SHIVAJI UNIVERSITY KOLHAPUR

AN ORDINANCE TO PROVIDE FOR THE EXAMINATION LEADING TO THE DEGREE OF MASTER OF PHARMACY IN THE FACULTY OF ENGINEERING & TECHNOLOGY

Shivaji University offers Master of Pharmacy (M. Pharm.) in the following specializations

1) Pharmaceutical Chemistry.
2) Biopharmaceutics.
3) Pharmaceutics.
4) Quality Assurance*.
5) Pharmacology.
6) Pharmacognosy.
7) Pharmaceutical Technology.
8) Pharmaceutical Analysis.
9) Quality Assurance Techniques*.
10) Pharmaceutics (Drug Regulatory Affairs).

*Syllabus for the M.Pharm. course 4 and 9 is same and question papers for both courses are also common.

1. Duration:

The duration of Master of Pharmacy (M. Pharm) Course is of two Years, divided into four semesters.

2. Eligibility for Admission to M. Pharm. Course:

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

For Non-Sponsored category of students

Admission to fulltime PG programme for non-sponsored category of students should be made through GATE. When the GATE Qualified students are not available, the admission may be given to non GATE candidates on Merit who have passed B. Pharm. degree examination of any statuary/recognized University with at least 55% of aggregate marks or equivalent grade (50% 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 55% marks or equivalent grade (50 % marks for those who are teachers in pharmacy college or polytechnic)

3. Admissions to M. Pharm. Course:

The admission to this 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. 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.

4. Fees:

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

5. Grant of Terms:

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

6. Scheme of Teaching:

The syllabi of the subjects are given as under.

7. Scheme of Examination:

There shall be a university examination at the end of First & Second semester & one examination of third & fourth semester at the end of fourth semester. The examination shall be as per the scheme mentioned.

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.

8. Standard of Passing:

a. 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 'B' Grade in Seminar. In addition, he should have obtained at least 50% of the aggregate marks assigned to the examination of each semester.

b. The student will be declared to have passed Third & Fourth Semester Examinations, if he has obtained at least 50% of the total marks and at least 'B' grade in colloquium on his/her dissertation.

9. 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.

10. Seminar:

The student will have to give one seminar in First & Second Semester each and colloquium before submission of the dissertation.

11. 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	-	60% but less than 70% marks.
B	-	50% but less than 60% marks.
C	-	Less than 50% marks.

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

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

12. 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.

13. 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 and Fourth Semester. {Third & Forth Semester Examinations taken together.}

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.

14. 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 applications 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.

15. Dissertation:

Every student before appearing for the M. Pharm. Fourth Semester Examination is required to submit 3 typewritten copies 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 before 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,

a. He/she pays the prescribed fees as fixed by the university.
b. His/her application is received by the registrar not later than one month before the date of commencement of the examination.
c. He/she submits his/her thesis on the same subject on or before the examination date.
d. Examinee whose thesis has not been accepted shall resubmit his/her work, with such additional work as may be directed, at the next examination.
e. 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.

16. a) 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 200 marks.

The examiners will jointly assign the marks for dissertation and viva-voce on dissertation. This test will be of 150 and 50 marks respectively. The student will have to defend the dissertation. The examiners will jointly assign the mark for Seminar & 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	25
2.	Experimental work	50
3.	Scientific contents	20
4.	Presentation/Communication	25
5.	Result/Conclusion	30
	Total	**150**

Viva-voce:

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

M. Pharm. Course Structure
Pharmaceutical Chemistry

Semester	Subject Code	Title of Paper	Scheme of Teaching Hours / week		Scheme of Examination				Total
					Theory		Practical		
			Lectures	Practical	Hours	Marks	Hours	Marks	
Sem – I	**MAT**	Modern Analytical Techniques	03	06	03	100	06	100	200
	APC-I	Advanced Pharmaceutical Chemistry – I	03	06	03	100	06	100	200
	ELE-I	Elective – I	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		15	--		--	--	--
Sem – II	**APC-II**	Advanced Pharmaceutical Chemistry – II	03	06	03	100	06	100	200
	APC-III	Advanced Pharmaceutical Chemistry – III	03	--	03	100	--	--	100
	ELE-II	Elective – II	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		20	--	--	--	--	--
Sem – III & Sem – IV		Colloquium *	One per student		A^+ / A / B / C		--	--	--
	THESIS	Research, Dissertation and viva voce	--	50	--	--	--	200	200
		GRAND TOTAL							**1100**

* The seminar / colloquium shall carry 50 marks

M. Pharm. Course Structure
Biopharmaceutics

Semester	Subject Code	Title of Paper	Scheme of Teaching Hours / week		Scheme of Examination				Total
					Theory		Practical		
			Lectures	Practical	Hours	Marks	Hours	Marks	
Sem – I	**MAT**	Modern Analytical Techniques	03	06	03	100	06	100	200
	PK	Pharmacokinetics	03	06	03	100	06	100	200
	ELE-I	Elective – I	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		15	--		--	--	--
Sem – II	**NDDS**	Novel Drug Delivery Systems	03	06	03	100	06	100	200
	BAB	Biopharmaceutics (Bioavailability & Bioequivalence)	03	--	03	100	--	--	100
	ELE-II	Elective – II	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		20	--	--	--	--	--
Sem – III & Sem – IV		Colloquium *	One per student		A^+ / A / B / C		--	--	--
	THESIS	Research, Dissertation and viva voce	--	50	--	--	--	200	200
		GRAND TOTAL							**1100**

* The seminar / colloquium shall carry 50 marks

M. Pharm. Course Structure
Pharmaceutics

Semester	Subject Code	Title of Paper	Scheme of Teaching Hours / week		Scheme of Examination				Total
					Theory		Practical		
			Lectures	Practical	Hours	Marks	Hours	Marks	
Sem – I	**MAT**	Modern Analytical Techniques	03	06	03	100	06	100	200
	AP-I	Advanced Pharmaceutics – I	03	06	03	100	06	100	200
	ELE-I	Elective – I	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		15	--		--	--	--
Sem – II	**AP-II**	Advanced Pharmaceutics – II	03	06	03	100	06	100	200
	AP-III	Advanced Pharmaceutics – III	03	--	03	100	--	--	100
	ELE-II	Elective – II	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		20	--	--	--	--	--
Sem – III & Sem – IV		Colloquium *	One per student		A^+ / A / B / C		--	--	--
	THESIS	Research, Dissertation and viva voce	--	50	--	--	--	200	200
		GRAND TOTAL							**1100**

* The seminar / colloquium shall carry 50 marks

M. Pharm. Course Structure
Quality Assurance

Semester	Subject Code	Title of Paper	Scheme of Teaching Hours / week		Scheme of Examination				Total
					Theory		Practical		
			Lectures	Practical	Hours	Marks	Hours	Marks	
Sem – I	**MAT**	Modern Analytical Techniques	03	06	03	100	06	100	200
	QAT-I	Quality Assurance Techniques – I	03	06	03	100	06	100	200
	ELE-I	Elective – I	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		15	--		--	--	--
Sem – II	**QAT-II**	Quality Assurance Techniques – II	03	06	03	100	06	100	200
	QAT-III	Quality Assurance Techniques – III	03	--	03	100	--	--	100
	ELE-II	Elective – II	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		20	--	--	--	--	--
Sem – III & Sem – IV		Colloquium *	One per student		A^+ / A / B / C		--	--	--
	THESIS	Research, Dissertation and viva voce	--	50	--	--	--	200	200
		GRAND TOTAL							**1100**

