.A.; Brown, C.W.; Lavery, D.S. "Nonlinear multicomponent analysis by infrared spectrophotometry"; Anal. Chem., 1983, 55, 1694
8. Pharmeuropa, Special Edition, Technical Guide, Council of Europe: Strasbourg, 1993.
9. Standards in Absorption Spectrometry, Techniques in Visible and Ultraviolet Spectrometry: Volume 1; Burgess, C.; Knowles, A., Eds.; Chapman & Hall: London, 1981.

i) Paper : 2 PRACTICAL

ii) Title of Paper : ADVANCED PHARMACEUTICAL ANALYSIS-I APA-I

iii) Specific Objectives:

1. To improve skills for precise and accurate qualitative and quantitative analysis of drugs, phytoconstituents, excipients and products containing multiples of these components.
2. To improve skills for performance of microbiological assays and manipulations to serve the practical objectives.
3. To update and improve skill sets essential for structure elucidation of drugs and related products from physical, physicochemical and chemical characterization.

iv) Note:

1. Basic knowledge of semi-micro qualitative chemical analysis, microbiology and spectroscopic analysis is a prerequisite.

APA-I ADVANCED PHARMACEUTICAL ANALYSIS-I Practical (6 hrs/wk)

Unit	Experiments
1.	Chemical Tests for Identification of Alkaloids, Glycosides and steroids in extracts.
2.	To carry out microbiological assay of antibiotics by Cup Plate and turbidimetric method
3.	UV spectroscopic analysis of two component formulation by simultaneous equation and differential spectroscopic method
4.	Visible spectroscopic method development involving transition metal and ion pair complex
5.	Proposing structures of compounds at least three on analysis of UV, IR, NMR and mass spectra
6.	DSC and XRD spectra analysis to study drug-excipient interactions
7.	Particle size analysis by calibrated Nephalo-turbidimetry
8.	ED50 and LD50 Estimation and Probit analysis

(vi) Recommended Reading:

a) Basic Reading:

1. Silverstein, R. M. and Webstar, F. X. Spectrometric identification of organic compounds.

2. Siddiqui, A.A. Natural products Chemistry: Practical Manuals.
3. Wilkinson, J. B.and Moore, R. J. Harry's cosmetology.
4. Kokare, C.R. Textbook of Practical Biotechnology.
5. Sharma, B. K. Instrumental Methods of Chemical Analysis, 20th edition, Krishna Prakashan Media (P) Ltd. Meerut, 2001.
6. Martin, Swarbrick and Commarata Physical Pharmacy.
7. Kemp, W. Organic Spectroscopy, 3rd edition, Palgrave, New Yark, 1991.
8. Vogel, G. H. Drug discovery and evaluation, pharmacological assay, 2nd edition, Springer, 2002.

b) Additional Reading:

1. Beckett, A. H. and Stenlake, J. B. Text book of Practical Pharmaceutical chemistry, Vol. I & II, CBS publishers and distributors, U.K. 1988.
2. Chatwal, G. R. and Anand, S. K. Instrumental Methods of Chemical Analysis, 5th edition, Himalaya Publishing House, Mumbai, 2003.
3. Kokate, C. K.; Purohit, A. P. and Gokhale S. B Textbook of Pharmacognosy.
4. Snyder, L. R., Kirkland, J. J. and Glajch, J. L. Practical Method Development, 2nd edition, John Wiley and Sons, Inc., Hoboken, 1997.
5. Conners, K.A. A Textbook of Pharmaceutical Analysis, 3rd edition, Wiley-Interscience Publication, John Wiley & Sons, New Yark, 1982.
6. Floray, K. Analytical profiles of Drug Substances, Academic Press, 2005.

c) References:

i) Books:

1. Skoog, D. A., Holler, F. J. and Timothy, A. N. Principles of Instrumental Analysis, 5th edition, Saunders College Publishing. Harcourt Brace College Publishers. Sweeden, 2005.
2. Schirmer, R. E. Modern Methods of Pharmaceutical Analysis, 2nd edition, CRC Press, Florida, 1991.
3. Willard, et.al, Instrumental Methods of Analysis, 7th edition, CBS Publishers and Distributors, Delhi, 1986.

ii) Periodicals/Journals:

1. Wang, L. and Asgharnejad, M. (2000). Second-derivative UV spectrometric determination of simvastatin in its tablet dosage form. J. Pharm. Biomed. Anal., 21, 1243- 1248.
2. Alaa El-Gindy , Ahmed Ashour , Laila Abdel-Fattah ,Marwan M. Shabana , HPLC and HPTLC-densitometry method for the simultaneous determination of benazepril hydrochloride and hydrochlorothiazide , J. Pharm. Biomed. Anal, 25 ,2001, 171–179.
3. Argekar A. P. and Sawant J. G.; ' A gradient reversed phase HPLC method for simultaneous determination of hydrochlorthaizide and losartan potassium

from tablet'; Anal. Lett., 2000,33(5),869-880

4. Barman RK, Anwar UL. Simultaneous high-performance liquid chromatographic determination of atenolol and amlodipine in pharmaceutical-dosage form, Pak. J. Pharm. Sci., 2007; 20: 274-279.
5. Basvaiah, K., Chandrashkher, U. and Nagegowda, P., Titrimetric, Spectrophotometric and kinetic methods of atenolol using bromated – bromide and methyl orange. J. Serb. Soci. Chemicals, 2006, 71, 5, 553-563.

ii) Paper : 2 THEORY

iii) Title of Paper : ANALYTICAL INSTRUMENTATION AND TECHNOLOGY AIT

iv) Specific Objectives:

1. To familiarize graduates with engineering aspects of analytical instruments with an objective of understanding maintenance and troubleshooting.
2. To equip students with preliminary skills essential to assess the functional status of analytical instruments commonly used in chemical, biological, food and pharmaceutical industries**.**

iv) Note:

1. Basic knowledge of physicochemical properties of matter, spectroscopy and physical chemistry is a prerequisite.

AIT ANALYTICAL INSTRUMENTATION AND TECHNOLOGY Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**pH, Conductivity and dissolved component analysis:** Instrumentation and engineering of Conductivity meters and pH meters, dissolved oxygen, hydrogen analyzers – sodium analyzer, silica analyzer and sampling systems	06	10-12
2.	**Gas analyzers**: Instrumentation and engineering of all detectors. Thermal conductivity types, CO monitors, NOX analyzers, oxygen analyzer, paramagnetic type, detectors and sampling systems. H2S analyzer system and sampling, Industrial analyzer circuits, Theory and problems on Beer and Lambert laws.	06	10-13
3.	**UV, VIS Spectrophotometers – Instrumentation and engineering of** single beam, double beam and other variants, Instrumentation associated with the above Spectrophotometers, Light sources, optics and detectors.	05	12-15
4.	**Flame emission and atomic absorption spectrophotometer** – Instrumentation and engineering of atomic absorption and flame emission spectrophotometer, sources for Flame Photometers and online calorific value measurements.	04	8-10
5.	**NMR and Mass Spectrophotometry**: Instrumentation and engineering of NMR Spectrophotometer and mass spectrophotometers.	04	10-12
6.	**Radio Activity Measurement**: Instrumentation and engineering of Nuclear radiation detectors, Ionization chamber, GM Counter,	04	10-13

Proportional Counter, Solid state detectors.

7.	**ESR Spectrophotometry**: Instrumentation and engineering of ESR spectrophotometry	03	8-10
8.	**FT-IR Spectrometer** - Instrumentation and engineering of IR Spectrophotometers.	04	12-15

(vi) Recommended Reading:

a) Basic Reading:

1. Sharma, B. K. Instrumental Methods of Chemical Analysis, 20th edition, Krishna Prakashan Media (P) Ltd. Meerut, 2001.
2. Beckett, A. H. and Stenlake, J. B. Text book of Practical Pharmaceutical chemistry, Vol. I & II, CBS publishers and distributors, U.K. 1988.
3. Willard, et.al, Instrumental Methods of Analysis, 7th edition, CBS Publishers and Distributors, Delhi, 1986.
4. Chatwal, G. R. and Anand, S. K. Instrumental Methods of Chemical Analysis, 5th edition, Himalaya Publishing House, Mumbai, 2003.
5. Hamilton, R. J. Introduction to High Performance Liquid chromatography.

b) Additional Reading:

1. Khandpur, T. M. H Handbook of Analytical Instruments.
2. Jones, B.E. Instrument Technology,Butterworth Scientific Publ., London, 1987.
3. Jain, R.K. Mechanical and Industrial Measurements, Khanna Publishing, New Delhi, 2/e, 1992.
4. Mann, C.K.; Vickerks T.J. and Gullick W.H. Instrumental Analysis, Harper and Row Publishers, New York, 1974.

c) References:

i) Books:

1. Skoog, D. A., Holler, F. J. and Timothy, A. N. Principles of Instrumental Analysis, 5th edition, Saunders College Publishing. Harcourt Brace College Publishers. Sweeden, 2005.
2. Schirmer, R. E. Modern Methods of Pharmaceutical Analysis, 2nd edition, CRC Press, Florida, 1991.
3. Floray, K. Analytical profiles of Drug Substances, Academic Press, 2005.
4. Kemp, W. Organic Spectroscopy, 3rd edition, Palgrave, New Yark, 1991.
5. Conners, K.A. A Textbook of Pharmaceutical Analysis, 3rd edition, Wiley-Interscience Publication, John Wiley & Sons, New Yark, 1982.

6. http://jntu.ac.in/dap/syl.html

ii) Periodicals/Journals:

1. Vibrational Spectroscopy, Elsevier Publication (Science Direct).
2. International Journal of Measurement Technologies and Instrumentation Engineering, IGI Global Publishing House.
3. Industrial and Engineering Chemistry, ACS Publications.
4. Fourier-Transform Spectroscopy Instrumentation Engineering, SPEI Digital Library.
5. Journal of Instrumentation, IOP Science.
6. Journal of Near Infrared Spectroscopy, IM Publications.
7. Journal of Applied Spectroscopy, Springer Publishing House.
8. http://www.engineering-resource.com/Files/Instrumentation%20Reports/07-chem-63.pdf
9. www.eutechinst.com/brochures/.../eutech_plus_series_family.pdf
10. depts.washington.edu/uwmip/Week_3/RadDetect08.pdf

i) Paper : 6 THEORY

ii) Title of Paper : ADVANCED PHARMACEUTICAL ANALYSIS-II APA-II

iii) Specific Objectives:

1. To develop understanding of factors affecting separation in various chromatographic techniques/electrophoresis for application to developing solutions for separations of complex mixtures and pharmaceutical formulations.
2. To equip graduates with knowledge about reference standards and various guidelines for validation of analytical methods involving chromatographic/electrophoretic analysis. And separation and about all technical aspects with basic principles of method development in brief.

iv) Note:

1. Basic knowledge of organic and physical chemistry is a prerequisite. Molecular interaction simulations in the form of images and videos can be used to improve understanding of the separation phenomenon.

APA-II ADVANCED PHARMACEUTICAL ANALYSIS-II Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1.	**HPLC and UPLC:** Introduction, principle, chemistry of stationary phases, stationary and mobile phase selection, retention parameters and their correlation, calibration, validation and applications.	06	12-14
2.	**Methods for Sensitivity and Selectivity Enhancement in HPLC:** Pre-column Derivatization, Post-column Derivatization, Ion Suppression and Ion Pair chromatography.	05	12-14
3.	**HPTLC:** Introduction, principle, Instrumentation, calibration, validation and applications.	05	10-12
4.	**Hyphenated Techniques:** GC-MS, LC-MS, LC-MS-MS, LC-NMR and their application in structural elucidation and quantitative analysis of complex mixtures.	05	10-12
5.	**Chromatographic Method Development:** Objective, principle, steps involved in resolution and peak shape optimization, techniques for method development, sample preparation and HPLC assay of multi-component formulations containing hydrochlorothiazide official in USP with reference to choice of stationary and mobile phase.	04	10-12

6.	**Validation:** Guidelines for analytical and bio-analytical methods validation as per ICH, AOAC and USFDA guidelines.	03	08-12
7.	**Reference Standards:** Introduction, preparation, types, storage, record keeping and validation. USP-NF reference standards, compendial reference standards, non-compendial reference standards and their applications in analysis.	04	10-12
8.	**Electrophoresis:** Introduction stationary phases, mobile phases and application of paper, starch, agarose gel, acrylamide and Capillary electrophoresis.	04	08-12

(vi) Recommended Reading:

a) Basic Reading:

1. Snyder, L. R., Kirkland, J. J. and Glajch, J. L. Practical Method Development, 2nd edition, John Wiley and Sons, Inc., Hoboken, 1997.
2. Ministry of Health and Family Welfare, Indian Pharmacopoeia, 4th edition, Government of India, CBS Publishing House, New Delhi, 1996.
3. United State Pharmacopeia and National Formulary.
4. Sharma, B. K. Instrumental Methods of Chemical Analysis, 20th edition, Krishna Prakashan Media (P) Ltd. Meerut, 2001.
5. Pal, P.K. and Ganesan, M. Bioavailabity and Bioequivalence in Pharmaceutical Technology, 1st edition, CBS Publishers and Distributors, New Delhi. 1999.
6. Beckett, A. H. and Stenlake, J. B. Text book of Practical Pharmaceutical chemistry, Vol. I & II, CBS publishers and distributors, U.K. 1988.
7. Willard, et.al, Instrumental Methods of Analysis, 7th edition, CBS Publishers and Distributors, Delhi, 1986.
8. ICH Q2A. (1994). Text on Validation of Analytical Procedures.
9. ICH Q2B. (1996). Validation of Analytical Procedures: Methodology.
10. USFDA guidelines for Bio-analytical method validation.
11. Kemp, W. Organic Spectroscopy, 3rd edition, Palgrave, New Yark, 1991
12. Chatwal, G. R. and Anand, S. K. Instrumental Methods of Chemical Analysis, 5th edition, Himalaya Publishing House, Mumbai, 2003.
13. Hamilton, R. J. Introduction to High Performance Liquid chromatography.

b) Additional Reading:

1. Conners, K.A. A Textbook of Pharmaceutical Analysis, 3rd edition, Wiley-Interscience Publication, John Wiley & Sons, New Yark, 1982.
2. Floray, K. Analytical profiles of Drug Substances, Academic Press, 2005.

c) References:

i) Books:

1. Skoog, D. A., Holler, F. J. and Timothy, A. N. Principles of Instrumental Analysis, 5th edition, Saunders College Publishing. Harcourt Brace College Publishers. Sweeden, 2005.
2. Schirmer, R. E. Modern Methods of Pharmaceutical Analysis, 2nd edition, CRC Press, Florida, 1991.

ii) Periodicals/Journals:

1. Wang, L. and Asgharnejad, M. (2000). Second-derivative UV spectrometric determination of simvastatin in its tablet dosage form. J. Pharm. Biomed. Anal., 21, 1243- 1248.
2. Alaa El-Gindy , Ahmed Ashour , Laila Abdel-Fattah ,Marwan M. Shabana , HPLC and HPTLC-densitometry method for the simultaneous determination of benazepril hydrochloride and hydrochlorothiazide , J. Pharm. Biomed. Anal, 25 , 2001, 171–179.
3. Argekar A. P. and Sawant J. G.; ‘ A gradient reversed phase HPLC method for simultaneous determination of hydrochlorthaizide and losartan potassium from tablet’; Anal. Lett., 2000, 33(5),869-880
4. Barman RK, Anwar UL. Simultaneous high-performance liquid chromatographic determination of atenolol and amlodipine in pharmaceutical-dosage form, Pak. J. Pharm. Sci., 2007; 20: 274-279.
5. Basvaiah, K., Chandrashkher, U. and Nagegowda, P., Titrimetric, Spectrophotometric and kinetic methods of atenolol using bromated – bromide and methyl orange. J. Serb. Soci. Chemicals,2006, 71, 5, 553-563.
6. Huba Kalász, Maria Báthori Pharmaceutical Applications of TLC LC•GC Europe - May 2001
7. D.H. Shewiyo, E. Kaaleb , P.G. Rishab, B. Dejaegherc, J. Smeyers-Verbekec , Y. Vander Heyden HPTLC methods to assay active ingredients in pharmaceutical formulations: A review of the method development and validation steps Journal of Pharmaceutical and Biomedical Analysis 66 (2012) 11–23.

i) Paper : 6 PRACTICAL

ii) Title of Paper : ADVANCED PHARMACEUTICAL ANALYSIS-II APA-II

iii) Specific Objectives:

1. To improve skills for precise and accurate qualitative and quantitative analysis of drugs, phytoconstituents, excipients and products containing multiples of these components.
2. To improve skills for performance of microbiological assays and manipulations to serve the practical objectives.
3. To update and improve skill sets essential for structure elucidation of drugs and related products from physical, physicochemical and chemical characterization.

iv) Note:

1. Basic knowledge of spectroscopic and chromatographic analysis is a prerequisite.

APA-II ADVANCED PHARMACEUTICAL ANALYSIS-II Practical (6 hrs)

Unit	Experiments
1.	Fluorometric assay of pharmaceuticals
2.	Study of simple chemical changes on λ max and absorbtivity of chemical compounds and drugs
3.	Development and validation of UV-Visible spectrophotometric method for multi-component pharmaceutical formulations
4.	Identification and separation of drugs by paper, thin layer and column chromatography
5.	Structural Elucidation using UV-Visible, IR, NMR and Mass spectroscopy
6.	Estimation of drugs from body fluids
7.	Identification and separation of drugs and their related products

(vi) Recommended Reading:

a) Basic Reading:

1. Beckett, A. H. and Stenlake, J. B. Text book of Practical Pharmaceutical chemistry, Vol. I & II, CBS publishers and distributors, U.K. 1988.
2. Silverstein, R. M. and Webstar, F. X. Spectrometric identification of organic compounds.
3. Kokare, C.R. Textbook of Practical Biotechnology.
4. Pal, P.K. and Ganesan, M. Bioavailabity and Bioequivalence in Pharmaceutical

Technology, 1st edition, CBS Publishers and Distributors, New Delhi. 1999.