* The seminar / colloquium shall carry 50 marks

M. Pharm. Course Structure
Pharmacology

Semester	Subject Code	Title of Paper	Scheme of Teaching Hours / week		Scheme of Examination				Total
					Theory		Practical		
			Lectures	Practical	Hours	Marks	Hours	Marks	
Sem – I	**MAT**	Modern Analytical Techniques	03	06	03	100	06	100	200
	APCOL-I	Advanced Pharmacology – I	03	06	03	100	06	100	200
	ELE-I	Elective – I	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		15	--		--	--	--
Sem – II	**APCOL-II**	Advanced Pharmacology – II	03	06	03	100	06	100	200
	APCOL-III	Advanced Pharmacology – III	03	--	03	100	--	--	100
	ELE-II	Elective – II	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		20	--	--	--	--	--
Sem – III & Sem – IV		Colloquium *	One per student		A^+ / A / B / C		--	--	--
	THESIS	Research, Dissertation and viva voce	--	50	--	--	--	200	200
		GRAND TOTAL							**1100**

* The seminar / colloquium shall carry 50 marks

M. Pharm. Course Structure
Pharmacognosy

Semester	Subject Code	Title of Paper	Scheme of Teaching Hours / week		Scheme of Examination				Total
					Theory		Practical		
			Lectures	Practical	Hours	Marks	Hours	Marks	
Sem – I	**MAT**	Modern Analytical Techniques	03	06	03	100	06	100	200
	APCOG-I	Advanced Pharmacognosy – I	03	06	03	100	06	100	200
	ELE-I	Elective – I	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		15	--		--	--	--
Sem – II	**APCOG-II**	Advanced Pharmacognosy – II	03	06	03	100	06	100	200
	APCOG-III	Advanced Pharmacognosy – III	03	--	03	100	--	--	100
	ELE-II	Elective – II	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		20	--	--	--	--	--
Sem – III & Sem – IV		Colloquium *	One per student		A^+ / A / B / C		--	--	--
	THESIS	Research, Dissertation and viva voce	--	50	--	--	--	200	200
		GRAND TOTAL							**1100**

* The seminar / colloquium shall carry 50 marks

M. Pharm. Course Structure
Pharmaceutical Technology

Semester	Subject Code	Title of Paper	Scheme of Teaching Hours / week		Scheme of Examination				Total
					Theory		Practical		
			Lectures	Practical	Hours	Marks	Hours	Marks	
Sem – I	**MAT**	Modern Analytical Techniques	03	06	03	100	06	100	200
	APT-I	Advanced Pharmaceutical Technology – I	03	06	03	100	06	100	200
	ELE-I	Elective – I	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		15	--		--	--	--
Sem – II	**APT-II**	Advanced Pharmaceutical Technology – II	03	06	03	100	06	100	200
	BBME	Biopharmaceutics and Biomedical Engineering	03	--	03	100	--	--	100
	ELE-II	Elective – II	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		20	--	--	--	--	--
Sem – III & Sem – IV		Colloquium *	One per student		A^+ / A / B / C		--	--	--
	THESIS	Research, Dissertation and viva voce	--	50	--	--	--	200	200
		GRAND TOTAL							**1100**

* The seminar / colloquium shall carry 50 marks

M. Pharm. Course Structure
Pharmaceutical Analysis

Semester	Subject Code	Title of Paper	Scheme of Teaching Hours / week		Scheme of Examination				Total
					Theory		Practical		
			Lectures	Practical	Hours	Marks	Hours	Marks	
Sem – I	**MAT**	Modern Analytical Techniques	03	06	03	100	06	100	200
	APA-I	Advanced Pharmaceutical Analysis – I	03	06	03	100	06	100	200
	ELE-I	Elective – I	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		15	--		--	--	--
Sem – II	**APA-II**	Advanced Pharmaceutical Analysis – II	03	06	03	100	06	100	200
	FBCA	Food, Biologicals and Cosmetic Analysis	03	--	03	100	--	--	100
	ELE-II	Elective – II	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		20	--	--	--	--	--
Sem – III & Sem – IV		Colloquium *	One per student		A^+ / A / B / C		--	--	--
	THESIS	Research, Dissertation and viva voce	--	50	--	--	--	200	200
		GRAND TOTAL							**1100**