5. Kemp, W. Organic Spectroscopy, 3rd edition, Palgrave, New Yark, 1991.
6. Chatwal, G. R. and Anand, S. K. Instrumental Methods of Chemical Analysis, 5th edition, Himalaya Publishing House, Mumbai, 2003.
7. Sharma, B. K. Instrumental Methods of Chemical Analysis, 20th edition, Krishna Prakashan Media (P) Ltd. Meerut, 2001.
8. Ministry of Health and Family Welfare, Indian Pharmacopoeia, 4th edition, Government of India, CBS Publishing House, New Delhi, 1996.
9. Kasture, A.V.; Wadodkar, S. G.; Mahadik, S.G. and More, H. N. Pharmaceutical Analysis, Vol-I, 10th edition, Nirali Prakashan, Pune., 2004.
10. Willard, et.al, Instrumental Methods of Analysis, 7th edition, CBS Publishers and Distributors, Delhi, 1986.

b) Additional Reading:

1. Snyder, L. R., Kirkland, J. J. and Glajch, J. L. Practical Method Development, 2nd edition, John Wiley and Sons, Inc., Hoboken, 1997.
2. Conners, K.A. A Textbook of Pharmaceutical Analysis, 3rd edition, Wiley-Interscience Publication, John Wiley & Sons, New Yark, 1982.
3. Vogel, G. H. Drug discovery and evaluation, pharmacological assay, 2nd edition, Springer, 2002.
4. Floray, K. Analytical profiles of Drug Substances, Academic Press, 2005.

c) References:

i) Books:

1. Skoog, D. A., Holler, F. J. and Timothy, A. N. Principles of Instrumental Analysis, 5th edition, Saunders College Publishing. Harcourt Brace College Publishers. Sweeden, 2005.
2. Schirmer, R. E. Modern Methods of Pharmaceutical Analysis, 2nd edition, CRC Press, Florida, 1991.

ii) Periodicals/Journals:

1. Wang, L. and Asgharnejad, M. (2000). Second-derivative UV spectrometric determination of simvastatin in its tablet dosage form. J. Pharm. Biomed. Anal., 21, 1243- 1248.
2. Alaa El-Gindy , Ahmed Ashour , Laila Abdel-Fattah ,Marwan M. Shabana , HPLC and HPTLC-densitometry method for the simultaneous determination of benazepril hydrochloride and hydrochlorothiazide , J. Pharm. Biomed. Anal, 25 ,2001, 171–179.
3. Argekar A. P. and Sawant J. G.; ' A gradient reversed phase HPLC method for simultaneous determination of hydrochlorthaizide and losartan potassium from tablet'; Anal. Lett., **2000,**33(5),869-880
4. Barman RK, Anwar UL. Simultaneous high-performance liquid chromatographic determination of atenolol and amlodipine in pharmaceutical-dosage form, Pak. J. Pharm. Sci., 2007; 20: 274-279.
5. Basvaiah, K., Chandrashkher, U. and Nagegowda, P., Titrimetric, Spectrophotometric and kinetic methods of atenolol using bromated – bromide and methyl orange. J. Serb. Soci. Chemicals,2006, 71, 5, 553-563.

i) Paper : 7 THEORY

ii) Title of Paper : FOOD, BIOLOGICALS AND COSMETIC ANALYSIS FBCA

iii) Specific Objectives:

1. To improve the awareness about the methodology, significance and regulations pertaining to analysis of food, cosmetics, nutraceuticals and herbal medicine.
2. To enhance the understanding of the application of chemical, biochemical and instrumental methods of analysis to food, biologicals and cosmetics.
3. To equip graduates with necessary analytical skill set for seeking employment in the food, nutraceutical, cosmetic and wine manufacturing and developing industries.

iv) Note:

1. Basic knowledge of organic, physical and bio- chemistry and biology is a prerequisite.

FBCA FOOD, BIOLOGICALS AND COSMETIC ANALYSIS Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Analysis of food:** Analytical methods for food constituents like carbohydrates, fats and proteins with special emphasis on determination of moisture, ash, elemental analysis, trace component analysis, physical constants and toxicological testing (NELA and FDA).	05	12-14
2.	**Analytical Methods for milk products:** Methods for analysis of milk, milk constituents and milk products like ice products, milk powder, butter, cheese including adulterants and contaminants of milk.	06	12-15
3.	**Analysis of fermentation products like wine, spirits, beer and vinegar.**	03	6-8
4.	**Analysis of Cosmetics:** Analysis of raw materials used in cosmetic industry including quality control tests for the following products such as baby care, skin care products, dental products, personal hygiene preparations, lips sticks, hair products, antiperspirants, deodorant, sunscreen skin creams. CTFA guidelines for cosmetic stability, in relation to ingredients and finished products.	07	12-15
5.	**Safety legislation to cosmetic products and different toxicity tests for cosmetics.**	03	6-8

6.	**Nutraceuticals:** Concept, use and testing as per USP-NF, guidelines for raw material and final products of various nutra-ceuticals.	04	10-12
7.	**Analytical Techniques used in Food, Cosmetic and Nutra-ceuticals analysis:** Principle and applications of Near IR, SP Radio-immune assay, Raman spectroscopy, X ray fluorescence, Particle size analysis, ICP in Analysis of Food, Cosmetic and Nutra-ceuticals.	04	12-14
8.	**Herbal Medicines:** Standard requirement of herbal medicines, traditional and folk remedies, preparation and their quality, safety and efficacy assessment with respect to WHO and FDA guidelines	04	10-14

(vi) Recommended Reading:

a) Basic Reading:

1. The Chemical Analysis of Foods and Food Products (1938), Morris Boris Jocobs, Van Nostrand Co., Inc., New York City.
2. Hand Book of Analysis and Quality Control for Fruit and Vegetable Products (2nd Edition, 2004), S. Ranganna, McGraw Hill Education.
3. Official Methods of Analysis (1990), Association of Official Analytical Chemists.
4. Analysis of Food Constituents (1997), Jean Louis Multon, Lance Dieter, Wiley – VCH.

b) Additional Reading:

1. Hand Book of Cosmetic Sciences and Technology (3rd Edition, 2009), Andre O. Barel, Marc PAYE, Howard I. Maibach, Informa Healthcare USA, Inc
2. Modern Cosmetics. By Edgar George Thomssen, Francis Chilson(1947). Drug and Cosmetic Industry.
3. Harry's Cosmetology (8th Edition, Volume 2, 2000), Ralph Gordon Harry, Martin M. Rieger, Chemical Publishing Company.

c) References:

i) Books:

1. Introduction of Chemical Analysis of Food (1994), Nielsen, S. Suzanne Nielsen, Jones and Bartlett Publishers.
2. The Chemical Analysis of Food (1938), Edward Cox Henry, David Pearson. J. and A. Churchill Limited.

ii) Periodicals/Journals:

1. Journal of Food Composition and Analysis, Elsevier Publication (Science

Direct).
2. Journal of Trace Analysis in Food and Drugs, Columbia International Publishing.
3. Journal of Food Science, Wiley Online Library.
4. Journal of Near Infrared Spectroscopy, IM Publications.
5. Journal of Raman Spectroscopy, Wiley Online Library.
6. http://lactose.ru/present/4Rachid_Kouaouci.pdf
7. http://ebookbrowse.com/analytical-methods-dry-milk-products-pdf-d246549596
8. International Journal of Food Sciences and Nutrition,
9. http://www.niro.com/niro/cmsdoc.nsf/webdoc/ndkw6tmfag
10. www.niro.com/niro/cmsdoc.nsf/webdoc/ndkw6tmfag
11. proj3.sinica.edu.tw/~chem/servxx6/.../paper_7365_1233827183.pdf
12. safecosmetics.org/downloads/PrettyScary_Oct2709.pdf dravyagunatvpm.files.wordpress.com/2010/10/nutraceutical.pdf
13. www.ker.com/library/advances/203.pdf
14. rjptonline.org/RJPT_%20Vol1(4)/6.pdf

OTHER FEATURES*

*Except list of LABORATORY EQUIPMENTS (c), all points (1, 2, 3, 4) coming under OTHER FEATURES from Syllabus of M. PHARM., (Pharmaceutical Chemistry) are same.

(c) LABORATORY EQUIPMENTS:

In addition to routinely required equipments like melting/boiling point apparatus, pH meter, oven, incubator, conductometer, computers, etc. the following specific equipments and accessories are necessary.

1. HPLC
2. Double beam UV-Vis spectrophotometer
3. IR spectrophotometer (shared)
4. Flame photometer
5. Digital polarimeter
6. Fluorimeter
7. Karl Fischer Titrator
8. Electrophoresis system
9. Cooling centrifuge (shared)
10. Ultrasonicator

SYLLABUS FOR M. PHARM (QUALITY ASSURANCE TECHNIQUES)*

*Syllabus for M. PHARM (QUALITY ASSURANCE TECHNIQUES) is same as that of M. PHARM (QUALITY ASSURANCE), as given earlier.

SYLLABUS FOR M. PHARM. (PHARMACEUTICS DRUG REGULATORY AFFAIRS)

SPECIALIZATION: PHARMACEUTICS DRUG REGULATORY AFFAIRS

(i) Course objectives:

The major objective of this course is to provide an interdisciplinary knowledge of pharmacy and law as applicable in the field of pharmaceutical regulation. This course will help them understand the fundamental and concepts of regulation prevailing in various countries. The course prepares the students to pursue career in pharmaceutical industry, drug licensing and control authorities, and export-import agencies dealing with the pharmaceuticals. It will enhance their knowledge and skills in the field of Regulatory affairs.

The objectives of the course are:

1. To create experts in the field of RA documentation and research.
2. To encourage continuous learning and development in RA field.
3. To update knowledge of existing RA professionals.

ii) Paper : 2 THEORY

iii) Title of Paper: DRUG REGULATORY AFFAIRS –I DRA-I

iv) Specific Objectives:

1. To provide knowledge to the student about drug substances, drug product development, analytical research, method development for inprocess control, manufacturing, quality control and quality assurance.

v) Note:

1. Students shall be able to understand concept of drug regulatory affairs.

DRA-I DRUG REGULATORY AFFAIRS –I Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1.	**Drug substances:** Identification and selection of chemicals and solvents, lead compound development and optimization, high through put screening (HTS), combinational chemistry, SAR optimization. Structure elucidation, process development, process validation, Demo batches, technology transfer and analytical transfer.	04	10
2.	**Drug product:** Rational of development of drug product, Preformulation study-Stage I, Product development-Stage II. As per different guidance and as per chemical patentability.Requirement for each dosage forms, process development, optimization. In-vitro drug release studies, BA/BE study requirements as per FDA and other agencies	06	15-20
3.	**Analytical Research:** Analytical API method development for reaction	05	15-20

	monitoring; KSM study, method development for drug substance, structure determination. Impurity identification and impurity guidelines ICH, Q2. Analytical method validation, including force degradation study of assay and impurity methods.		
4.	**Manufacturing:** GMP, Schedule M, Process validation, BMR preparation and Process analytical technology	08	15
5.	**Quality control:** Analysis of raw materials, In-process AND finished goods. GLP of non clinical laboratories, Working standard preparation reference standard preparation, Quality Control responsibilities.	03	05-10
6.	**Quality Assurance:** Change Control, cleaning validation, SOP preparation, quality assurance responsibilities, internal audit, and quality guideline. Validation and qualification of analytical labs and manufacturing equipment	03	05-10
7.	**Selection of Technology transfer:** Process validation, optimization, packing development, requirement of exhibit batches.	03	05
8.	**Method development for in process control:** In-vitro drug release method developments, assay method, impurity methods, dissolution method, validation & force degradation study, preformulation methods, Quality by design, Pharmaceutical experimental design and optimization. Analytical method transfer to locations exhibiting base requirements and Specification. Preparation of API, raw material and Drug product. Working standard preparations /Reference standard, potency, cancellation, dissolution calculation.	04	10

(vi) Recommended Reading:

a) Basic Reading:

1. S. Weinberg, Good laboratory practice Regulations, Marcel and Dekker.
2. J. Swarbrick Boylan, Encyclopedia of Pharmaceutical Technology, Marcel and Dekker.
3. J.R. Berry and R.A. Nash, Pharmaceutical process validation. Marcel and Dekker.
4. S.H. Will and J.R. Stoker, good manufacturing Practices for Pharmaceutics, Marcel Dekker.
5. R.F. Brewer, Design of experiments for process improvement and quality Assurance Narrosa.
6. B. Othery. ISO 14000 and ISO 9000 Gower.
7. D.H. Stamatis, Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.
8. J. F. Despautz, Automation and validation of information in Pharmaceutical

Processing, Marcel and Dekker

9. Martin A. Bustamante P. and Chun A.H. Physical Pharmacy; Wavery
10. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
11. Rubinstein M. N.; Pharmaceutical Technology, Drug stability, John Wiley and sons.
12. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.

b) Additional Reading:

1. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
2. Tarcha P. J.; Polymer for Controlled Drug Delivery, CRC Press.
3. List P. H .and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
4. Robinson; Novel Drug Delivery Systems, Marcel Dekker.

c) References:

i) Books:

1. Parikh D.M., Handbook of Pharmaceutical Granulation Technology; Marcel Dekkar
2. Brittain H. G.; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
3. Cartensen J. T.; Drug Stability; Marcel Dekker.
4. Kithard A. and Watanabe A. Electrical phemanomena at interfaces; Marcel Dekkar
5. Martin A. Bustamante P. and Chun A.H. Physical Pharmacy; Wavery
6. Alderborn G and. Nystrom C; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
7. Stanley N. G. – Wooed; Enlargement and compaction of particle solids; Butterworths.

ii) Periodicals/Journals:

1. Journal of Pharmaceutical Regulatory Affairs
2. International Journal of Pharmaceutical Sciences
3. Pharmaceutical Regulatory Affairs

i) Paper : 2 PRACTICAL

ii) Title of Paper : DRUG REGULATORY AFFAIRS –I DRA-I

iii) Specific Objectives:

1. To provide knowledge to the student about drug substances, drug product development, analytical research, method development for inprocess control, manufacturing, validation of equipment and processes, quality control and quality assurance.
2. To provide hands on trainuing for designing and drafting of documents as per different regulatory requirements.

iv) Note:

1. Students will be able to understand concept of drug regulatory affairs.

DRA-I DRUG REGULATORY AFFAIRS –I Practical (6 hrs/wk)

Unit	Contents
1.	Sterility testing of medical devices. LVP antibiotics, ophthalmic preparation.
2.	Pyrogen testing.
3.	Microbiological limit test of starch, acacia and antacid preparation.
4.	Physical and Chemical Examination of plastic containers.
5.	Examination of labels, cartons and other printed materials.
6.	Designing of key documents: SOP on SOP, IPQC, Material receipt, sampling, dispensing and storage.
7.	Experiment & documentation of dissolution test
8.	IPQC tests for Tablets / Capsules / Injections / Liquid / Ointment
9.	Validation of equipments, autoclave, hot air oven, membrane filter.
10.	Validation of process, mixing drying and compression.
11.	Validation of an analytical method.

(vi) Recommended Reading:

a) Basic Reading:

1. S. Weinberg, Good laboratory practice Regulations, Marcel and Dekker.
2. J. Swarbrick Boylan, Encyclopedia of Pharmaceutical Technology, Marcel and Dekker.

3. Berry and Nash, Pharmaceutical process validation. Marcel and Dekker.
4. S.H. Will and J.R. Stoker, good manufacturing Practices for Pharmaceutics Marcel Dekker.
5. R.F. Brewer, Design of experiments for process improvement and quality Assurance Narrosa.
6. B. Othery. ISO 14000 and ISO 9000 Gower.
7. D.H. Stamatis, Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.
8. J. F. Despautz, Automation and validation of information in Pharmaceutical Processing Marcel and Dekker
9. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
10. Rubinstein M. N.; Pharmaceutical Technology, Drug stability, John Wiley and sons.
11. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.

b) Additional Reading:

1. Tarcha P. J.; Polymer for Controlled Drug Delivery, CRC Press.
2. List P. H .and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
3. Robinson; Novel Drug Delivery Systems, Marcel Dekker.

c) References:

i) Books:

1. Parikh D.M., Handbook of Pharmaceutical Granulation Technology; Marcel Dekkar
2. Brittain H. G.; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
3. Cartensen J. T.; Drug Stability; Marcel Dekker.
4. Martin A. Bustamante P. and Chun A.H. Physical Pharmacy; Wavery
5. Alderborn G and. Nystrom C; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
6. Stanley N. G. – Wooed; Enlargement and compaction of particle solids; Butterworths.

ii) Periodicals/Journals:

1. Journal of Pharmaceutical Regulatory Affairs
2. International Journal of Pharmaceutical Sciences
3. Pharmaceutical Regulatory Affairs

i) Paper : 3 THEORY

ii) Title of Paper : DEVELOPMENT OF DOSAGE FORMS DDF

iii) Specific Objectives:

1. To understand design and development of dosage forms.
2. To understand basic concepts like optimization, preformulation, validation, packaging of pharmaceuticals, GMP, technology transfer, technology transfer of dosage forms

iv) Note:

1. The topics must be conveyed through plenty of examples. Lecture classes must be conducted as lecture-cum-power point presentations.
2. It is a course that aims to develop skills. It is therefore "practical" in orientation. Plenty of exercises of various kinds must be done by the students.
3. The teacher must not depend on a single or a set of two or three text books. He must choose his materials from diverse sources.
4. Keeping in view the requirements of his students, the teacher may have to prepare some teaching and exercise material.
5. For better understanding, good video and animated clips can be used if the more advanced facilities are available. In fact they can be used very fruitfully.

DDF DEVELOPMENT OF DOSAGE FORMS Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Preformulation studies:** Objectives and applications, fundamental & derived properties. Study of particle morphology, particle size, shape, surface area, solubility, amorphism and polymorphism. Particle Characterization by optical and electron microscopy, spectroscopy, XRPD, chromatography, thermal techniques. Studies on drug-drug and drug-excipient interactions and their characterization.	05	10-15
2.	**Design of experiments and optimization:** Design of experiment, terminologies in experimental design. Product, process and response variables. Optimization methodologies with special reference to factorial design, central composite design and mixture designs. Response surface analysis.	04	10
3.	**Validation:** Concept and need of validation, types of validation, process validation, equipment and cleaning validation, validation master plan.	04	10
4.	**Packaging of pharmaceuticals:** Types of primary and secondary packaging materials for pharmaceuticals. Studies on types and suitability evaluation of glass, plastic and rubber as a primary packaging for non-sterile and sterile dosage forms. Regulatory requirements for	04	10

pharmaceutical packaging materials.

5.	**Interpretations of current good manufacturing regulations:** GMP – 21 CFR 210 and 211, Schedule M, Process validation, selection of equipment. In brief process flow chart for each dosage form.	04	10
6.	**Biomedical Applications of Polymers:** Polymers for therapeutic applications, biocompatible and biodegradable polymers, biodegradability and biodegradability testing of polymers, applications of biodegradable polymers in parenterals and surgical, polymer-drug conjugates, self-assembled polymeric carriers (polymeric micelles, polymer-coated liposomes, nanoparticles, microspheres, etc.). Solubility of polymers, methods of polymer characterization in solution (thermodynamics of polymer solutions), Viscosity and viscoelasticity of polymers, polyelectrolytes and polyampholytes, cross-linked polymers and polymer complexes.	05	10-15
7.	**Technology transfer**: Scope, role and functions. Technology transfer of new product from bench scale to commercialization of new product. Regulatory issues, NDA, ANDA regulatory requirements. Technology transfer of product from one site to another site, third party technology transfer.	06	10-15
8.	**Technology transfer of Dosage forms**: R and D to pilot scale to plant scale studies for dosage forms like liquid orals, solid dosage forms and sterile dosage forms with equipment and SOPs.	04	10-15

(vi) Recommended Reading:

a) Basic Reading:

1. Carstensen, J. T. Pharmaceutical Preformulation. Technomic Pub. Co. Lancaster, PA, 1998.
2. Lieberman, Lachmann and Schwartz. Pharmaceutical Dosage Form Tablets. Vol-I, II, III, Marcel Dekker, New York, 2nd ed. 2008.
3. N. G. Stanley – Wooed; Enlargement and compaction of particle solids; Butterworths.
4. D. M. Parikh; Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
5. H. G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
6. A. Kitahard and A. Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
7. J. T. Cartensen; Drug Stability; Marcel Dekker.
8. G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction

Technology; Marcel Dekker.

b) Additional Reading:

1. A. Martin, P. Bustamante and A. H. Chun; Physical Pharmacy; Waverly.
2. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
3. M. N. Rubinstein; Pharmaceutical Technology, Drug stability, John Wiley and sons.
4. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.
5. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
6. P. J. Tarcha; Polymer for Controlled Drug Delivery, CRC Press.
7. P. H. List and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
8. Robinson; Novel Drug Delivery Systems, Marcel Dekker.
9. N. K. Jain; Pharmaceutical product development, CBS publishers and distributors

c) References:

i) Books:

1. Parikh D.M., Handbook of Pharmaceutical Granulation Technology; Marcel Dekkar
2. Brittain H. G.; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
3. Cartensen J. T.; Drug Stability; Marcel Dekker.
4. Kithard A. and Watanabe A. Electrical phemanomena at interfaces; Marcel Dekkar
5. Martin A. Bustamante P. and Chun A.H. Physical Pharmacy; Wavery
6. Alderborn G and. Nystrom C; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
7. Stanley N. G. – Wooed; Enlargement and compaction of particle solids; Butterworths.

ii) Periodicals/Journals:

1. Pharmaceutical technology (findpharma)
2. Pharmaceutical Research (Springer)
3. Pharmaceutical Technology (Elsevier)
4. Indian Journal of Pharmaceutical Education and Research
5. Indian Drugs
6. International Journal Pharmaceutical Sciences
7. Acta Pharmaceutica
8. Advances in polymer technology- Wiley Online

9. Polymer Science and Technology – Elsevier
10. Polymers for Advanced Technologies - John Wiley & Sons.

i) Paper : 6 **THEORY**

ii) Title of Paper : DRUG REGULATORY AFFAIRS – II **DRA-II**

iii) Specific Objectives:

1. To provide knowledge to the student about preclinical trials, clinical trials and regulatory filling.
2. To provide knowledge about pharmaceutical excipients and preparation of regulatory dossier

iv) Note:

1. Students will be able to understand concept of drug regulatory affairs.

DRA-II DRUG REGULATORY AFFAIRS – II Theory (3 hrs/wk)

Unit	Contents	Hrs	Marks
1.	**Pre-clinical:** Animal pharmacology, animal toxicity, animal models, correlation of animal pharmacology to human pharmacology. Solution - dose testing, Efficacy – Invite animal study, Regulatory requirements	04	10-12
2.	**Clinical Trials:** Early clinical trials, clinical trial design statistical treatment of data, clinical trial phases – I to IV, clinical trial requirement as per category. BA/BE study requirements. – 21 CFR 225	05	10-12
3.	**Regulatory Agencies and Applications:** New drug application (NDA), ANDA, drug product application, Biopharmaceutical product application, Common Technical Document (CTD), its preparation and application through Compulsory drug testing (CDT), Supplemental application, Annual updates Drug Master File (DMF) 21 CFR 314.420(c), an overview of regulatory agencies and their guidelines.	05	10-16
4.	**Pharmaceutical excipient:** Excipient- Definition, selection, IIG data base. Requirement for excipient manufacturing as per International Pharmaceutical Excipients Council (IPEC). Approval of new excipient. Excipients –Functionality specifications and monograph	04	10-12
5.	**Preparation of Regulatory Dossier:** Generic product, Modified release product, Biological product, Device, Excipient, Investigation new drug application	05	10-12
6.	**Regulation filling with different agencies-** FDA, ATSSA, MHRA, EDQM, TGA.	05	10-12
7.	**Regulatory requirements for preclinical trials as per-** ICH, FDA, WHO, EMEA, IP, TGA etc.	04	10-12
8.	**Regulation requirements for clinical trials as per -**ICH, FDA, WHO, EMEA, IP, TGA etc.	04	10-12

(vi) Recommended Reading:

a) Basic Reading:

1. Novel and controlled drug delivery systems – N.K. Jain
2. Advances in Novel and Controlled Drug Delivery- N.K. Jain
3. Chien, Y.W.: Novel Drug Delivery Systems, Marcel Dekker, New York
4. Yie W. Chien. Novel drug delivery system – Marcel Dekker N.Y. Second Edition, Revised and Expanded by Vol- 50.

b) Additional Reading:

1. Controlled drug delivery system – Vicent H.L., Marcel Dekker Second Edition, Revised and Expanded by J. R. Robinson and Vincent H. L. Lee. Vol- 29.
2. Remington's pharmaceuticals sciences. 21 st Edition, Lippincott Wiilliams and Willkins- Vol. I & II

c) References:

i) Books:

1. Remington's pharmaceuticals sciences
2. Robinson, J.R. & Lee, V.H.I., Controlled and Novel Drug Delivery Marcel Dekker, New York.
3. E.A. Rawlin -Bentley's textbooks of pharmaceuticals
4. Novel drug delivery system – Marcel Dekker N.Y.
5. Controlled drug delivery system- Vincent H.L, Marcel Dekker
6. Bentley's textbook of pharmaceuticals – E. A. Rawlin
7. Novel and controlled drug delivery systems - N. K. Jain.

ii) Periodicals/Journals:

1. Indian Journal of Pharmaceutical Education and Research
2. International Journal Pharmaceutical Sciences
3. 4. Acta Pharmaceutica
4. European Journal of Pharmaceutical Sciences
5. Indian Journal of Pharmaceutical Sciences
6. International Journal of Pharmaceutics
7. International Journal of Pharmacy and Technology

i) Paper : 6 PRACTICAL

ii) Title of Paper : DRUG REGULATORY AFFAIRS – II DRA-II

iii) Specific Objectives:

1. To provide knowledge to the student about preclinical trials, clinical trials, regulatory

filling, Pharmaceutical excipients and preparation of regulatory dossier

iv) Note:

1. Students will be able to understand concept of designing, development and evaluation of novel drug delivery systems.

DRA-II DRUG REGULATORY AFFAIRS –II Practical (6 hrs/wk)

Unit	Contents
1	Formulation of sustained release tablet formulation.
2	Study of drug diffusion through various polymer membranes
3	Preparation and evaluation for occuserts.
4	Preparation and characterization of Microcapsules/Microspheres.
5	Preparation and evaluation of Transdermal films.
6	In-vitro permeation studies across skin and nasal mucosa.
7	Bioavailability study of nasal mucosa.
8	Formulation design and evaluation of: Liposomes and Multiple emulsions.
9	Demonstration of design of targeted drug delivery system

(vi) Recommended Reading:

a) Basic Reading:

1. Novel and controlled drug delivery systems – N.K. Jain
2. Advances in Novel and Controlled Drug Delivery- N.K. Jain
3. Chien, Y.W.: Novel Drug Delivery Systems, Marcel Dekker, New York
4. Yie W. Chien. Novel drug delivery system – Marcel Dekker N.Y. Second Edition, Revised and Expanded by Vol- 50.

b) Additional Reading:

1. Controlled drug delivery system – Vicent H.L., Marcel Dekker Second Edition, Revised and Expanded by J. R. Robinson and Vincent H. L. Lee. Vol- 29.
2. Remington's pharmaceuticals sciences. 21 st Edition, Lippincott Wiilliams and Willkins- Vol. I and II

c) References:

i) Books:

1. Remington's pharmaceuticals sciences
2. Robinson, J.R. & Lee, V.H.I., Controlled and Novel Drug Delivery Marcel Dekker, New York.
3. E.A. Rawlin -Bentley's textbooks of pharmaceuticals
4. Novel drug delivery system – Marcel Dekker N.Y.
5. Controlled drug delivery system- Vincent H.L, Marcel Dekker
6. Bentley's textbook of pharmaceuticals – E. A. Rawlin
7. Novel and controlled drug delivery systems - N. K. Jain.

ii) Periodicals/Journals:

1. Indian Journal of Pharmaceutical Education and Research
2. Indian Drugs
3. International Journal Pharmaceutical Sciences
4. Acta Pharmaceutica
5. Journal of Controlled Release
6. Pharmacognosy Reviews
7. Scientia Pharmaceutica

i) Paper : 7 **THEORY**

ii) Title of Paper : NOVEL DRUG DELIVERY SYSTEMS **NDDS**

iii) Specific Objectives:

1. To understand the fundamental concepts in the development of controlled release drug delivery systems.
2. To appreciate the contribution of physicochemical properties in the design of novel drug delivery systems.
3. To understand the different kinds of novel drug delivery systems.
4. To explore the use of polymers in the development of novel drug delivery systems.
5. To understand the formulation and in vitro evaluation methods of novel drug delivery systems.

iv) Note:

1. Students will be able to understand the fundamental concepts in the development of controlled release drug delivery systems.
2. They will be able to appreciate the contribution of physicochemical properties in the design of novel drug delivery systems.
3. They will be able to understand different kinds of novel drug delivery systems.
4. They will be able to explore the use of polymers in the development of novel drug delivery systems.
5. They will be able to understand formulation and in vitro evaluation methods of novel drug delivery systems.
6. They will be to study bioavailability and bioequivalence in order to correlate in vivo and in vitro release of drugs.
7. They will be able to understand the applications of pharmacokinetics in development of dosage forms.

NDDS **NOVEL DRUG DELIVERY SYSTEMS** **Theory (2 hrs/wk)**
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Modified release drug delivery systems:** Fundamental concepts of controlled release including Biopharmaceutical consideration of controlled release dosage forms, principles in modified release drug delivery systems, formulation, in vivo evaluation of drug delivery systems, osmotic pumps, membrane permeation, pH, controlled, ion exchange controlled, gel diffusion controlled, hydrodynamically balanced system, modulation of gastrointestinal transit time. Methods of gastro-retention and their evaluation	05	14-16
2.	**Mucosal Drug Delivery:** Mechanism of mucoadhesion, bioadhesive polymers, transmucosal penetration Enhancers. Development of buccal,	04	10-12

nasal, pulmonary, rectal and vaginal drug delivery system. In vitro, ex vivo and in vivo evaluation techniques.

3.	**Ocular drug delivery:** Ocular dug delivery mechanism, factors affecting ocular drug absorption and development of ocular drug delivery systems, mucoadhesive polymers, ocular inserts, iontophoresis, delivery of peptides and proteins.	04	08-12
4.	**Transdermal drug delivery:** Permeation through skin, physicochemical factors affecting in drug permeation, Permeation enhancers, iontophoresis drug delivery, approaches and technologies For developing transdermal drug delivery systems and their evaluation.	04	08-12
5.	**Parenteral drug delivery:** Liposomes and niosomes: Methods of preparation, characterization, stability applications and evaluation techniques. Loaded erythrocytes: methods of drug entrapment, characterization of loaded erythrocytes, stability, storage and release from the system. Applications and immunological consideration.	06	10-12
6.	**Colon specific drug delivery:** Advantage of colon specific drug delivery, disease of colon and drug absorption through colon. Factors affecting colonic absorption, absorption enhancers, Approaches to colon specific drug delivery, Coating with pH dependent polymers, Time release dosage forms, Delivery systems based on the metabolic activity of colonic bacteria, in vitro ex vivo and in vivo evaluation of colon specific drug delivery devices.	04	10-12
7.	**Pulsatile drug delivery:** Chronopharmacology and chronotherapeutics. Built in rhythms of human body, disorders showing chronological variations. Pulsatile delivery using Multiple unit particulate system (MUPS), Port system, Capsular system, Programmed polymer devices, TDDS, Floating pulsatile drug delivery system (DDS), chronotherapy in cancer treatment.	04	10-12
8.	**Protein and peptide drug delivery:** Structural complexity of protein and peptide drugs, routes for peptide delivery, physiological barriers in bioavailability of such molecules. Formulation considerations, Immunogenicity, stability in drug delivery of insulin, regulatory perspectives for such drugs.	05	10-12

vi) Recommended Reading:

a) Basic Reading:

1. Novel and controlled drug delivery systems – N.K. Jain
2. Advances in Novel and Controlled Drug Delivery- N.K. Jain

b) Additional Reading:

1. Controlled drug delivery system – Vicent H.L., Marcel Dekker 2nd ed, Revised and Expanded by J. R. Robinson and Vincent H. L. Lee. Vol- 29.
2. Remington's pharmaceuticals sciences. 21 st Edition, Lippincott Williams and Wilkins- Vol. I & II
3. Chien, Y.W.: Novel Drug Delivery Systems, Marcel Dekker, New York
4. Yie W. Chien. Novel drug delivery system – Marcel Dekker N.Y. Second Edition, Revised and Expanded by Vol- 50.

c) References:

i) Books:

1. Remington's pharmaceuticals sciences
2. Robinson, J.R. and Lee, V.H.I., Controlled and Novel Drug Delivery Marcel Dekker, New York.
3. E.A. Rawlins -Bentley's textbooks of pharmaceuticals
4. Novel drug delivery system – Marcel Dekker N.Y.
5. Controlled drug delivery system- Vincent H.L, Marcel Dekker
6. Bentley's textbook of pharmaceuticals – E. A. Rawlin
7. Novel and controlled drug delivery systems - N. K. Jain.

ii) Periodicals/Journals:

1. Indian Journal of Pharmaceutical Education and Research
2. International Journal Pharmaceutical Sciences
3. Acta Pharmaceutica
4. Advanced Drug Delivery Reviews
5. Drug Delivery
6. Drug Development and Industrial Pharmacy

OTHER FEATURES*

*Except list of LABORATORY EQUIPMENTS (c), all points (1, 2, 3, 4) coming under OTHER FEATURES from Syllabus of M. PHARM., (Pharmaceutical Chemistry) are same.

(c) LABORATORY EQUIPMENTS:

In addition to routine equipments like hot air oven, incubator, pH meter, etc. following specific equipments are necessary.

1. Tablet mini press (Shared)
2. Tablet Coating Pan (Shared)
3. Dissolution Test Apparatus
4. Stability Chamber
5. Freeze Dryer (desirable)
6. Spray Dryer (desirable)
7. Deep Freezer
8. Brookfield Viscometer (shared)
9. Karl Fisher Titrator
10. UV-Visible Spectrophotometer
11. FTIR (shared)
12. HPLC (shared)

List of Elective Subjects for Semester I

1. Drug Design
2. Bulk Drug Technology
3. Toxicology
4. Fundamental Biopharmaceutics
5. Medicinal Plant Biotechnology
6. Clinical Research
7. Advances in Drug Delivery
8. Product Development

9. Industrial Pharmacy & Production Management

10. Quality Assurance

List of Elective Subjects for Semester II

11. Cosmeticology

12. Phytopharmaceuticals

13. Sterile Product Formulation & Technology

14. Fermentation Technology

15. Quality Control

16. Immunopharmacology & Immunoassays

17. Polymer Technology

18. Clinical Pharmacy

19. Therapeutic Drug Monitoring

i) Paper : 4 (ELECTIVE) ELE-I

ii) Title of Paper : DRUG DESIGN

iii) Specific Objectives:

1. To create understanding of drug design and drug discovery process.
2. Develop understanding of moleculer modelling and protein structure prediction.
3. Improve the knowledge base related to recent advances in specific therapeutic agents

iv) Note:

1. Basic knowledge of life sciences, organic and medicinal chemistry is a prerequisite. Molecular models and interaction simulations in the form of images and videos can be used to improve understanding.

1. DRUG DESIGN **Theory (2 hrs/wk)**
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Introduction to drug design and Approaches to New Drug Discovery:** Drug design, drug design methodologies, challenges of drug design. A. Drugs Derived from Natural Products B. Existing Drugs as a Source for New Drug Discovery C. Using Disease Models as Screens for New Drug Leads D.Physiological Mechanisms: the Modern "Rational Approach" to Drug Design E: Modern Drug design a) Known Receptor b)Unknown Receptor	03	08-10
2.	**Approaches to Lead Optimization:** 1. Bioisosteric replacement 2. Conformation restriction a. Increase selectivity b. Increase affinity 3. Pharmacophore 4. Molecular dissection 5. Metabolic stabilization	03	08-10
3.	**Recent developments in Histamine receptor antagonists and antiulcer therapy:** Theory of histamine receptors, Design of H1 antagonists (Non sedating / Second generation analogs) and H2 antagonists (Ranitidine analogs, analogs for prolonged action viz. cimetidine), Design of proton pump inhibitors.	03	08-10
4.	**The basis of drug design and recent advances in Cardiovascular and CNS agents:** **Antihypertensive agents** - ACE inhibitors-The ACE active site, specificity for decrease in angiotensin-II formation, Actions of ACE inhibitors to inhibit kinase-II to potentiate bradykinin **Angiotensin-II receptor antagonists –** angiotensin receptor subtypes, and design of nonpeptide angiotensin-II receptor antagonists and Calcium channel antagonists – Chemical subtypes of antagonists with reference to mechanism of action	06	16-20

Antipsychotic agents - Development of dopamine selective legents viz.domperidone, isoxazole, pyrazole analogs. Different types of 5HT receptors and designing of protein kinase C activator. Design of serotonin blocking agents viz. Clozapine analogs. Designing of clonazepam analogs as GABA agonists.

5.	**Molecular modelling in Drug Design:**	05	8-10

Introduction, force field, quantum chemistry, Schrödinger equation, potential energy functions, energy minimization, local and global minima, saddle point, grid search, various approximations; LCAO, HF, semi-empirical calculations; single point calculations, full-geometry optimization methods, ZDO, MNDO, CNDO, NDDO, AM1, PM3, RM1, conformational search, Z-matrix, docking, molecular modeling packages Molecular mechanics and Quantum Mechanics.