* The seminar / colloquium shall carry 50 marks

M. Pharm. Course Structure
Quality Assurance Techniques

Semester	Subject Code	Title of Paper	Scheme of Teaching Hours / week		Scheme of Examination				Total
					Theory		Practical		
			Lectures	Practical	Hours	Marks	Hours	Marks	
Sem – I	**MAT**	Modern Analytical Techniques	03	06	03	100	06	100	200
	QAT-I	Quality Assurance Techniques – I	03	06	03	100	06	100	200
	ELE-I	Elective – I	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		15	--		--	--	--
Sem – II	**QAT-II**	Quality Assurance Techniques – II	03	06	03	100	06	100	200
	QAT-III	Quality Assurance Techniques – III	03	--	03	100	--	--	100
	ELE-II	Elective – II	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		20	--	--	--	--	--
Sem – III & Sem – IV		Colloquium *	One per student		A^+ / A / B / C		--	--	--
	THESIS	Research, Dissertation and viva voce	--	50	--	--	--	200	200
		GRAND TOTAL							**1100**

* The seminar / colloquium shall carry 50 marks

M. Pharm. Course Structure
Pharmaceutics (Drug Regulatory Affairs)

Semester	Subject Code	Title of Paper	Scheme of Teaching Hours / week		Scheme of Examination				Total
					Theory		Practical		
			Lectures	Practical	Hours	Marks	Hours	Marks	
Sem – I	**MAT**	Modern Analytical Techniques	03	06	03	100	06	100	200
	QAT-I	Drug Regulatory Affairs – I	03	06	03	100	06	100	200
	ELE-I	Elective – I	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		15	--		--	--	--
Sem – II	**QAT-II**	Advanced Pharmaceutics	03	06	03	100	06	100	200
	QAT-III	Drug Regulatory Affairs – II	03	--	03	100	--	--	100
	ELE-II	Elective – II	03	--	03	100	--	--	100
		Seminar *	One per student		A^+ / A / B / C		--	--	--
		Research Work		20	--	--	--	--	--
Sem – III & Sem – IV		Colloquium *	One per student		A^+ / A / B / C		--	--	--
	THESIS	Research, Dissertation and viva voce	--	50	--	--	--	200	200
		GRAND TOTAL							**1100**

* The seminar / colloquium shall carry 50 marks

SYLLABUS FOR M. PHARM (PHARMACEUTICAL CHEMISTRY)

MAT MODERN ANALYTICAL TECHNIQUES Theory (3 hrs/wk.)

		Hrs	Marks
1.	Biostatistics and Computer Application: Introduction to and pharmaceutical applications of Student's t-test, F test, Chi-square test, Analysis of variance (ANOVA), correlation and regression analysis, Factor analysis, Time series analysis and Multidimensional scaling. Applications of computers related to quantitative and statistical pharmaceutical analysis.	3	10-15
2.	Sample Preparation for Analysis: Different techniques of sample preparation from body fluids, tissue extracts, cell culture extracts and phyto-chemical extracts.	5	10-15
3.	Structural Elucidation by Spectroscopic Methods: UV-Visible, IR, NMR and Mass with examples.	5	15-20
4.	Applications of DSC and XRD: Analysis of raw material (APIs and excipients), packaging material and finished products.	4	10-15
5.	Reference Standards: Introduction, preparation, types, storage, record keeping and validation.	5	10-15
6.	ESR Spectroscopy: Introduction, calibration, validation and application (in brief). Circular Dicorism and ORD: Introduction, calibration, validation and application (in brief).	5	10-15
7.	Particle Size Analysis: Introduction, significance, methods used in particle size analysis. Gel Permeation Chromatography (GPC): Introduction, instrumentation (Stationary phases and Detectors) and its application (particle size analysis).	4	15-20
8.	Immunochemical Techniques: ELISA, Immuno- precipitation, Radio immuno assays and Radio-labeling.	5	20-25

Reference Books

1. Introduction To Biostatistics & Computer Science, Mr. Y. I. Shah Dr. A. R. Paradkar, Mr. Y. I. Shah, Mr. M. G. Dhayagude
2. Pharmaceutical statistics using SAS: a practical Guide, Ralph B. D'Agostino
3. Introduction to Pharmaceutical Calculations, Judith A. Rees
4. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.