6.	**Protein structure prediction:**	05	8-10

Protein Structure Prediction; Homology modeling, prediction of protein structure from sequences, functional sites, Protein folding problem, protein folding classes, protein identification and characterization. Introduction to AACompIdent, TagIdent, PepIdent and MultiIdent; PROSEARCH, PepSea, PepMAPPER, FindPept, Predicting transmembrane helices, Primary structure analysis and prediction, Secondary structure analysis and prediction, motifs, profiles, patterns and fingerprints search. Methods of sequence based protein prediction

7.	**Structural variations for drug design and drug target interactions:**	06	8-10

a. Drug design, variation of substituents.

b. Extension of structure, chain extensions / contraction.

c. Ring expansion / contractions.

d. Ring variations.

e. Ring fusions.

f. Isosters.

g. Simplification and rigidification of structures.

h. Conformation blockers.

8.	**The basis of drug design and recent advances in following:**	05	16-20

a. Antineoplastic agents – Origin of neoplasm and Design of drugs for various therapeutic targets.

b. Anti-AIDS agents – Life cycle of HIV and Design of drugs for various therapeutic targets.

c. Anticoagulant agents: introduction to various targets and recent advances in design of anticoagulants.

d. Drugs for tropical diseases:

1. Antimalarial 2. Antileshminal.

(vi) Recommended Reading:

a) Basic Reading:

1. Design of Drugs: Basic Principles and Applications, Poupaert, J.H. (Ed.) Marcel Dekker, 2002.
2. Structure-Based Drug Design, Veerapandian, P. (Ed.) Marcel Dekker, 1997.
3. The Organic Chemistry of Drug Design and Drug Action Silverman, R. (Ed.) Academic Press, 2004.
4. Pharmacophore Perception, Development, and Use in Drug Design Güner, O.F., (Eds.) International University Line, 2000. Guidebook on Molecular Modeling in Drug Design, Cohen, N. (Ed.) Academic Press, 1996.

b) Additional Reading:

1. Use of quantitative structure-activity relationships (QSAR) in drug design http://link.springer.com/article/10.1007%2FBF00765654
2. Pharmacophore-based virtual screening: a review of recent applications http://informahealthcare.com/doi/abs/10.1517/17460441003592072
3. QSAR and 3D QSAR in Drug Design, www.cmbi.kun.nl/edu/bioinf4/articles/pdf/qsa_kubinyi_2.pdf

c) References:

i) Books:

1. Modern Methods of Drug Discovery, Hillisch, A.; Hilgenfeld, R. (Eds.) Springer Verlag, 2003
2. Drug Design: Cutting Edge Approaches, Flower, D.R., (Ed.) Royal Society of Chemistry, 2003
3. Structure-based Ligand Design, Gubernator, K., Böhm, H.J., (Eds.)VCH Publishing, 1998.
4. Protein-Ligand Interactions : From Molecular Recognition to Drug Design, Böhm, H. J, Schneider, G., (Eds.) John Wiley & Sons, 2003.

ii) Periodicals/Journals:

1. Molecular Docking Screens Using Comparative Models of Proteins, Journal of Chemical. Information and Modelling, 10.1021/ci9003706 CCC
2. Protein Flexibility and Mobility in Structure-Based Drug Design, Frontiers in Drug Design & Discovery, 2007, 3, 000-000.
3. Chemical Property Calculation through JavaScript and Applications in QSAR, Molecules 1999, 4, 16–27
4. Quantum-Chemical Descriptors in QSAR/QSPR Studies, Chemical Reviews, 1996, 96, 1027-1043
5. Why Are Some Properties More Difficult To Predict than Others? A Study of

QSPR Models of Solubility, Melting Point, and Log P, Journal of Chemical. Information and Modelling. 2008, 48, 220-232.

i) Paper : 4 (ELECTIVE) ELE-I

ii) Title of Paper : BULK DRUG TECHNOLOGY

iii) Specific Objectives:

1. The objective of this subject is to expose students to one of the carrier oriented subject. By studying the subject students can briefly get accustomed to bulk drug manufacturing and rules and regulations governing the process of licensing and production and sales. A thought of becoming an entrepreneur will definitely come in the minds of student, as good quality of API's are required in large quantity.

iv) Note:

1. API manufacturing is one of the most lucrative options for students to become an entrepreneur. Exporting of quality bulk drug is one of the most profitable businesses in the field of Pharmaceuticals. Hence knowledge of world wide rules and regulations is must

2. BULK DRUG TECHNOLOGY **Theory (2 hrs/wk)**
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Concept of fine and Bulk drugs and their salient features:** World wide scenario. Past, present and future. Regulated and semi regulated markets, Intellectual property rights and regulatory requirements related to licensing and pollution control. Concepts like Drug Master File (DMF), European Drug Master File (EDMF).	03	05-08
2.	**GMP & Cgmp guidelines:** Guidelines from ICH, WHO, MHRA related to manufacturing of API. Bulk drugs	02	05-07
3.	**Stoichiometry:** Stoichiometry and its importance in the manufacture of drugs. Concepts like reaction stoichiometry, stoichiometric amount or stoichiometric ratio	02	05-08
4.	**Discussion on use of following types of reaction with** One example in manufacturing of drugs and drug intermediates Acetylation, Nitration, Sulphonation, chlorosulphonation, Oxidation, Reduction, alkylation, Halogenation, Carboxylation, Decarboxylation, Esterification, Addition, substitution, elimination & epoxidation. Important reactions used in drug synthesis.	07	15-17
5.	**Unit operation important to drug synthesis:** Brief information about concept of unit operations. Detail study of unit operations like mixing, distillation, drying, filtration, centrifugation, evaporation, crystallization, extraction with latest modernization concepts.	06	15-18
6.	**Detailed manufacturing aspects, inclusive of processes and operations involved-for :** One drug from following classes : Anti-inflammatory, anti-diabetic, anti-hypertensive, anti-histaminic, antitubercular, antibiotics, anticancer, antiHIV	05	15-18
7.	**Principles and design of the reactors & fomenters** Types of materials used in construction, factors to be considered in selection of material. Plant Design, Scale-up & Safety and Hazards concepts. Effluent treatment and Pollution Control	06	10-12
8	Industrial **fermentation technology** for **bulk production** of APIs, **antibiotic**, anticancer, aminoacid, **vitamin** and bioproducts in general,	05	10-12

(vi) Recommended Reading:

a) Basic Reading:

1. Cooper & Gun's Tutorial Pharmacy
2. Unit Operations of Chemical Engineering, Mechanical Operations Volume-1, R. S. Hiremath, A. P. Kulkarni
3. Introduction to Pharmaceutical Engineering, Anant Paradkar, Nirali Prakashan
4. Basics of Biotechnology| Author: Dr. A.J. Nair| Laxmi Publication

b) Additional Reading:

1. Pharmaceutical engineering unit operation-1, C.V.S. Subrahmanyan, J. Thimma Shetty.
2. M. Giarians : Fundamentals of Chemicals Engineering Operations
3. W. J. Badger and Banchero : Introduction to chemical engineering (McGraw Hill Services)
4. Ganderton G ; Unit processes in Pharmacy

c) References:

i) Books:

1. Organic Synthesis, Collective volume, John Wiley & Sons
2. Basic Biotechnology by Colin Ratledge (Editor), Bjorn Kristiansen, Paperback: 584 pages, Publisher: Cambridge University Press
3. Burger's Medicinal Chemistry & Drug Discovery, John Wiley & Sons

ii) Periodicals/Journals:

1. Journal of Technology Research
2. International Journal Of Innovative Research & Development

i) Paper : 4 (ELECTIVE) ELE-I

ii) Title of Paper : TOXICOLOGY

iii) Specific Objectives:

1. The chemical properties and the biological processes which modulate the toxicokinetics of chemical agents of public health importance.
2. To know the significance of biotransformation reactions as a determinant of the toxicokinetics and toxicodynamic activities of chemicals.
3. To describe molecular, cellular and pathophysiological responses resulting from exposure to chemical agents relevant to human health.
4. Identify underlying susceptibility factors which contribute to the ability of chemicals to elicit bioeffects which contribute to human disease

iv) Note:

1. The student should acquire the skills that are commensurate with science underlying testing for the ability of chemicals to elicit adverse human health effects.

2. To Put into perspective the role of toxicology in the risk assessment process
3. The Toxicology Division is responsible for the identification and investigation of potential health hazards associated with chemical contaminants, including those of environmental origin, agricultural chemicals, natural food toxicants and constituents, and food additives.
4. Research is carried out on the carcinogenic, mutagenic, reproductive, neurotoxic and other potentially harmful effects of these chemicals, including alterations to the immune system.

3. TOXICOLOGY **Theory (3 hrs/wk)**
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Fundamental Principles and Molecular aspects of toxicology** • Introduction, Toxicological Evidence, Common household poisons, description of sub disciplines of toxicology, qualitative and quantitative aspects of toxic effects. • Biotransformation: detoxication and bioactivation. • Absorption, distribution and elimination of xenobiotics. • Toxicokinetics ; quantitative aspect. • Dose time – effect relationships. Cytotoxicity – Molecular Mechanism of cell death, Genetic toxicology, Carcinogenicity ,mutagenicity ; Teratogenicity	06	10-12
2.	**Hematotoxicity** The origin, formation, and differentiation of blood cells • Clinical tests used to evaluate hematotoxicity • Oxygen transport by erythrocytes (red blood cells or RBCs) and interference with oxygen transport by drugs and chemicals • Chemicals that affect the formation of red blood cells, platelets, and white blood cells (bone marrow suppression) • Leukemias and lymphomas (cancers of the white blood cells) • Neurological and cardiovascular toxicities caused by interference with oxygen utilization (e.g., cyanide, hydrogen disulfide)	04	10-12

	• Medical treatment of hematotoxicity		
3.	**Respiratory and Gastrointestinal toxicology :** Toxicological Pathophysiology and mechanisms of toxicity, source of toxicity. • Hepatotoxicology: Mechanisms of liver toxicity and methodology aspects.	04	10-12
4.	**Cardiovascular and Nephotoxicology :** toxicological pathology and biochemical toxicology and mechanisms of toxicity of CVC and Kidney	04	10-12
5.	**Immunotoxicology:** Basic elements and functioning of the immune system • Types of immune reactions and disorders • Clinical tests to detect immunotoxicity • Tests to detect immunotoxicity in animal models • Specific chemicals that adversely affect the immune system • Multiple chemical sensitivity	04	10-12
6.	**Neuro and Reproductive toxicology:** • Functional neurotoxicology. Behavioral toxicology. Toxicant Effects on the Nervous and reproductive System, Mechanisms and Targets of Male and female Reproductive Toxicants.	04	10-12
7.	**Risk Assessment:** The basic steps of risk assessment and regulatory context • Differences between human health and ecological risk assessments • Differences in the estimation of cancer and non-cancer risks, deterministic and probabilistic risk assessments chemical exposure with other health risks • Issues associated with estimating risks from chemical mixtures •Risk communication from chemical exposure with other health risks	04	08-12
8.	**Applied Toxicology:** Toxicity Testing Forensic and Clinical Toxicology Prevention of Toxicity Analytical Methods in Toxicology	06	12-16

(vi) Recommended Reading:

a) Basic Reading:

1. Niesink R. J. M. de Vries J and Hollingers M. A. Toxicology, Principal and
2. Applications, CRC Press 1996
3. Amdur M. O Doul J and Klassen C. D. Casarett and Doull's Toxicology
4. Gupta P, K and Salunkhe D. K. Modern toxicology Vol. -I, II and III (Metropolitan, New Delhi).
5. Dart RC. Ellenhorn's Medical Toxicology: Diagnosis and Treatment of Human Poisoning. Edition 3. Philadelphia: Lippincott Williams & Wilkins, 2003.
6. A Textbook of Modern Toxicology Ernest Hodgson - 09-Apr-2004

b) Additional Reading:

1. Hardman JG, Limbird LE (ed). Goodman and Gilman's The Pharmacological Basis of Therapeutics. Edition 10. New York: McGraw-Hill, 2001.
2. Timbrell J. Introduction to Toxicology. Edition 3. London: Taylor & Francis, 2002 (ISBN 0 415 24763 2).
3. Casarett & Doull's Toxicology: The Basic Science of Poisons Curtis Klaassen - 20-Nov-2007

c) References:

i) Books:

1. Recent developments in TDM & Clinical toxicology – I. Sunshine –Marcel – Dekker – 1992.
2. Essentials of Toxicology. Klaassen CD, Watkins JB III, eds. New York: McGraw-Hill, 2003.
3. Toxicology: the nature, effects and detection of poisons, with the diagnosis and treatment of poisoning Cassius M. Riley1901
4. Toxicology: Principles and Applications Raymundus Johannes Maria Niesink, John De Vries, John De Vries Mannfred A. Hollinger – 1996
5. Principles of Toxicology: Environmental and Industrial Applications Phillip L. Williams, Robert C. James, Stephen M. Roberts - 24-Oct-2003
6. Acute Toxicology Testing: Perspectives and Horizons Shayne C. Gad, Christopher P. Chengelis - 15-Dec-1988

ii) Periodicals/Journals:

1. Clinical toxicology
2. Journal of toxicological sciences
3. Cell biology and toxicology
4. Cardiovascular toxicology
5. Regulatory toxicology and pharmacology
6. Toxicon
7. Chemical research in toxicology
8. Toxicological sciences
9. Journal of pharmacological and toxicological methods
10. Immunopharmacology and Immunotoxicology

i) Paper : 4 (ELECTIVE) ELE-I

ii) Title of Paper : FUNDAMENTAL BIOPHARMACEUTICS

iii) Specific Objectives:

1. To understand how drugs can be utilized optimally in the treatment of diseases through design and development of new drugs and dosage forms.
2. To understand design of dosage regimen & individualization of drug therapy.

3. Application of pharmacokinetic principles in clinical situations
4. To understand importance of Therapeutic Drug Monitoring in achieving optimal drug therapy.

iv) Note: Students should be able to

1. Describe all concepts & terms in Biopharmaceutics & Pharmacokinetics.
2. Explain mechanisms and kinetics of drug absorption, distribution, metabolism and excretion.
3. Give mathematical treatment to various pharmacokinetic data.
4. Calculate pharmacokinetic parameters based on compartmental & non-compartmental analysis.

4. FUNDAMENTAL BIOPHARMACEUTICS

Theory (3 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Introduction to Biopharmaceutics and clinical pharmacokinetics:** Definition of Biopharmaceutics, Pharmacokinetic, clinical Pharmacokinetic and its importance, Applications of pharmacokinetics in design and development of NDDS	02	04-06
2.	**Basic concepts:** Definition and introduction to absorption rate constant, bioavailability, bioequivalence, volume of distribution, distribution half-life, elimination half-life, elimination rate constant. Clearance, extraction ratio, area under curve, means residence time, protein binding and tissue binding. Calculation of parameters from plasma and urine data.	04	08-10
3.	**Compartment modeling and Non-compartmental Analysis:** One compartment open model : I. V. route of administration; Disposition viewed from plasma (t1/2, Vd, 1st order examination, fraction of dose remaining) total clearance, renal clearance, disposition viewed from urine only and estimation of pharmacokinetic parameters, Excretion rate & sigma minus method. E. V. route of administration, kinetics of absorption, assessment of pharmacokinetic parameters, method of residuals, Wagner-Nelson method, evaluation of urine data after E. V. administration, use of Laplace transform for pharmacokinetic analysis. Multi compartment modeling : Two compartment and three compartment models, determination of	08	20-24

parameters after I. V. & E. V. administration, Loo-Riegelman method

Non compartmental Analysis :

Determination of pharmacokinetic parameters based on statistical moment theory, deconvolution method for determination of absorption rates

4. Absorption of drugs: 05 08-10

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

5. Distribution of drugs: 04 08-10

Rate of distribution; factors affecting distribution of drugs; permeability & perfusion limitation; extent of distribution; estimation of volume of distributions (One & Multi-compartmental and non-compartmental analysis); relation between volume of distribution, drug binding & elimination; tissue & protein binding; fraction unbound; drugs with small volume of distribution.

6. Elimination of drug: 04 08-10

Concept of clearance, organ clearance, extraction ratio; Hepatic metabolism: chemical pathways and factors affecting it; effect of perfusion, protein binding & enzyme activity on hepatic clearance; Renal excretion: principle processes and factors affecting it; Non renal excretion; dependency of half life on clearance and volume of distribution.

7. Bioavailability: 06 18-22

- Objective of bioavailability studies; determination of bioavailability; parameters of bioavailability; relative bioavailability; determination of AUC (using planimeter, counting squares trapezoidal rule and cutting and weighing studies)
- Drug dissolution, permeation and bioavailability

  Theories of dissolution; in-vitro drug dissolution testing models; bio-relevant media; invitro – invivo correlation; BCS & Prediction of IVIVC; development of level A correlation.
- Study design & conduct of BA/BE studies; regulatory guidelines; statistical analysis of data.

8. Non linear Pharmacokinetics: 03 06-08

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

(vi) Recommended Reading:

a) Basic Reading:

1. D.M. Brahmankar, S.B. Jaiswal. (1997), Biopharmaceutics & Pharmacokinetics – A treatise. Vallabh Publications, New Delhi.
2. Introduction to Biopharmaceutics. – G. P. –Shriwastav
3. Jean- Pierre Labaune; Handbook of Pharmacokinetics; John Wiley Sons.

b) Additional Reading:

1. Leon Shargel. (2003), Applied Biopharmaceutics & Pharmacokinetics, Prentice Hall International, London.
2. Milo Gibaldi & Donald Perrier (1992). Pharmacokinetics, , Marcel Dekker, New York.
3. P.L. Madan. (2000) Biopharmaceutics & Pharmacokinetics, , Jaypee publications, New Delhi.
4. 4. Malcohm Rowland C., Thomas N. Tozer. (1987), Clinical Pharmacokinetics – Concept & Application., Lea & Febiger Book

c) References:

i) Books:

1. J. B. Blanchard, R. J. Sawchul and B. B. Brodie; Principle and perspectives in drug bioavailabilty; K. Karger Publication.
2. P. G. Welling and F. L. S. Tse; Pharmacokinetics, Regulatory- Industrial – Academic perspectives; Marcel Dekker.
3. P. Jenner and B. Testa; Concept in drug metabolism; Marcel Dekker.
4. Jerry L. Hamelink, Peter F. Landrum, Harold L. Bergman, William H. Benson. Bioavailability. Physical, chemical, and biological interactions. Lewis publishers
5. Rober E. Notary. 1987 Bio-pharmaceutics & Pharmacokinetics – An introduction, , Marcel Dekker, New York.
6. Gibaldi & Pancot. 1992 Handbook of clinical pharmacokinetics., Marcel Dekker, New York.
7. Swarbrik 1987. Biopharmaceutics., Lea & Febiger book publication. U. K

ii) Periodicals/Journals:

1. Journal of Pharmacokinetics & Biopharmaceutics
2. Journal of Clinical Pharmacokinetics
3. Journal of Pharmaceutical Sciences.
4. Journal of Clinical Pharmacology
5. Pharmaceutical Research

6. Clinical Pharmacology & Therapeutics

i) Paper : 4 (ELECTIVE) ELE-I

ii) Title of Paper : MEDICINAL PLANT BIOTECHNOLOGY

iii) Specific Objectives:

1. To promote and strengthen the area of Medicinal Plant Biotechnology.
2. Quality and Quantity improvement and basic research in the area of plant molecular

biology.