5. Practical Method Development, Snyder, L. R., Kirkland, J. J. and Glajch, J. L.
6. Principles of Instrumental Analysis, Skoog.
7. Textbook of Practical Biotechnology, C.R. Kokare.
8. Organic Spectroscopy, William Kemp
9. Physical Pharmacy – Martin, Swarbrick and Commarata
10. Physical Chemistry – Bahl and Tuli
11. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
12. I. P., B.P. and U.S.P.
13. Instrumental Methods of Analysis, Chatwal & Anand,
14. A Textbook of pharmaceutical analysis, K. A. Connors.
15. Pharmaceutical Analysis, Ashutosh Kar.
16. Instrumental and Chemical Analysis, B.K. Sharma.

MAT Pr **MODERN ANALYTICAL TECHNIQUES** **Practical (6 hrs/wk.)**

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. ED_{50} and LD_{50} Estimation and probit analysis

Reference Books

1. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.
2. Textbook of Pharmacognosy, Kokate C. K. Purohit A. P. and Gokhale S. B.
3. Pharmacognosy and Phytochemistry, Vol. I & II, V.D.Rangari.
4. Natural products Chemistry Practical Manuals, A.A.Siddiqui.
5. Indian Pharmacopoeia.
6. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
7. Harry's cosmetology, J. B. Wilkinson and R. J. Moore.
8. Textbook of Practical Biotechnology, C.R. Kokare.
9. Research Articles on Analytical Method Development in Journals
10. Physical Pharmacy – Martin, Swarbrick and Commarata
11. Physical Chemistry – Bahl and Tuli

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

		Hrs	Marks
1.	**Molecular basis of drug action:** Receptor, Drug Receptor Interaction. 1.Types of receptors 2. Drug target binding forces. 3. Receptor structure and signal transduction. 4. Changes in receptor shape. 5. Design of agonist and antagonist. 6. Above concepts with special reference to Opioid, Histaminergic, Adrenergic and GABA nergic receptors. 7. Recent advances & trends in the drugs acting on above mentioned categories of receptors.	12	25-35
2.	**Enzyme Inhibition:** 1. Enzyme Inhibitors - Reversible, irreversible, Kcat inhibitors. Transition state analogs and their application with respect to drug design. 2. Enzyme Inhibitors of - ACE, leukotrienes, Lipoxygenase, Cycloxygenase, Aromatase, Xanthine oxidase, DNA Polymerase Inhibitors, HIV - Protease / Reverse Transcriptase, Integrase and Cytochrome P-450 Inhibitors, purine, pyrimidine inhibitors, DHFR inhibitors as drugs. 3. Recent advances & trends in the above mentioned categories of drugs.	14	30-40
3.	**Design and application of prodrugs:** 1. Prodrug concept. 2. Prodrugs of various functional groups like carbonyl, hydroxy. amide, amines. 3. Application of Prodrug approach to: i. Improvement of bioavailability ii. Prevent first pass metabolism iii. Reduction of side effects iv. Prolong duration of action v. Site specific delivery 4. PDEPT (Polymer-Directed Enzyme Prodrug Therapy); ADEPT (Antibody-Directed Enzyme Prodrug Therapy); GDEPT/VDEPT (Gene-Directed Enzyme Prodrug Therapy/Virus-Directed Enzyme Prodrug Therapy);	07	15-25

4. **Synthon approach:** 12 30-40

- Definition of terms - disconnection, synthon, functional group interconversion (FGI).
- Basic rules in Disconnection.
- Use of synthon approach in synthesis of following compounds

Trimethoprim, Terfenadine, lbuprofen, Propanolol, Fentanyl, Cimetidine, Ciprofloxacin, Piroxicam, Rosiglitazone, Diclofenac, Captopryl, Nifedipine, Losartan.

- Recent advances & trends in the above mentioned categories of drugs.

Reference Books:

1. Graham and Patrick An Introduction To Medicinal Chemistry.
2. Foye's: Principles of Medicinal Chemistry (Varghese & Co.)
3. Ledinicer: Organic Drug synthesis Vol. 1, 2, 3, 4 (John Wiley & Sons N.Y.)
4. Ariens: Medicinal Chemistry Series
5. Ellis and West: Progress in Medicinal Chemistry Series
6. Bunerworther Progress in Medicinal Chemistry Series
7. Wilson & Gisvold - Text book of Medicinal Chemistry (J.B. Lippincoff cam)
8. Stuart Warren: Organic Synthesis- The Disconnection, approach (John Wiley & Sons)
9. Stuart Warren : Designing Organic Syntheses: A Programmed Introduction to the Synthon Approach
10. Comprehensive Medicinal Chemistry - Series –I – VI (Academic Press)
11. Burger: Medicinal Chemistry (John Wiley & Sons N.Y.)

APC – I Pr **ADVANCED PHARMACEUTICAL CHEMISTRY – I** **Practical** **(6 hrs/wk.)**

1. Study and applications of enzymes Kinetics, Inhibition and Immobilization.
2. Determination of partition coefficient.
3. Synthesis of drugs mentioned in the theory using basic operations like Molecular distillation, fractional crystallization, and purification by column chromatography, preparative TLC.
4. Synthesis of drugs using synthon approach.
5. Structure confirmation by spectroscopic studies.
6. Mixture analysis of 2/3 organic compounds.

Reference Books:

1. Organic Synthesis; Fieser and William Son (CBS Publishers)
2. Mann and Saunders. Practical Organic Chemistry (Orient Longman)
3. A. l. Vogel, Practical Qualitative and Quantitative Organic Chemistry (Orient Longman)

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

		Hrs	Marks
1.	**Combinatorial Chemistry:** Introduction, combinatorial approaches, small molecule libraries, applications, methodology, combinatorial organic synthesis, screening of combinatorial libraries, introduction to high throughputs screening (HTS).	11	25-35
2.	**Chiral Technology:** Introduction to Chirality and Techniques used asymmetric synthesis of Diltiazem, Timolol, Vitamin C, Ampicillin, Dextrapropoxyphen, Thienamycin, Citrenalol, Propranolol, Atenolol, and Naproxen.	10	20-30
3.	**Bioconversions in Drug Synthesis and Development:** Bio conversions of drugs like steroids, prostaglandin, antibiotics, enzyme immobilization Techniques. Chiral bioconversion of NSAID's using esterases.	10	20-30
4.	Agents used in Neurodegenerative diseases: like Alzheimer's and Parkinsonism. Therapeutic targets for their treatment. Recent advances and trends.	06	15-20
5.	Agents used in treatment of AIDS: Life cycle of HIV and various therapeutic targets for their treatment with examples. Recent Advances and Trends.	08	20-25

Reference Books:

1. Graham and Patrick An Introduction To Medicinal Chemistry.
2. Foye's: Principles of Medicinal Chemistry (Varghese & Co.)
3. Ledinicer: Organic Drug synthesis Vol. 1,2,3,4 (John Wiley &. Sons N.Y.)
4. Ariens : Medicinal Chemistry Series
5. Ellis and West : Progress in Medicinal Chemistry Series
6. Butterworther: Progress in Medicinal Chemistry Series
7. Wilson and Gisvold: Text book of Medicinal Chemistry (J.B. Lippincot)
8. Stuart Warren : Organic Synthesis – The Disconnection Approach (John Wiley & Sons)
9. Comprehensive Medicinal Chemistry - Series -I-VI (Academic Press)
10. Burger: Medicinal Chemistry (John Wiley & Sons N.Y.)