3. To deal with interventions for conservation, micropropagation, production of Secondary metabolites, biotransformation of intermediates into pharmaceutically important products and genetic improvement.
4. To acquire knowledge of Plant genetic material and conservation of plant gene data.
5. To study different aspects of plant tissue culture techniques with application of modern scientific tools.

iv) Note:

1. Student be supposed to knowledgeable with the subject medicinal plant biotechnology.
2. Student should know use of Secondary metabolites to treat different kinds of diseases.
3. Student should know Plant Genetic Structure and Molecular Biology.

5. MEDICINAL PLANT BIOTECHNOLOGY **Theory (2 hrs/wk)**
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Introduction to Plant Genetic Structure and Molecular Biology**	03	08-10
2.	**Plant gene Mapping & molecular maps of plant genomes**	04	10-12
3.	**Methods of Quality improvement of plants** a. Chemodemes b. Hybridization c. Mutation d. Polyploidy	04	10-12
4.	**Gene transfer in plants** a. Using Vectors of Agrobacterium Ti, co-integrative, Intermediate plasmid b. DNA mediated gene transfer Electroporation, Microprojectiles, Micro and macro injection, Liposomes Ultrasonication	04	10-12
5.	**Localization of transferred gene in genetically modified plants** a. Plant chromosome analysis b. Gene mapping	04	10-12

c. Use of markers
d. DNA hybridization

6.	**Applications of Transgenic plants** a. Resistance to herbicides, insects, fungus and virus, physiological stress b. Edible vaccines c. Production Systems for Pharmaceuticals d. Transgenic plants and human health and safety	05	10-12
7.	**Plant Tissue Culture** a. Principles of Plant Tissue Culture, Terminology b. Requirements of tissue culture Facilities c. Totipotency d. Culture media e. Types of cultures f. Cell suspension, Organogenesis, Embryogenesis, Protoplast culture g. Cell Immobilization **(survey of recent advances)** h. Biotransformation i. Germplasm conservation	07	12-16
8.	**Application of Plant tissue Culture** a. Biotechnological interventions for enhancing secondary metabolite production b. Recent advances in elicitor techniques and production of biological active constituents in static, suspension, multiple shoot cultures.	05	10-14

(vi) Recommended Reading:

a) Basic Reading:

1. P. K. Gupta, Elements of Biotechnology
2. Narayanswamy, S. ; Tata McGraw-Hill Publishing Company, Ltd. , New Delhi Plant tissue culture
3. Razdan, An introduction to Plant tissue culture

b) Additional Reading:

1. Samtel., Plant biotechnology
2. J. M. Walter, E. D. Gingo, Molecular biology and biotechnology
3. Dovid F. A., George M. M., Essentials of molecular biology**.**

c) References:

i) Books:

1. Angela Stafford, Open University press, Buckingham. (1991)., Plant tissue culture.
2. Dixon (47), Plant tissue culture
3. Vyas, Dixit, CBS Publishers, New Delhi. 1998., Pharmaceutical Biotechnology.
4. Trease W. C., Evans G. E., Baillerie & Tindall, 15th Edi, Pharmacognosy.
5. Street, H.C., Blackwell scientific, London, Plant Cell and Tissue Culture
6. Gamborg, O.L. and Wetter, L.R National research council of Canada, Saskatchewan. Plant tissue culture methods.
7. Ashutosh Kar, New Age International Publishers, Pharmacognosy and Pharmacobiotechnology.
8. Vinod D. Rangari, Career publication, Nasik Pharmacognosy and Phytochemistry.
9. Wickery, M.L., MC Millan Press, London. Secondary Plant Metabolism
10. Hosevear Kennedy Cabral & Bicker staff, Immobilization of cells and enzymes.
11. E.T. Murray., Gene transfer and expression protocols, Vol. VII, Methods in Molecular Biology.
12. Julio E. Celis., Cell Biology, Vol. I, II and III
13. Takashashi N. (1986). Chemistry of Plant Hormones, CRC Press Inc., Florida

ii) Periodicals/Journals:

1. Plant Cell Tissue and Organ Culture
2. Plant Cell Reports
3. Plant Growth Regulation
4. Journal of Plant Physiology

5. Plant Science
6. Journal of Natural Products

i) Paper : 4 (ELECTIVE) ELE-I

ii) Title of Paper : CLINICAL RESEARCH

iii) Specific Objectives:

1. To understand the different techniques in drug Clinical and Preclinical Trials.
2. To understand the basic fundamental principles of drug Screening.
3. To gain knowledge of laws, regulations, and policies related to clinical research on the development and implementation of protocols.

iv) Note:

1. To understand the key concepts in the responsible conduct of research and be able to conduct research that conforms to the highest standards for the protection of human research subjects**.**
2. To understand how novel compounds are evaluated for the desired activity and to understand the limitations of such designing trials.
3. To be able to current states of pre-clinical evaluation of novel compounds for included pharmacological class.
4. To know Ethical guidelines for Clinical and Preclinical Trials.

6. CLINICAL RESEARCH **Theory (3 hrs/wk)**
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Discovery of new pharmaceutical entities** Introduction, market needs, historical aspects of new drug discovery, Impact of pharmacogenomics, proteomics and bioinformatics in new drug discovery, concepts of high through put screening and combinatorial chemistry.	04	05-07
2.	**Characterization of new drug molecules** Solubility studies, spectroscopic characterization (UV-Vis, IR, NMR, Mass,and other techniques), thermal analysis, X ray diffraction, optimization of synthetic procedure, impurity profile, scale up.	05	10-15
3.	**Pre clinical studies** Introduction, risk benefit assessment, Good laboratory Practices, experimental design, single dose and repeated dose studies, safety pharmacological studies, teratogenicity and oncogenicity studies, animal pharmacokinetic studies and invitro screening tests for safety and efficacy	05	10-12
4.	**Phase studies** Introduction, study design, conduct, monitoring of phase I, II, III and IV	06	10-12

Studies

5.	**Regulatory aspects of clinical trials** Historical aspects of clinical trails, declaration of Helsinki, Belmont report, Nuremberg code, Tuskgee trial. Composition, functions & operations of IRB/IEC ethics of clinical trials in developed and developing countries,ICH GCP, WHO guide lines, USFDA guidelines, UK drug regulatory procedure, CDSCO/ICMR guidelines, schedule Y, regulatory and clinical trails system in Japan, Australia and Canada	05	15-17
6.	**Biostatistics and data management** Importance of statistics in clinical research Statistical considerations at the design, analysis and reporting stage. Data management, Data validation, SAE reconciliation, query management Software considerations	05	15-18
7.	**Clinical research management** Preparation of a successful clinical study, Study management, Project management Documentation, Monitoring, Audits and Inspections Pharmacovigilance Training in clinical research Budgeting in clinical research, Supplies and vendor management	04	10-12
8.	**Ethics in clinical research** Ethical Theories and Foundations, Ethics Review Committee and Informed Consent Process, Integrity & Misconduct in Clinical Research Conflicts of Interest	02	05-07

(vi) Recommended Reading:

a) Basic Reading:

1. Essentials of Clinical Research. Dr Ravindra ghooi and Sachin Itkar
2. Lelia Duley Barbara. Clinical Trials. 2002, Viva Books Pvt. Ltd.
3. Cocchetto, Nardi. Managing the Clinical Drug Development Process, 1987, Marcel Dekker Inc.
4. Handbook of Clinical Research Law and Compliance by John Steiner
5. Fundamentals of Clinical Trials by David L. DeMets
6. The Investigator's Guide to Clinical Research (Second Edition) by Dr. David Ginsberg

b) Additional Reading:

1 www.fda.gov/cder/handbook/preclin

2. www.cato.com/biotech/bio-prod-cro

3 . www.niaid.nih.gov/hivvaccines/preclinrd

4. www.qservegroup.com/consulatancy/services/pre_clinical

5. www.pharmahungary.com

c) References:

i) Books:

1. John P. Griffin, John O'Grady. Pharmaceutical medicine. 2003, British Medical Journal, UK
2. Francis L. S. Tse, James M. Jaffe. Preclinical Drug disposition.1987, Marcel Dekker Inc.
3. Andrew J. Fletcher, Lionel D. Edwards, Anthony W. Fox, Peter Stonier, Pharmaceutical medicine. 2002, John Wiley & Sons, Ltd.
4. Conducting Clinical Research,Stone, Judy, Biblio Distribution
5. Clinical Research Coordinator Handbook, Norris, Deborrah, Plexus Pub.

ii) Periodicals/Journals:

1. BMJ : British Medical Journal
2. Journal of Clinical Medicine Research Publisher: Elmer Press Inc
3. International Journal of Clinical Pediatrics. Elmer Press Inc
4. Contemporary Clinical Trials. Imprint: ELSEVIER
5. Journal of Clinical Research Best Practices
6. Instasci Journal of Medical Sciences and Clinical Research
7. Journal of Clinical and Diagnostic Research
8. Asian Journal of Medical and Clinical Sciences
9. Clinical Research and Regulatory Affairs
10. Clinical Toxicology

i) Paper : 4 (ELECTIVE) ELE-I

ii) Title of Paper : ADVANCES IN DRUG DELIVERY

iii) Specific Objectives:

1. The objective of this subject is to expose students to the latest novel drug delivery systems which are at market and those under research in the laboratories. By knowing the need of advanced drug delivery systems, one can think of superior tailormade systems offering excellent patient compliance and improved therapeutic efficacy

iv) Note:

1. The need and rational of the development of particular drug delivery should be known to the students. Secondly, the prospective candidates for the below mentioned drug deliveries should be addressed by them with reasoning. The formulation design along with the drug release kinetics and dosage form evaluation methodology is expected to be understood by the students.

7. ADVANCES IN DRUG DELIVERY **Theory (3 hrs/wk)**
Tutorial (1 hr/wk)

Unit	Unit contents	Hrs	Marks
1.	**Protein & peptide drug delivery system** Physical aspects, biochemistry of protein drug (structure, properties & stability) general methods of analysis of protein' & peptide drugs, barrier to transport & pharmacokinetics, different route of delivery. Toxicity immunogenicity, 'stability & regulatory perspective.	06	15-18
2.	**Mucosal drug delivery models:** Buccal, rectal: & vaginal drug delivery. Mechanisms of transports of drugs trough mucosal routes	04	08-11
3.	**Occular Drug Delivery:** Occular delivery mechanisms & development of Ocular controlled release system	05	11-14
4.	**Transdermal drug delivery system:** Permeation through skin including mechanism, permeation enhancers, invitro skin permeation, technologies for developing Transdermal drug delivery system & evaluation thereof.	06	13-16
5.	**Oral & Parenteral controlled release system:** Scope, terminology & techniques used, injectable controlled release formulation. Long acting contraceptive formulations. Implantable drug	05	12-14

delivery, microspheres liposomes, & nanoparticles & quality control.

6.	**Site specific drug delivery system:** Active & passive targeting, resealed erythrocyte, monoclonal antibodies drug targeting particulate carrier system, specific drug delivery to targeted organs like brain & colon, freeze drying of Parenteral, environmental controlled Parenteral manufacturing.	04	11-13
7.	**Intrauterine drug delivery system:** Medicated IUDs,, 'Copper lUDs, Harmone released lUDs	03	05-07
8.	**Regulatory considerations in controlled release modification:** Requirements to demonstrate safety, efficiency & controlled release nature, Bioavailability, assurance, WHO & Indian condition	03	05-07

(vi) Recommended Reading:

a) Basic Reading:

1. Novel and controlled drug delivery systems - N. K. Jain.
2. Novel and controlled drug delivery systems Y. W. Chien

b) Additional Reading:

1. Novel drug delivery system – Marcel Dekker N. Y.
2. Controlled drug delivery system- Vincent H. L, Marcel Dekker
3. Bentley's textbook of pharmaceuticals – E. A. Rawlin
4. Biopharmaceutics and Pharmacokinetics: a treatise Bramhanakar and S B Jaiswal

c) References:

i) Books:

1 Remington's pharmaceuticals sciences

ii) Periodicals/Journals:

1. Journal of Controlled release
2. International journal of Pharmaceutics.
3. AAPSPharmScitech
4. AAPS journal
5. Current drug delivery
6. Advanced drug delivery reviews.
7. Journal of Pharmaceutical Sciencs

i) Paper : 4 (ELECTIVE) ELE-I

ii) Title of Paper : PRODUCT DEVELOPMENT

iii) Specific Objectives:

1. Students are introduced to the development process of tablet, capsules, suspensions, emulsions dosage forms.
2. They know how the Design of experiment and Optimization methodologies for the dosage forms.
3. They know the process validation during manufacturing and packaging of products.
4. The students develop through understanding about the Regulatory requirements require for new product development and approval process.

iv) Note:

1. The student is well versed with the detailed process of product developments.

8. PRODUCT DEVELOPMENT **Theory (3 hrs/wk)**
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Preformulation studies:** Introduction, □haracterization of fundamental & derived properties of drug molecules. Study of particle morphology, particle size, shape, purity, surface area, pKa, partition coefficient, solubility, dissolution, ageing and polymorphism, temperature, Ph, co-solvancy. Particle Characterization by optical and electron microscopy, spectroscopy, thermal techniques.	06	10-15
2.	**Design of experiments and optimization:** Design of experiment, Product, process and response variables. Optimization methodologies with special reference to factorial design, central composite design and mixture designs & D optimal design, Response surface analysis, Sequential optimization methodology, Artificial neural network.	05	05-10
3.	**Dosage form development:** Types, components, manufacturing and evaluation of tablets (coated, uncoated, layered and immediate release, advances in coating), capsules (HGC, SGC, microcapsules), liquids like oral solution (dry mixtures, ORS, syrups, elixirs), suspension (coarse suspension, nano suspension), emulsion (conventional, multiple, microemulsion, nanoemulsion) Cgmp as followed in the manufacturing of above dosage forms.	10	30-35

4.	**Validation:** Concept and need of validation, types of validation, process validation, equipment validation and cleaning validation, validation master plan.	05	05–10
5.	**Packaging of pharmaceuticals:** Types of primary and secondary packaging materials for pharmaceuticals. Studies on types and suitability evaluation of glass, plastic, metal, films, paper and rubber as a primary packaging for non-sterile and sterile dosage forms. Regulatory requirements for pharmaceutical packaging.	05	10–15
6.	**Statistics in product development** Data collection, summarizing data, statistical models like linear and multiple regression analysis, significance testing using 't' test, 'z' test, and 'chi square' test. Analysis of variance (one way and two way ANOVA, 'F' test)	05	10-15
7.	**Drug regulatory affairs:** Need of harmonization in pharmaceutical sector, Regulatory requirements of US, UK, domestic and other markets. Concept of NDA and ANDA with the process of patent filing.	04	05–10
8.	**Stability Studies:** Basic concepts, consideration of physical and chemical stability studies, Stability test protocol. Accelerated stability studies	05	05-10

(vi) Recommended Reading:

a) Basic Reading:

1. N. K. Jain, Pharmaceutical Product Development. 2006, CBS Publishers & Distributors, New Delhi.
2. Martin Rhodes, Principles in Powder Technology Edited by , John Wiley & Sons Limited, Chichester, 1990.
3. Avis, Leon Lachman and Herbert A. Lieberman, Pharmaceutical Dosage Forms-Disperse Systems,1998, Volume 1 and 2 Marcel Dekker.
4. A. Martin,P. Bustamante, and A. H. C. Chun., Physical pharmacy: Physical and chemical principles in the pharmaceutical sciences, 1999, 4 th ed.,Waverly Pvt. Ltd., New Delhi.
5. G. Alderborn and C. Nystrom, Pharmaceutical Powder Compaction Technology, 1996, Marcel Dekker.

b) Additional Reading:

1. McCauley, J. A. and Brittain, H. G., Thermal methods of analysis. In Physical Characterization of Pharmaceutical Solids,1995, Marcel Dekker.

2. Carstensen JT , Drug Stability: Principles and Practices, 1995, 2nd ed. Marcel Decker, New-York.
3. M. N. Rubinstein; Pharmaceutical Technology, Drug stability, 1987, Ellis Horwood Ltd., John Wiley & Sons, UK.
4. James J. Wells; Pharmaceutical Preformulation,1988, Ellis Harwood Ltd Wells, , Chichester, UK.

c) References:

i) Books:

1. Tarcha,. P.J., Polymers for Controlled Drug Delivery, 1991, CRC Press, Boca Raton.
2. List PH and Schmidt PC, 1989, Phytopharmaceutical Technology, 1989, 1 edi.CRC Press, Publisher.
3. Robinson; Novel Drug Delivery Systems, 1987, Marcel Dekker Inc, New York.
4. N. G. Stanley, Enlargement & Compaction of Particulate Solids, 1983, N.G. Stanley-Wood, Butterworth & Co. Ltd.

ii) Periodicals/Journals:

1. Asian Journal of Pharmaceutical Science
2. Asian Journal of Pharmaceutics
3. Drug Development and Industrial Pharmacy (USA)
4. Drug Delivery (England)
5. Drug Development Research (USA)
6. Indian Journal of Pharmaceutical Education and Research (India)
7. Indian Journal of Pharmaceutical Sciences (India)
8. Pda Journal Of Pharmaceutical Science And Technology (USA)
9. Pharmaceutical Research (USA)

i) Paper : 4 (ELECTIVE) ELE-I

ii) Title of Paper : INDUSTRIAL PHARMACY AND PRODUCTION MANAGEMENT

iii) Specific Objectives:

1. To gain an insight in the basic principles of improvement in the pharmaceutical processes and avoid scale-up problems.
2. To understand preformulation studies, understand production planning and control pharmaceutical processes.
3. To understand quality management system and different sterilization processes require for different steps of production.
4. To understand different Industrial hazards & safety majors, pollution control and effluent treatment.

iv) Note:

1. The student should have a basic knowledge of formulations such as tablet manufacturing, Capsules manufacturing, Liquids orals, and Parental.
2. For better understanding, good video and animated clips can be used if the more advanced facilities are available. In fact they can be used very fruitfully.