APC-II Pr **ADVANCED PHARMACEUTICAL CHEMISTRY – II** **Practical** **(6 hrs/wk.)**

1. Asymmetric synthesis.
2. Application of partition coefficient, pKa, Stearic factor, electronic factors in QSAR studies with examples. Use of statistical regression analysis.
3. Microbial conversion for drug synthesis.
4. Resolution of racemic mixture.
5. Synthesis of compounds using 3/4 steps, structure confirmation by spectroscopic methods.
6. Synthesis of drugs by combinatorial approach.
7. Multi-component synthesis approach.
8. Synthesis based on Solvent free reactions and reactions involving water as a solvent.

Reference Books:

1. Organic Synthesis; Fieser and William Son (CBS Publishers)
2. Mann and Saunders. Practical Organic Chemistry (Orient Longman)
3. A. l. Vogel, Practical Qualitative and Quantitative Organic Chemistry (Orient Longman)

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

		Hrs	Marks
1.	**Drug Discovery:** 1. Historical perspective. 2. Drug Discovery Strategies in Direct Drug Design (Structure based) and indirect drug design. advantages and limitations of both. 3. Target selection and lead identification i. Natural product sources ii. Fermentation / Microbial sources iii. Synthetic 4. Structure activity relationships - Binding role of –OH groups, -NH_2 groups, aromatic rings, double bonds, ketones and amides. 5. Bioinformatics in drug discovery.	09	20-28
2.	**Pharmacogenomics and informatics:** Genomics – types of genomics, bioinformatics, chemoinformatics, proteomics, barriers to progress of pharmacogenomics progress.	09	20-28
3.	**QSAR:** 1. Parameters - Lipophilicity, electronic, Stearic factors. 2. Quantitative Models: i. Hansch analysis. ii. Free Wilson Analysis. iii. Mixed approach. 3. Other QSAR Approaches. 4. Applications of Hansch Analysis, Free Wilson Analysis.	09	20-28
4.	**Molecular Modeling in Drug Design:** Introduction to Molecular Modeling: Concepts and Methods. 1. Molecular Mechanics - force fields (Potential energy function). 2. Energy Minimization Methods - Steepest, descent. Conjugate gradients, Newton methods (Non mathematical). 3. Conformational Analysis i) Systematic search. ii) Monte Carlo simulations. iii) Molecular dynamics simulations. 4. Ligand design based on 3D structure of receptor /enzyme. 5. Computer assisted drug design.	09	20-28

5.	**Proteins and Peptide drugs:** Chemistry, structure and stability, Reactivity of proteins and peptides. Different ways to synthesize these drugs - study of Insulin, Relaxin, Somatostatin, DNAse Interferon. Peptides in molecular biology.	09	20-28

Reference Books:

1. Graham and Patrick An Introduction To Medicinal Chemistry.
2. Hugo Kubingi - QSAR, Hansch Analysis and Related approaches Vol I.
3. Poul Krogsgaand Larsen: A textbook of Drug Design and Development First Edi.
4. Thomas J. Penim, C.L-Propst - Computer Aided Drug Design.
5. Pandi Veerapandian - Structure Based Drug design.
6. Paul S. Charifson - Practical Applications of Computer Aided Drug Design (Marcel & Dekkar Inc. New York)
7. Paul Leff-Receptor Based Drug Design.
8. Bernard Testa, Walter Fuh rer – Perspectives in-Medicinal Chemistry.
9. C. Hansch Comprehensive Medicinal Chemistry Vol.-IV.

SYLLABUS FOR M. PHARM (BIOPHARMACEUTICS)

MAT MODERN ANALYTICAL TECHNIQUES Theory (3 hrs/wk.)