9. INDUSTRIAL PHARMACY AND PRODUCTION MANAGEMENT **Theory (3 hrs/wk)** **Tutorial (1 hr/wk)**

Unit	Contents	Hrs	Marks
1.	**Production planning & control and documentation:** Production scheduling, forecasting, vendor development, capacity assessment (plant, machines, human resources), production management, production organization, objectives and policies. Productivity, management and cost controls.	06	10-15
2.	**Preformulation studies:** Introduction, purity, particle size, shape and crystallinity, solubility, pH solubility profile, dissolution & intrinsic dissolution rate, partition coefficient, melting point, polymorphism, hygroscopicity, volatility, flow properties, stability, drug-excipient compatibility, significance of preformulation studies.	05	10-12
3.	**Pilot plant scale up techniques:** Significance, pilot study of some important dosage forms such as tablets, capsules and liquid orals, discussion on important parameters such as formula, equipments, product uniformity and stability, raw material process and physical layouts, personnel requirements and reporting responsibilities.	05	10-13

4.	**Sterilization process:** Basic concepts, F, D, Z values, sterilization methods and equipments, sterility testing: principle, advantages and disadvantages, general procedure, control tests, sterility testing of ophthalmic preparations, surgical sutures and ligatures, surgical dressings; ampoules, vials, transfusion bottles and other parenterals; vaccine bottles, syringes and needles. Applications of different sterilization methods in pharmaceutical industry, biological indicators.	04	10- 12
5.	**Industrial hazards, safety, pollution control and effluent treatment:** Introduction, factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, electrical hazards, chemicals hazards and management of over exposure to chemicals, gas hazards and handling of gases, dust explosion and its control, fire prevention and control.	04	10-12
6.	**Optimization Techniques and Quality Assurance:** Optimization parameters, classical optimization, statistical design and applied optimization methods, GMP considerations, quality assurance and process control. Total quality management and productivity. ISO 9000 Salient features.	04	10-12
7.	**Automation:** Flexible manufacturing system. Computer control systems: data acquisition, distribution control and centralized control system. Typical models for solid and liquid manufacturing.	04	10-12
8.	**Drugs and Cosmetics Act:** Requirement related to manufacturing and sale of drugs.	04	10-12

(vi) Recommended Reading:

a) Basic Reading:

1. A. Jaiswal: Management of quality control and standardization: Kanishka Publisher, New Delhi, 1998.
2. Woodard F. Industrial Waste Treatment Handbook. Butterworth-Hienneman, Avenue of the Americas, New York.
3. G. C. Cole: Pharmaceutical production facilities, design and application: 2nd Ed. Taylor & Francis, 1998.
4. J. M. Juran and A. B. Godfrey: Juran's quality handbook, 5th Ed, McGrawHill, 1998.
5. Lachman L., Lieberman H.A., Kanig J.L. The Theory and Practice of Industrial Pharmacy, 3rd ed. Philadelphia: Lea & Febiger, 28, 1976.
6. Swarbrick J., Boylan J.C. Encyclopedia of Pharmaceutical Technology. Vol.1-19, M. Dekker, Inc. New York 1988.

b) Additional Reading:

1. P. Gilson. G. Green halgh and K. Kerr: Manufacturing management: Chapman and Hall.
2. D. H. Stamatis: Understanding ISO 9000 and implementing the basics to quality: Marcel Dekker Inc, New York, 1995.
3. B. Rothery: ISO 14000 and ISO 9000; The University of Michigan, Gower, 1995.
4. J. F. Despautz: Automation and validation of information in Pharmaceutical processing: Marcel Dekker. 35, 1998.
5. J. R. Berry and R. A. Nashi Pharmaceutical process validation, Inc, New York, 1995.

c) References:

i) Books:

1. S. S. Rao: Optimization theory and applications, Wiley Eastern Limited, 2nd ed. New Delhi, 1984.
2. R. F. Brewer, Design of Experiments for process improvement and quality Assurance: Narosa.
3. S. H. Will and J. R. Stoker; Good Manufacturing Practices for Pharmaceutical: Marcel Dekker, 2nd ed., New York, 1982.
4. P. R. Watt: Tablet machine instruments in pharmaceuticals; John Wiley and Sons, Rothery, 2011.
5. Willing S.H., Stoker J.R. Good Manufacturing Practices in Pharmaceuticals- A Plan for Total Quality Control. Marcel Dekker, Inc.
6. Jacobsen T.M. Modern Pharmaceutical Industry: A Primer. Jones & Bartlett Publishers, 2010.

ii) Periodicals/Journals:

1. Journal of Pharmaceutical marketing and Management.
2. Pharmaceutical science and technology today

i) Paper : 4 (ELECTIVE) ELE-I

ii) Title of Paper: QUALITY ASSURANCE

iii) Specific Objectives:

1. To provide a comprehensive overview of the requirements for effective management of the quality assurance function includes its role in supporting the quality, productivity control and improvement efforts in drug manufacturing. To provide the student with an understanding of key methods of Quality.
2. To introduce basic concepts of quality control and quality assurance, to give an overview of quality assurance in the drug industry, regulatory guidelines of quality assurance tools with applications in the drug manufacturing industry, and to cover up-to-date topics of quality assurance as they relate to drug industry.

iv) Note:

1. The student should gain basic concepts of quality assurance, documentation, good laboratory practices along with basic knowledge of the regulatory bodies. The content will provide thrust on good manufacturing practices, quality audits, documentation and validation with a view to create total quality consciousness. For better understanding, animated video clips can be used if the more advanced facilities are available.

10. QUALITY ASSURANCE **Theory (3 hrs/wk)**
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Introduction:** Basic concepts of Quality, Quality control, Quality Assurance and Good Manufacturing Practice as applied to the pharmaceutical Industry. Organization & functions of the Federal Food & Drug Administration of USA.	05	10-13
2.	**Documentation related to Pharmaceutical Industry:** Manufacturing documents: BMR, routine records, downtime records, calibration and validation records, Consumer related documents: Product recall, complaint traceability printed packing, preventive maintenance records, Returned and Salvaged Drug products, Repacking and Re-labeling. **Store management documents:** Stock reconciliation records for raw material, finished products and packaging materials, Maintenance and Environment control related documents.	05	10-12

3.	**Validation :** Definition & concept of validation, types, scope, objectives of validation. Benefits and types of process validation, validation protocol, process characterization and optimization. Validation of processes: Mixing, granulation, drying, compression, filtration. **Equipment Validation:** Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification, Validation of following equipment - HPLC, UV and dissolution test apparatus.	05	12-15
4.	**New drug applications:** NDA and ANDA requirements, Data presentation, verification and grant by FDA. Preparation of documents for New Drug Application (NDA) as per requirements of FDA and EUDRA guidelines. GMP requirements for FDA, and ICH.	04	12-15
5.	**Pharmaceutical Quality Audits**: Plant Level documentation, Plant Level Department wise Quaternaries, Principle of Quality Audit. Finished product release, Quality review, Quality audit. Batch release documents.	04	10-13
6.	**Good laboratory Practices (GLP):** Regulations , Scope, Organization, personnel- technical competence, desirable qualities of analyst, analyst validation, responsibilities of key personnel in the QC laboratories, biological evaluation microbiological limit tests, sterility tests for effectiveness of antimicrobial preservative, clinical trials, Bioassays.	04	10-12
7.	**Related quality systems:** Brief introduction to following regulatory agencies. ISO, WHO, USFDA, TGA, MCC, MHRA, ICH. Introduction to latest ISO Guide lines and I C H Guidelines, Pharmaceutical Quality System (ICH Q10), WHO Guide lines and their applications in pharmaceutical industry.	05	10-12
8.	**Quality by Design and Quality risk management:** (ICH Q8 & Q9).	04	06-08

(vi) Recommended Reading:

a) Basic Reading:

1. Total Quality Management- Guiding Principle for Application, J. P. Peker, ASTM manual series, Philadelphia.
2. Total Quality Management – The Key to Business Improvemetn, Champman & Hall, Londan.
3. A guide to Total Quality Management – Kaushik Maitra and Sedhan K.Ghosh.
4. ISO 9000 and Total Quality Management – Sadhank. G. Ghosh.

5. Drugs and Cosmetics Rules-1945, Schedule-M.India.
6. Quality Assurance of pharmaceuticals: A compendium of guidelines and related materials: Vol. 2: Good manufacturing Practice, World Health Organisation, Geneva-1999.
7. Good Laboratory Practice Regulations, Sandy Weinberg, Vol. 124, Marcel Dekker Inc., New York.
8. Good laboratory Practice, Jurg Seiler, Springer New York.
9. Good Laboratory Practice and Regulatory Issues, P. V. Mohanan, Educational book centre, Mumbai.
10. How to Practice GLP, P. P. Sharma, Vandana Publication, New Delhi.
11. The rules governing medicinal products in European Union: Vol. 4: Good Manufacturing Practice: Medicinal products for human and veterinary use. 1998 Edition: European commission, Directorate General III-Industry, Pharmaceuticals and Cosmetics.
12. Code of Federal Regulations Parts 210 and 211 of U.S.A.
13. IDMA – APA guidelines on Stability Testing of existing drug substances and products. Technical monograph No.1 Oct. 2002.
14. IDMA – APA guidelines on Test Standards for primary and secondary chemical reference substances. Technical Monograph No.2 Sept. 2004.
15. S. Weinberg, Good laboratory practice Regulations, Marcel and Dekker.
16. J. Swarbrick Boylan, Encyclopedia of pharmaceutical technology, Marcel and Dekker.
17. J.R. Berry and R.A. Nash, Pharmaceutical process validation. Marcel and Dekker.
18. S.H. Will and J.R. Stoker, Good manufacturing Practices for Pharmaceutics Marcel Dekker.
19. R.F. Brewer, Design of experiments for process improvement and quality Assurance Narrosa.
20. B. Othery. ISO 14000 and ISO 9000 Gower.
21. D.H. Stamatis, Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.
22. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh.
23. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition by Douglas J. Pisano and David S. Mantus.
24. Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug Development Series, Vol 1) by Helene I. Dumitriu
25. Pharmaceutical Patent Law by John R. Thomas.
26. How to Practice GMPs 2nd ed. by Sharma P. P., Vandana publishing, New Delhi.

b) Additional Reading:

1. S.O.P. content, Format and Management By Carol De Sain, Published by Advanstar Communications Cleveland Ohio. U.S.A.
2. Designing the perfect Changes Control System By David M. Stephon, Assistant Director, Compliance and Training, Elan Pharmaceutical Technologies. Journal of GXP compliance Vol. S. No. 4: July 2001.
3. Validation of Manufacturing Process PP 53 to 70. Quality Assurance of Pharmaceuticals Vol.2. W.H.O. Geneva.

c) References:

i) Books:

1. Pharmaceutical Process Validation 2nd Edition By Ira R. Berry and Robert A. Nash. Marcel Dekkar Inc. 1993.
2. Validation of Pharmaceutical Processes (Sterile Products) 2nd Edition. By Fredrick J. Carletion and James P. Agalloco. Marcel Dekker Inc. 1999.
3. Pharmaceutical Quality Assurance by Prof. M.A. Potdar, Nirali Prakashan, Pune – India 2006.

ii) Periodicals/Journals:

1. Journal of GXP compliance ((Springer)
2. Pharmaceutical technology (findpharma)
3. Pharmaceutical Research (Springer)
4. Pharmaceutical Technology (Elsevier)

i) Paper : 8 (ELECTIVE) ELE-II

ii) Title of Paper : COSMETICOLOGY

iii) Specific Objectives:

1. Students are introduced to the overall process of cosmetic manufacturing.
2. They know how the cosmetic product manufacturing, evaluation and packaging, has evolved and what are recent developments in this field.
3. The students develop through understanding about the FDA guidelines about cosmetic product manufacturing, testing, saling, export and import policies.

iv) Note:

1. The student is well versed with the detailed cosmetics products including herbal cosmetics formulations and novel materials used for better effects of cosmetics.

11. COSMETICOLOGY

Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Physiological Consideration:** Skin, hair, nail and eye- in relation to cosmetic application.	03	08-10
2.	**Properties, significance & applications:** Excipients used in various cosmetic formulations, colors, surfactants, preservative, fragrances and antioxidant	03	08-10
3.	**Manufacturing techniques:** Cleansing creams, Emollient creams, Hand creams, hormone cream, face powders, Deodorants, antiperspirants, suntan preparations, anti-aging products, dentifrices, Rouges, Lipsticks, Shampoos, hair grooming preparations, preshave & after shave preparations, depilatories & hair dyes, Nail lacquers, Nail lacquers removers, Eye shadow, mascara, eyeliners, eye cover-up makeup, eye lashes, eye make-up remover.	10	12-17
4.	**Evaluation of cosmetics:** Performance, physicochemical, and microbiological evaluation of mentioned cosmetics products in chapter 3.	05	12–15
5.	**Clinical safety testing:** Irritation, sensitization, ocular irritation and protocols for the same.	03	08–10
6.	**Regulatory requirements:** Manufacturing, sale, labeling, packaging standards, export & import policy of cosmetics in national & international level	03	08-10
7.	**Advance in cosmetics:** Liposomes, multiple and micromulsions, hair	05	12–14

waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses. Introduction to Herbal cosmetics

8.	**Packaging:** Package development and design for cosmetics including aerosol packs, containers & closures, pouches.	04	12-14

(vi) Recommended Reading:

a) Basic Reading:

1. M. S. Balsam, Edward Sagarin, Edward Sagarin, Cosmetics Science And Technology, 1972, 2 ed. 3 vols., John Wiley & Sons.
2. R. J. Moore, J. B. Wilkinson, Harry's Cosmeticology, 1982, 7th Edition ,Chemical Publishing Co Inc.,U.S.
3. Thomssen EG , Modern cosmetics 2006, Universal Publishing Corporation, Bombay.
4. Sanju Nanda, Arun Nanda and Roop K. Khar, Cosmetic Technology, 2005, Birla Publications Pvt. Ltd., Delhi.
5. J.Knowlton and S.Rearce, Handbook of cosmetic science and technology,1993, 1st edition; Elsevier science publisher; oxford, UK.

b) Additional Reading:

1. R. L. Elder; Cosmetic Ingredients, their safety assessment; Pathotox
2. H.R.Moskowitz, Cosmetic product testing: a modern psychophysical approach".Cosmetic Science and Technology series, 1984, Vol.3 -Marcel Dekker, INC.
3. Waggoner W. C., Clinical safety and efficacy testing of cosmetic, 1984, Marcel Dekker, New York.
4. C. G. Gebelein, T. C. Cheng and V. C. Yang, Cosmetic and Pharmaceutical Applications of Polymers,1991, Plenum Press, New York.

c) References:

i) Books:

1. Appell, Louis, The Formulation and Preparation of Cosmetics, Fragrances and Flavors, 1994, Weymouth, Dorset, England: Micelle Press.
2. Poucher's perfumes, cosmetics and soaps, 1993, 9th edn, vol. 3. London. : Chapman and Hall.
3. Dennis Laba, Rheological properties of cosmetics and toiletries, Edited by, “Cosmetic science and technology series; 1993, v.13, Marcel Dekker, Inc., Newyork.
4. Katju SN. Laws and drugs. ., 2004., 3rd publications, Law Publishers Pvt. Ltd..

ii) Periodicals/Journals:

1. Pharma review
2. Color Research and Application Journal
3. Cosmetic Dermatology Journal
4. Cosmetics And Toiletries Journal
5. Dyes and Pigments Journal
6. Flavour and Fragrance Journal
7. Journal of Cosmetic Science (England) Journal
8. Pharmaceutical and Cosmetic Review Journal

i) Paper : 8 (ELECTIVE) ELE-II

ii) Title of Paper: PHYTOPHARMACEUTICALS

iii) Specific Objectives:

1. To gain an insight in the phytopharmaceuticals, neutraceuticals and cosmeceuticals
2. To understand the role and adventages of phyto-based excipients used in Pharma related industries.
3. The student will gain a good understanding of how to obtain phytoconstituents in pure form to be used as drugs and excipients in different disorders along with their physic-chemical properties, formulation development and efficacy.

iv) Note:

1. The student should have a basic knowledge of the extraction and purification techniques of phytoconstituents.
2. Students should have knowledge of pharmaceutical and Ayurvedic dosage forms.

12. PHYTOPHARMACEUTICALS Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Pharmaceutical natural excipients:** physical, chemical and biological properties of natural excipients and polymers. Studies on drug-excipient interactions and their characterization. Standardization of excipients	04	08-10
2.	**Modern techniques of isolation and purification of phytoconstituents:** Counter current extraction techniques, Flash chromatography, SCF extraction, Microwave extraction technique, HPLC, HPTLC, LC-Mass, Ion exchange chromatography, Ion –resin extraction, Electrophoresis.	04	08-10
3.	**Study of Herbal Extracts:** Processing, equipment and analytical profiles. Sterility, stability and preservation of extracts.	02	04-06
4.	**Source**, phytochemistry (isolation, identification, chemical nature) and physiological activities of following phytopharmaceuticals. **Anticancer:** Taxol, other taxanes, Camptothecin, vinblastine, Genistein, Etoposide.	08	20-24
5.	**Nervous system activities:** Hypericin, Valepotriates, Gingkolides.	04	08-10
6.	**Anti-inflammatory:** Curcuminoids, Guggulipids, Boswellic acid, Serratioptidase.	04	08-10
7.	**CVS activities:** Colenol, Streptokinase, Tinosporin	03	06-08

8.	**Miscellaneous:** Silymarin, Artemisinin, Omega-3 fatty acids, Charantin and momordicosides, Resveretrol, Protamine sulphate, Andrographolides	07	18-22

(vi) Recommended Reading:

a) Basic Reading:

1. Shah and Quadri Text Book of Pharmacognosy.
2. Chopra, Indigenous drug of India.
3. Rangari V.D., Pharmacognosy & Phytochemistry, Vol I, II, Career Publication, Nashik
4. Wealth of India. The Raw Materials.
5. K. M. Nadkarni, Materia Medica. Vol.I-II
6. The Practical Evaluation of Phytopharmaceuticals.by Brain & Turner.
7. WHO, Quality Control methods for medicinal plant material
8. Chemistry of Natural Products, P.S Kalsi
9. Chaudhari R D, Herbal Drug Industry, Eastern publication
10. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons
11. E. Ramstad, Modern Pharmacognosy, Mc-graw hill Book Company

    Wagner, Plant Drug Analysis PDR for Herbal Medicines, Second Ed., Medicinal Economic Company, New Jersey
12. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
13. Standardisation of Botanicals by V.Rajpal, Vol.1, Eastern Publishers, New Delhi, 2002.

b) Additional Reading:

1. Agrawal O.P., Chemistry of Organic Natural Product, Goel Publication House, UP.
2. Pharmacognosy : Kokate, Puruhit, Gokhale, Nirali Prakashan, Pune, 15th edtn.
3. Wealth of India.
4. WHO guidelines for standardization of medicinal plants Geneva 2002.
5. Chopra, Indigenous drugs of India.

c) References:

i) Books:

1. Plant drug analysis Peach and Tracy Narosa Publishing house Delhi
2. H.G.Brittain, Physical Characterization of Pharmaceutical solids, Marcel Dekker
3. Tarcha, P. J. Polymers for controlled Drug Delivery; CRC Press. 1991.
4. Remington's Pharmaceutical Sciences. 21-st editions, Vol. I-II Lippincott

Williams and Wilkins.
5. Phytochemical methods : J. B. Harborne
6. Ayurvedic Pharmacopoeia.
7. Indian Pharmacopoeia.
8. British Pharmacopoeia
9. Quality Standards of Indian Medicinal Plants, Vol -I, ICMR, New Delhi.

ii) Periodicals/Journals:

1. Journals published by NISCAIR
2. Pharmaceutical Research Journals(Springer)
3. Pharmacognosy and natural products journals

i) Paper : 8 (ELECTIVE) ELE-II

ii) Title of Paper : STERILE PRODUCT FORMULATION AND TECHNOLOGY

iii) Specific Objectives:

1. Students are introduced to the overall preformulation studies of sterile products.
2. Students know about the official requirements, components and different special types of parenterals.
3. Students focused with development process of ophthalmic and sustained release parenterals
4. Students be acquainted with the modern techniques used in manufacturing of parenterals
5. Students ripen through understanding about the regulatory guidelines

iv) Note:

1. Student be supposed to knowledgeable with the detailed formulation and technology of Sterile products
2. Student should have methodical sympathetic by sterile product.

13. STERILE PRODUCT FORMULATION AND TECHNOLOGY Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
A)	**FORMULATIONS:**		
1.	**Preformulation:** Physico-chemical properties of materials used in perenteral formulations. Selection of polymeric components. Selection of packaging components.	03	08-10
2.	**Formulation of SVP:** Requirement, components, materials, Pharmacopoeial requirements	04	08-10
3.	**Formulation of LVP:** Requirement, components, materials, Parenterals such as liquids, solids, suspensions, emulsions, dried forms, sterile diagnostics and radiopharmaceuticals.	05	10-12
4.	**Ophthalmic Products:** Ocular anatomy and physiology relevant to ocular drug delivery, ocular pharmacokinetics, conventional products, ocular inserts, particulate and liposomal drug delivery, protein and prptide delivery.	05	12-16
5.	**Sustained Release Parenterals: -** Liposomes, and niosomes, nanoparticles, proteins and peptides, implants, loaded erythrocytes.	06	16-20
B)	**TECHNOLOGY: Manufacturing of Parenterals:**		

6.	**Environmental control:** Temperature and humidity control, air handing systems and their validation.	04	08-10
7.	**Industrial sterilization:** Large scale sterilization processes, process selection, specifications, development and validation of process and equipment.	05	10-12
8.	**Guidelines:** Overview of GMP and regulatory guidelines.	04	08-10

(vi) Recommended Reading:

a) Basic Reading:

1. K. E. Avis, H. A. Liberman and Lanchman; Pharmaceutical dosage forms: Parenteral Medications: Vol. 1, 2, 3, Marcel Dekker.
2. J. Swarbrick and J. C. Boylan; Encyclopedia of Pharmaceutical Technology: Vol. 1, 2, 3, Marcel Dekker,Inc.
3. S. J. Turco; Sterile dosage forms: their preparation and clinical application; Lee and Febiger.

b) Additional Reading:

1. F. J. Carleton and J. P. Agalloco; Validation of aseptic pharmaceutical processes: Marcel Dekker.
2. L. A. Trissel: Handbook on injectable drugs; American Society for Hospital Pharmacist Publication

c) References:

i) Books:

1. N. A. Halls; Achieving sterility in medical and pharmaceutical products; Marcel and Dekker.
2. N. K. Jain; Controlled and novel drug delivery: CBS Publication.
3. J. R. Robinson and H. L. Lee; Controlled drugs delivery: Fundamentals and Applications; Marcel Dekker.

ii) Periodicals/Journals:

1. International Journal of Pharmaceutics.
2. European Journal of Pharmaceutics.
3. Journal of Controlled Release

i) Paper : 8 (ELECTIVE) ELE-II

ii) Title of Paper : FERMENTATION TECHNOLOGY

iii) Specific Objectives:

1. The subject offers to know the basics of Fermentation Processes and industrially improved strains for microbial production of proteins, polysaccharides, amino acids, etc.,
2. The advanced fermenter designs improves the quality and increased yield of products like biopharmaceuticals, single cell proteins, alcohols, acids, nitrogen fertilizers etc.,
3. The production and quality of products are in hands of purification and downstream processing for vaccines, monoclonal antibodies, recombinant proteins, biofertilizers, etc.,

iv) Note:

1. To know the various improved strains of microorganisms and immobilized cells in production of biopharmaceuticals.
2. Bioprocess and Biochemical Engineering aspects of Fermenter Designs in increasing yield of products.
3. To know the guidelines of industrial microbiology for biotechnological products.

14. FERMENTATION TECHNOLOGY Theory (2 hrs/wk)

Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Introduction to fermentation processes** Industrial Microorganisms: Source, characteristics, growth and genetics. Aerobic and anaerobic fermentations; Kinetics of growth and product formation - chemically structured models; mass transfer diffusion, membrane transport	03	05-06
2.	**Molecular engineering** Important strains and pathways – types, development of cultivations systems for aerobes and anaerobes, mutation and genetic engineering for strain improvements, product formation and inhibition pathways and their regulations; applications in medicine, agriculture and industry.	04	10-12
3.	**Bioreactors** Introduction to bioreactors; Batch and Fed-batch bioreactors, Continuous bioreactors; Immobilized cells reactors; Bioreactor operation; Sterilization; Aeration; Sensors; Instrumentation; Culture-specific design aspects: plant/mammalian cell culture reactors, Aeration and agitation in	07	15-20

fermentation: Oxygen requirement, measurement of adsorption coefficients, bubble aeration, mechanical agitation, correlation between mass-transfer coefficient and operating variables, hollow fibre reactors.

4.	**Bioseparations and Down Stream Processing**	07	15-20

- Harvesting: Sedimentation, centrifugation, filtration.
- Cell Disintegration: Non-mechanical method such as wet milling, high pressure homogenization, treatment extrusion and ultra-sonication.
- Clarification of crude extract.
- Product Enrichment: precipitation, ultrafiltration, extraction.
- Chromatography: Gel filtration, ion exchange, hydrophobic and affinity type

5.	**Bioprocess Technology and Bioengineering Aspects**	04	10-12

Strategies of biopharmaceutical production using microbiological processes and mammalian cell culture, Operating considerations for bioreactors for suspension and immobilized cultures, Aeration, mixing and hydrodynamics in bioreactors, Fed-batch cultivation of mammalian cells for the production of recombinant proteins, Optimization of high cell density perfusion bioreactors,

6.	**Microbial production of :**	04	10-12

Antibiotics : Penicillin, streptomycin; Enzymes : Proteases, amylases, Organic acids : Citric acid, acetic acid; Vitamins : Vit B12, B2; Amino acids: Glutamic acid, Lysine; Alkaloids; Alcohol, beer, wine, sake; Polysaccharides, Single Cell Protein, Nitrogen fertilizers

7.	**Biotransformation**	03	05-06

Types, methods and processes, analysis and isolation of products, applications in waste management, medicine and agriculture; Biogas production – pathways, regulation/modulation, advanced biomethanation systems and their applications.

8.	**Interiors of Fermentation Plant**	04	10-12

Critical process utilities for water and clean steam, Equipment cleaning (Clean-In-Place, Clean-Out-of-Place), Sterilization of Equipment, Piping and Process Fluids (Steam-In-Place, Autoclave Sterilization, Biowaste Treatment), cGMP and BPE guidelines. Examples of sanitary equipment and components. Biopharmaceutical manufacturing facility – block flow diagram and conceptual layout. People, materials and equipment flows. Room classification. HVAC design requirements. Validation of biopharm facilities. Validation basics, equipment and facility qualification.

(vi) Recommended Reading:

a) Basic Reading:

1. Casida L. E. Industrial Microbiology: Wiley Eastern Limited.
2. Pirt S.J. Principles of Microbial and Cell Cultivation. Blackwell Scientific Publication, London.
3. Chand., Fermentation Biotechnology: Industrial Perspectives

b) Additional Reading:

1. Cruger, Biotechnology - A Text Book of Industrial Microbiology.
2. Belter, P.A. Cussler, E.L. Bioseparation: Downstream processing for Biotechnology
3. Stanbury P.F., Whitaker A. & Hall S.J., (2007). Principles of Fermentation Technology. Elsevier India Pvt Ltd.,
4. Schuler and Kargi (2002). Bioprocess Engineering: Basic Concepts 2nd Edition, Prentice Hall.
5. Veith W.F., Bioprocess Engineering Kinetics, Mass Transport, Reactors, and Gene expressions by John Wiley and Sons.
6. Roger Harrison et al., (2003). Bioseparations Science and Engineering, Oxford University Press.

c) References:

i) Books:

1. Shuler M. & Kargi F., (2002). Bioprocess Engineering: Basic Concepts, 2nd Edn., Prentice Hall.
2. Stanbury, P.F., Whitekar A., (1995). Principles of Fermentation Technology by and Hall.
3. Lydersen B. D'Elia N. & Nelson K., (1994). Bioprocess Engineering: Systems, Equipment and Facilities. John Wiley & Sons, Inc.

ii) Periodicals/Journals:

1. Product recovery in bioprocess technology, BIOTOL Series, VCH, 1990.
2. Desai M. A. (2000). Downstream processing of proteins: methods and protocols (methods in biotechnology); Humana Press.

i) Paper : 8 (ELECTIVE) ELE-II

ii) Title of Paper : QUALITY CONTROL

iii) Specific Objectives:

1. To know and understand effective pharmaceutical quality system to enhance the quality and availability of medicines around the world in the interest of public health.
2. To give an overview of existing legislation related to pharmaceutical quality systems, and further, on the efficient implementation of such systems.

iv) Note:

1. The topics must be conveyed through plenty of examples. Lecture classes must be conducted as lecture-cum-power point presentations.
2. The teacher must not depend on a single or a set of two or three text books. He must choose his materials from diverse sources.

15. QUALITY CONTROL **Theory (2 hrs/wk)**
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Biopharmaceutics:** Concept of Therapeutic equivalence and Pharmaceutical equivalence, General steps in Conduct and Analysis of Bioavailability and Bioequivalence Studies.	04	08-10
2.	**Good Manufacturing Practices:** The basic concepts of Quality Assurance (QA), Good Manufacturing Practices (GMP), and quality control (QC), their relationships and their fundamental importance to the production and control of drugs.	04	08-10
3.	**Quality Risk Management**: Introduction to Quality Risk Management (QRM), Scope, Principles of QRM, Risk management methodology, applications of QRM.	04	08-10
4.	**Pharmaceutical Quality System (PQS)**: ICH Quality Roadmap, Quality by Design (QbD), Introduction and scope, Management responsibility, Continual improvement of Process performance & Product quality, Continual improvement of PQS. Comparison of QC and QA aspects in International and National Pharmacopoeias.	06	16-20
5.	**Stability Studies:** Stability testing of API and pharmaceutical products. Evaluation of stability data and stability data package for registration applications.	04	08-10
6.	**Clinical Trials:** General considerations for clinical trials, Protection of clinical trial subjects, Scientific approaches in design and analysis,	04	08-10

development methodology.

7.	**Pharmaceutical Packaging:** Evaluation of pharmaceutical container closure systems (Official and in-house methods). Development of 'Package inserts' and 'Drug information leaflets.	04	08-10
8.	**Process Technology:** Statistics in drug product development and regulatory approval processes. In-process quality control tests, introduction to Process Analytical Technology (PAT) as a framework for innovative pharmaceutical manufacturing and QA.	06	16-20

(vi) Recommended Reading:

a) Basic Reading:

1. Oliver Schmidt. Pharmaceutical Quality Systems, Interpharm Press Inc, Denver, Colorado, US. 2000.
2. Jens T. Carstensen, Christopher Rhodes. Drug Stability: Principles and Practices (Drugs and the Pharmaceutical Sciences) by M. Dekker, New York. 2000.
3. G. Ignazio, Routledge. Principles of Clinical Research, 1 ed. 2001.

b) Additional Reading:

1. Introduction: Process Analytical Technology, http://www.fda.gov/der/OPS/PAT.htm.
2. Daniel Farb, Anthony Luttrell, Robert Kirsch Pharmaceutical Quality Control Lab, Guidebook.
3. Shayne C. Gad Pharmaceutical manufacturing handbook. John Wiley and Sons, Hoboken New Jersy, Canada, 2008.
4. Shein-Chung Chow and Jen-Pei Liu. Biostatistics: Design and Analysis of Bioavailability and Bioequivalence studies, New York, Marcel Dekker, 2000.
5. A WHO guide to good manufacturing practice (GMP) requirements, World Health Organization, Geneva, 1997.
6. James L.Vesper. Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple, PDA book store, 2006.

c) References:

i) Books:

1. Patient Package Insert as a Source of Drug Information Edited by M. Bogaert, R. v. d. Stichele, J. -M. Kaufman, R. Lefebvre, Excerpta Medica.
2. Katherine A. Bakeev. Process Analytical Technology: John Wiley and Sons, Chihester, West Sussex, UK, 2010.
3. Bert Spilker. Guide to Clinical Trials. 1st ed., Lippincott Williams & Wilkins; 1991.

4. Richard Guarino. New Drug Approval Process, Fourth Edition, Informa Healthcare, USA.

ii) Periodicals/Journals:

1. Indian Journal of Pharmaceutical Sciences
2. Pharmaceutical Research
3. Indian Journal of Pharmaceutical Education and Research

i) Paper : 8 (ELECTIVE) ELE-II

ii) Title of Paper : IMMUNOPHARMACOLOGY AND IMMUNOASSAYS

iii) Specific Objectives:

1. To gain an insight in the basic principles of immunology and pharmacological aspects of clinical conditions involving immunological mechanisms.
2. Knowing and being able to implement the current concepts of immunopharmacology in research and therapy of various diseases.
3. The student will gain a good understanding of methods for (invitro and invivo) evaluation of drugs influencing immune system.

iv) Note:

1. The student should have a basic knowledge of Anatomy, Physiology, Immunity, Pathology and Pharmacology.
2. For better understanding, good video and animated clips can be used if the more advanced facilities are available. In fact they can be used very fruitfully.

16. IMMUNOPHARMACOLOGY AND IMMUNOASSAYS

Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Basics of Immunology** Definitions of pathogen, virulence, attenuation, exaltation, antigens, antibodies and antisera - defense mechanisms of host - non-specific (skin and mucous membranes, phagocytosis, complement system, inflammation, host damage with exotoxins and endotoxins) - specific defense mechanisms - cellular immunity - humoral immunity - Immunity - types of immunity (natural, naturally acquired, acquired (active and passive) Types and Structure of immunoglobulins.	06	15-18
2.	**Preclinical aspects of Immunopharmacology** Study of basic principles involved in development of immunocompromised animal models	03	05-07
3.	**Immunological therapy and products Vaccinology** Preparation and standardization of vaccines, sera, allergenic extracts, diagnostics, biologicals, immunomodulating substances, lymphokines **Hybridoma Technology** Preparation of monoclonal antibodies, structure of chimeric, and humanized monoclonal antibodies, Applications of monoclonal antibodies.	06	15-18

4.	**Computational Polypharmacology** Computational Polypharmacology with text mining and ontologies, Sytems biology, artificial neural networks	04	05-07
5.	**Basics of Immunoassays** **General principles of immunoassay** : Theoretical basis, optimization of immunoassay, Heterogeneous immunoassay system, Homogeneous immunoassay systems. **Production of Immunoassay reagents** Introduction, receptors or binders, unlabelled ligands calibrators, Labelled ligands and receptors, separation techniques, buffers.	04	10-12
6.	**Immunoassay techniques** Radioimmunoassay (RIA), Enzyme multiplied Immuno assay techniques (EMIT) Fluorescence polarization Immunoassay (FPIA) Enzyme linked Immunosorbent Assay (ELISA) Apoenzyme - Reactivation Immunoassay (NIIA) Substrate labeled fluorescence immunoassay (SLFIA) Prosthetic group labeled Immunoassay (PGLI)	06	15-18
7.	**Immunodiagnostic methods** **Immuno-haematology testing** Blood groups, blood transfusion and Rh incompatibilities. Epitope design and its application in immunodiagnosis tests. **In vitro diagnostic methods** Agglutination, precipitation, complement fixation, FACS calibur. Immunoblotting assays **In vivo diagnostic methods –** Skin test and immune complex tissue demonstration.	04	10-13
8.	**Immuno-Informatics** Molecular dynamics simulations of desired antigens, Structure-based Prediction of MHC Binding Peptides, Searching and Mapping of B-cell and T-cell epitopes in Bcipep, SYFPEITHI database	03	05-07

(vi) Recommended Reading:

a) Basic Reading:

1. Understanding Medical Immunology by Kirkwood E and Catriona L. (John

Wiley and Sons New York)

2. Immunology for students of Medicine by Humphrey J. H., White R. G. (Blackwell Scientific Publication London)
3. The pharmacological Basis of Therapeutics by Goodman and Gilmans. (9th Ed) McGraw Hill 1996.
4. Kuby Immunology by Thomas J. Kindt, Richard Goldsby, Barbara A. Osborne, Janis Kuby, Publisher- Macmillan Higher Education.
5. Microbiology by Pelczar, Publisher- Tata McGraw- Hill.
6. Fundamental Immunology by William E. Paul, Publisher- Lippincott Williams and Wilkins
7. Basic Immunology: Functions and Disorders of Immune System by Abul K. Abbas, Andrew H. Lichtman and Shiv Pillai, Publisher- Elsevier.
8. Vaccinology: Principles and Practice by W. John W. Morrow, Nadeem A. Sheikh, Clint S. Schmidt, D. Huw Davies, Publisher- John Wiley & Sons.
9. Basic Immunology by Jacqueline Sharon, Publisher- Williams & Wilkins.
10. Immunology: Understanding the Immune System by Klaus D. Elgert, Publisher- Wiley-Blackwell.
11. Enzyme Immuniassays: From Concept to Product Development by S. S. Deshpande, Publisher- Chapman and Hall.

b) Additional Reading:

1. Cellular and Molecular Immunology by Abul K. Abbas, Andrew H. Lichtman and Shiv Pillai, Publisher- Elsevier
2. Inflammation, Chronic Diseases and Cancer – Cell and Molecular Biology, Immunology and Clinical Bases, Mahim Khatami, ISBN 978-953-51-0102-4
3. Immunotherapy and Vaccins by Stanley J. Kryz.
4. Basic and Clinical Immunology by H. Hugh Fudenberg, Daniel P. Stites, Publisher- Lange Medical Publications.
5. Textbook of Immunology by Constantin A. Bona, Publisher- Harwood Academic Publishers.
6. ELISA and other Solid Phase Immunoassays: Therotical and Practical Aspects by D. M. Kemeny and S. J. Challacombe, Publisher- John Wiley & Sons.

c) References:

i) Books:

1. Immunology by Donald Mackay Weir, John Stewart, Publisher- Churchill Livingstone.
2. Immunology for Medical Students by Roderick Nairn and Matthew Helbert, Publisher- Mosby.
3. Immunology by David K. Male, Publisher- Elsevier Health Sciences.
4. Immunobiology: The Immune System in Health and Diseases by Charles

Janeway, Publisher- Garland Science.

5. Immunology for Pharmacy Students by Wei-Chiang Shen and Stan G. Louie, Publisher Harwood Academic Publishers.
6. Immunoassay: A Practical Guide by Brian Law, Publisher- Taylor and Francis.
7. Immunoinformatics: bioinformatics strategies for better understanding of immune function, Novartis Foundation,ISBN 0-470-85356-5
8. Hybridoma Technology in the Biosciences and Medicine by Timothy A. Springer.
9. Polypharmacology in Drug Discovery by Jens – Uwe Peters, Publisher- John Wiley & Sons.
10. Exploring Immunology: Concepts and Evidence by Gordon MacPherson and Jon Austyn, Publisher- Wiley-Blackwell.
11. Immunopharmacology by Manzoor M. Khan, Publisher- Springer.
12. Immunoassay by Eleftherios P. Diamandis and Theodore K. Christopoulos, Publisher- Academic Press INC.

ii) Periodicals/Journals:

1. International Journal of Immunopharmacology (Elsevier)
2. Immunopharmacology (Springer)
3. International Immunology (pubget)
4. Immunity (pubget)
5. Infection and Immunity (pubget)
6. Immunogenetics (pubget)
7. Immunologic Research (pubget)
8. International Immunopharmacology (pubget)

i) Paper : 8 (ELECTIVE) ELE-II

ii) Title of Paper : POLYMER TECHNOLOGY

iii) Specific Objectives:

1. The syllabus of this subject is designed to provide a general understanding of the polymer science.
2. It includes general concepts learned in polymer, pharmaceutical and medical fields and will further extend the understanding about the interactions at the interface of material and biological systems and their applications.
3. Current applications of polymers will be evaluated to provide an understanding of material bulk and surface properties, degradation processes, various biological responses to the materials and the clinical context of their use.

iv) Note:

1. The topics must be conveyed through plenty of examples. Lecture classes must be conducted as lecture-cum-power point presentations.
2. It is a course that aims to develop skills. It is therefore "practical" in orientation. Plenty of exercises of various kinds must be done by the students.

17. POLYMER TECHNOLOGY **Theory (2 hrs/wk)**
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Introduction to Pharmaceutical Polymers:** Structure and properties: molecular weight distribution, conformation and configuration, solid state properties such as flow characteristics, crystallinity, etc. Classification of polymers. Selection criteria for pharmaceutical polymers such as biodegradability, safety, toxicity, leachability, etc.	05	10 -12
2.	**Polymer Synthesis and Modification:** Synthesis of polymers: general methods of preparation of polymers like solution bulk, suspension and emulsions polymerizations with examples. Polymer modification .	04	10 -13
3.	**Characterization of polymers:** Solid state characterization: Thermal, spectral, rheological, surface topography by microscopic techniques, chromatography, etc. Liquid state characterization: Solubility of polymers, methods of polymer characterization in solution (thermodynamics of polymer solutions), viscosity and viscoelasticity of polymers, etc.	05	15 - 17

4.	**Pharmaceutical Applications of Polymers:**	08	15 -18
	Drug delivery: polymers in conventional dosage form, controlled release dosage forms, osmotic delivery systems, ion-exchange systems, polymeric prodrugs, etc. Surgicals. Polymers for drug packaging device components. Polymers in tissue engineering.		
5.	**Polymer Dissolution:**	05	10-13
	Polymer dissolution behavior: surface layer formation and mechanisms of dissolution, effect of polymer molecular weight and polydispersity, effect of polymer structure, composition and conformation, effects of different solvents and additives, effect of environmental parameters and processing condition. Polymer dissolution models: phenomenological models, external mass transfer arguments, stress relaxation and molecular theories, anomalous transport models and scaling laws, molecular theories in a continuum framework.		
6.	**Advances in Pharmaceutical Polymers:**	04	10 - 12
	Polymer grafting, functional polymers, polymeric immunoadjuvants and immunomodulators, polymer therapeutics, molecularly imprinted polymers, genetically engineered polymers, thiomers, polymer genomics, multivalent protein polymers, dendrimers, biomimetic polymers, peptoids etc.		
7.	**Biointeractions of Polymers:**	03	05 - 07
	Interactions of polymers with tissues and cells, Pharmacokinetics of polymer therapeutics, targeted polymer therapeutics, passive targeting of polymeric drugs, enhanced permeation and retention effect (EPR)		
8.	**Regulatory issues of pharmaceutical polymers**	02	05 - 08

(vi) Recommended Reading:

a) Basic Reading:

1. C. Tanford, Physical Chemistry of Macromolecules, John Wiley, NY, 1961.
2. F. W. Billmeyer, Jr., Textbook of Polymer Science, 3rd Ed. , J. Wiley, New York, 1984.
3. B. D. Ratner, A. S. Hoffman, F. J. Schoen, J. E. Lemons, Biomaterials Science. An Introduction to Materials in Medicine, Academic Press, San Diego, 1996.

b) Additional Reading:

1. J. Brandrup, E. H. Immergur. Polymer Handbook; 4th ed., John Wiley and Sons, 2003.
2. L. H. Sperling, Introduction to Polymer Science, Wiley, NY, 1992.
3. H. Morawetz, Macromolecules in Solution, 2nd ed., Wiley-Interscience, NY,

1975

4. Charles G. Gebelein, T.C. Chin and V. C. Yang; Cosmetic and Pharmaceutical Applications of Polymers; Plenum Press, New work.
5. D. S. Soane; Polymer Applications for Biotechnology; Prentice Hall Inc. 1994.
6. J. R. Robinson and V.cH. Lee: Controlled Drug Delivery – Fundamentals and Application; Marcel Dekker. 1987

c) References:

i) Books:

1. N. K. Jain; Controlled and Novel Drug Delivery; CBS publications, 2008.
2. P. J. Tarcha; Polymers for controlled Drug Delivery; CRC Press, 1991.
3. A. F. Kydonieus; Controlled Release Technologies: Methods, Theory and Application, Vol-I & II; CRC Press Inc. Academic/Plenum Publishers, NY, 2001.
4. A. V. Kabanov, P. L. Felgner, L. W. Seymour. Self-Assembling Complexes for Gene Delivery. From Laboratory to Clinical Trial. John Wiley & Sons: New York, 1998.

ii) Periodicals/Journals:

1. Advances in polymer technology- Wiley Online
2. Polymer Science and Technology – Elsevier
3. Polymers for Advanced Technologies - John Wiley & Sons

i) Paper : 8 (ELECTIVE) ELE-II

ii) Title of Paper : CLINICAL PHARMACY

iii) Specific Objectives:

1. To equip the pharmacy professional with the required skills, attitudes and knowledge to become a practicing clinical pharmacist and mould him as an efficient member of the health care team.
2. To promote effective and rational use of medicinal products in treatment of diseases.
3. To train the students to take part in conduct of clinical research.

iv) Note: Students should be able to:

1. Understand and perform the daily activities of clinical pharmacy practice
2. Identify relevant tests for specific disease states and interpretation of selected laboratory results (as monitoring parameters in therapeutics).
3. Identify appropriate sources of drug/medical information
4. Efficiently retrieve relevant and current literature and evaluate them
5. Give appropriate recommendations for clinical dosing of specific drugs.
6. Understand the conduct of clinical trials and use of statistical tests.

18. CLINICAL PHARMACY **Theory (2 hrs/wk)**
Tutorial (1 hr/wk)

Unit	Contents	Hrs	Marks
1.	**Introduction to Clinical Pharmacy**: Scope & Development of Clinical Pharmacy; Practice of Clinical Pharmacy in hospitals & community	03	04-06
2.	**Activities of Clinical Pharmacist & Drug Information:** Drug Therapy Monitoring (Medication Therapy Management, Medication Chart Review, Pharmacist Interventions); Ward Round Participation; ADR Management/Drug-drug interactions; Medication History/ Case taking; Patient Counseling; Pharmaceutical care; Drug Utilization evaluation/ review; Quality assurance of clinical pharmacy services; Introduction to information resources available, development of drug information services, drug literature utilization, selection & evaluation.	05	18-22
3.	**Therapeutic Use of Medicine:** Drug Selection & Administration: Problems associated with concomitant therapy; Patient sensitivities, allergies; Precautions during the use; Diet control. . Reasons for noncompliance & Strategies for Improving	05	08-10

Compliance; Use of drugs in Geriatric, Pediatric patients & in Pregnancy

4.	**Monitoring The Patient In Health & Illness:**	05	08-10
	Fluid & electrolyte imbalance; Cardio-pulmonary dysfunction; Metabolic disorders; Patient follow-up; Discharge interview for hospitalized patients; Precautions & Directions during use of medication; Pharmacological & biochemical examinations, their significance; Supervision of therapeutic success, side effects & adverse effects		
5.	**Patient Data Analysis:**	05	08-10
	The patients case history; its structure and use in evaluation of drug therapy; common medical abbreviations & terminologies in clinical practices; mediation history; Clinical lab tests used in evaluation of disease states and interpretation of tests like liver, renal, cardiac, thyroid, pulmonary etc; Microbiological culture sensitivity tests; Drug adjustment in renal failure, hepatic dysfunction, geriatric and pediatric patients		
6.	**Therapeutic management of following diseases:**	06	20-24
	Cardiovascular diseases: Myocardial ischemia; Myocardial infraction; Congestive cardiac failure; Cardiac arrhythmias; Hypertension; Hyperlipidemia		
	Renal disorders: Acute renal failure; Chronic renal failure		
	Respiratory disorders: Bronchial asthma; Chronic obstructive lung disease		
7.	**Clinical testing of drugs:**	04	08-10
	Introduction, various phases, ICH guidelines, regulatory affairs		
8.	**Statistical methods in pharmacy:**	03	06-08
	Mean, statistical analysis of data including various, standard derivation student ‘t’ test ANOVA, of Non-parametric analysis, correlation of data & its interpretations. Bio-statistics for clinical trials.		

(vi) Recommended Reading:

a) Basic Reading:

1. Clinical pharmacy practice; C.W. Blissit
2. Applied therapeutics for clinical pharmacists; Koda Kimble M.N, Applied Therapeutic Inc. San, Fransico.
3. Handbook of Pharmacy Healthcare Diseases & Patient Advice; Ed; R.J. Harman, Pharmaceutical Press; London.
4. Bennett P.N, Brown M.J. (2003) Clinical Pharmacology. (9th ed.) Churchill living stone, New Delhi.
5. Tipnis H. P., Dr. Bajaj Amrita, Clinical Pharmacy, Career Publication.

b) Additional Reading:

1. Clinical pharmacy practice; C.W. Blissit
2. Roger walker, Clive Edwards, Clinical Pharmacy & therapeutics, (3rd Ed.), Churchill Livingstone.
3. Andrew S. Robson, Pharmaceutical & Medicine Information Management; Principles & Practice;, Churchill - Livingston.
4. Parrthsarthi G, Hansen Kavin Nytort & Nahata Milap C. A. Textbook of Clinical Practice: Essential Concepts & skills, Orient Longman.
5. Roger walker, Clive Edwards, Clinical Pharmacy & therapeutics, (3rd Ed.), Churchill Livingstone.
6. Good Clinical Practices : GOI Guidelines for clinical trials on Pharmaceutical Products in India
7. Textbook of clinical pharmacy by Parthasarthi
8. Katzung B.G, (2001) Basic & Clinical Pharmacology. (8th ed.), Mc-graw Hill, New Delhi.
9. 5. Raymond J.M., Niesink, John de vries., Hollinger M.A. Toxicology- Principle and applications, CRC, Florida

c) References:

i) Books:

1. Dipiro J.L. (2004) Pharmacotherapy Handbook. (5th ed.) Tata McGraw Hill New Delhi..
2. Computer & bio statistics: Paradkar
3. Goodman Gilman, (2001) The pharmacological basis of therapeutics. (10th ed.) Mc-graw Hill New Delhi.
4. Grahame-Smith D.G., Aronson J.K. (2002) Oxford textbook of clinical Pharmacology and drug therapy. (3rd ed.) Oxford University press London.
5. Therapeutic drug monitoring - B. Widdop
6. TDM & Clinical biochemistry – Mike Hallworth
7. Eric T. Herfindel, Dick. R. Gourle. Textbook of therapeutics, drug & disease management. (7th ed.)
8. Recent developments in TDM & Clinical toxicology.I. Sunshine - Marcel – Dekker 1992
9. Handbook of TDM. – Simkin

ii) Periodicals/Journals:

1. Pharmaceutical Journal. Royal Pharmaceutical Society,London
2. JournalofPharmacyPracticeandResearch.SocietyofHospitalPharmacistsofAustralia
3. International Journal of Phanacy Practice, United Kingdom
4. Indian Journal of Hospital

5. Hospital Pharmacist , UK
6. American Journal of Health System Pharmacy (AJHP)

i) Paper : 8 (ELECTIVE) ELE-II

ii) Title of Paper : THERAPEUTIC DRUG MONITORING

iii) Specific Objectives:

1. To gain an insight in the production process and bioavailability of dosage forms produced in the pharmaceutical industry.
2. Knowing and being able to implement the techniques for the analysis of biotechnological drugs. It makes students to gain an insight in pharmacy questions with regard to the delivery of drugs.
3. To understand a thoroughly developed analytical procedure, and necessary to carry out the Estimation of the Drug concentration in body fluids

iv) Note:

1. To understand the organization and effectiveness service Information requirement of TDM
2. The student should have a basic knowledge of the Commonly used laboratory techniques, analytical methods and instrumentation
3. The student should acquire the skills that are commensurate with the expected
4. Knowledge and Perform a number of service activities e.g. therapeutic drug monitoring, pharmacovigilance, pharmacoeconomics, Pharmacoepidemiology

19. THERAPEUTIC DRUG MONITORING Theory (2 hrs/wk)
Tutorial (1 hr/wk)

Unit	contents	Hrs	Marks
1.	**Fundamentals of diseases and drug therapy** Symptoms and diseases identification, ADRs, prevention of communicable diseases, drug selection and administration, patient non compliance, strategy to improve the compliance	03	05-07
2.	**Monitoring the patient in health and illness** Fluid and electrolyte imbalance, cardio-pulmonary dysfunction, metabolic disorders, precautions and directions during used of medication, pharmacological and biochemical examinations	04	10-12
3.	**Therapeutic management of diseases** Cardiovascular, renal, respiratory and metabolic disorders	05	10-12
4.	**Introduction to therapeutic drug monitoring** Definition & introduction.	05	10-12

_ Indication for TDM & clinical applications.

_ Monitoring plasma drug levels.

_ Role of Clinical pharmacist in TDM

5.	**Techniques used in TDM** a) Physical methods HPLC, HPTLC, GC b) Immunoassays. RIA, ELISA, EMITH, NIIA	05	10-15
6.	**Importance of TDM with reference to adverse drug Reaction**	03	08-10
7.	**Variation of clinical laboratory tests due to drugs** **Tests: -** Serum Creatinine, blood urea, nitrogen, plasma, glucose, Creatine kinase, phosphatase, amylase, Bilirubin, serum proteins, globulins, complete blood count & differential blood count	05	12-14
8.	**Futuristic application and TDM of specific drugs** Clinical pharmacokinetics, general guidelines, sample collection, time of sample collection, clinical comments, clinical monitoring parameters, usual dosing parameters, common toxicities, adverse drug reactions & drug interactions, techniques used for estimation, importance of 1. Digoxin 2. Lithium 3. Phenobarbitone 4. Gentamicin. 5. Theophylline 6. Carbamazepine 7. Lidocaine 8. Phenytoin 9. Valproic acid 8 TDM of antiretroviral and anti tubercular drugs	06	15-18

(vi) Recommended Reading:

a) Basic Reading:

1. Therapeutic Drug monitoring and clinical Biochemistry by- Mike Hallworth and Nigel capps
2. Principles of pharmacokinetics and Therapeutic Drug monitoring by Nitin mahurkar
3. Biopharmacetics Pharmacokinetics by Milo gibaldi
4. Clinical pharmacy practice - C. W. Blissit.
5. Therapeutic drug monitoring - B. Widdop
6. TDM & Clinical biochemistry – Mike Hall worth

b) Additional Reading:

1. Henry's Clinical Diagnosis and Management by Laboratory Methods. 21st ed.

McPherson R, Pincus M, eds. Philadelphia, PA: Saunders Elsevier: 2007, 308- 309.

2. Bottorff, M. Toxicology, Clinical Pharmacokinetics and Therapeutic Drug Monitoring. ARUP's Guide to Clinical Laboratory Testing //www.aruplab.com/guides/clt/tests/clt_fr15.jsp.
3. Labcorp. (© 2001) Therapeutic Drug Monitoring [On-line information]. http://www.labcorp.com/datasets/labcorp/html/appendix_group/appendix/section/tdm.htm through http://www.labcorp.com.

c) References:

i) Books:

1. Clinical pharmacy practice - C. W. Blissit.
2. Therapeutic drug monitoring - B. Widdop
3. TDM & Clinical biochemistry – Mike Hall worth
4. Textbook of therapeutics, Drug & disease management - 7th edition -
5. Eric T. Herfindel,Dick. R. Gourley.
6. Recent developments in TDM & Clinical toxicology – I. Sunshine
7. Marcel – Dekker – 1992.
8. Handbook of TDM. – Simkin
9. TDM – Abbot

ii) Periodicals/Journals:

1. The Japanese Journal of Therapeutic Drug Monitoring
2. Journal of Clinical and Diagnostic Research
3. Asian Journal of Medical and Clinical Sciences
4. Clinical Research and Regulatory Affairs
5. Clinical Toxicology
6. Therapeutic Drug Monitoring
7. Clinical Pharmacology
8. New England Journal of Medicine
9. British Journal of Clinical Pharmacology