		Hrs	Marks
1.	Biostatistics and Computer Application: Introduction to and pharmaceutical applications of Student's t-test, F test, Chi-square test, Analysis of variance (ANOVA), correlation and regression analysis, Factor analysis, Time series analysis and Multidimensional scaling. Applications of computers related to quantitative and statistical pharmaceutical analysis.	3	10-15
2.	Sample Preparation for Analysis: Different techniques of sample preparation from body fluids, tissue extracts, cell culture extracts and phyto-chemical extracts.	5	10-15
3.	Structural Elucidation by Spectroscopic Methods: UV-Visible, IR, NMR and Mass with examples.	5	15-20
4.	Applications of DSC and XRD: Analysis of raw material (APIs and excipients), packaging material and finished products.	4	10-15
5.	Reference Standards: Introduction, preparation, types, storage, record keeping and validation.	5	10-15
6.	ESR Spectroscopy: Introduction, calibration, validation and application (in brief). Circular Dicorism and ORD: Introduction, calibration, validation and application (in brief).	5	10-15
7.	Particle Size Analysis: Introduction, significance, methods used in particle size analysis. Gel Permeation Chromatography (GPC): Introduction, instrumentation (Stationary phases and Detectors) and its application (particle size analysis).	4	15-20
8.	Immunochemical Techniques: ELISA, Immuno- precipitation, Radio immuno assays and Radio-labeling.	5	20-25

Reference Books

1. Introduction To Biostatistics & Computer Science, Mr. Y. I. Shah Dr. A. R. Paradkar, Mr. Y. I. Shah, Mr. M. G. Dhayagude
2. Pharmaceutical statistics using SAS: a practical Guide, Ralph B. D'Agostino
3. Introduction to Pharmaceutical Calculations, Judith A. Rees
4. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.

5. Practical Method Development, Snyder, L. R., Kirkland, J. J. and Glajch, J. L.
6. Principles of Instrumental Analysis, Skoog.
7. Textbook of Practical Biotechnology, C.R. Kokare.
8. Organic Spectroscopy, William Kemp
9. Physical Pharmacy – Martin, Swarbrick and Commarata
10. Physical Chemistry – Bahl and Tuli
11. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
12. I. P., B.P. and U.S.P.
13. Instrumental Methods of Analysis, Chatwal & Anand,
14. A Textbook of pharmaceutical analysis, K. A. Connors.
15. Pharmaceutical Analysis, Ashutosh Kar.
16. Instrumental and Chemical Analysis, B.K. Sharma.

MAT Pr **MODERN ANALYTICAL TECHNIQUES** **Practical (6 hrs/wk.)**

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. ED_{50} and LD_{50} Estimation and probit analysis

Reference Books

1. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.
2. Textbook of Pharmacognosy, Kokate C. K. Purohit A. P. and Gokhale S. B.
3. Pharmacognosy and Phytochemistry, Vol. I & II, V.D.Rangari.
4. Natural products Chemistry Practical Manuals, A.A.Siddiqui.
5. Indian Pharmacopoeia.
6. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
7. Harry's cosmetology, J. B. Wilkinson and R. J. Moore.
8. Textbook of Practical Biotechnology, C.R. Kokare.
9. Research Articles on Analytical Method Development in Journals
10. Physical Pharmacy – Martin, Swarbrick and Commarata
11. Physical Chemistry – Bahl and Tuli

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

		Hrs	Marks
1.	**Introduction**	3	05 – 10
	Introduction to pharmacokinetics, mathematical fundamentals, Pharmacokinetic models, application of pharmacokinetics in clinics and drug product development, toxicokinetics and its application.		
2.	**Therapeutic regimen**	4	10 – 10
	Therapeutic response and toxicity, constant rate regimen and multiple dose regimens		
3.	**Physiological concepts and kinetics**	8	10 – 15
	Zero order and first order kinetics, movement of drug through membrane, absorption kinetics (intravascular and extravascular), distribution and elimination kinetics, integration with kinetics.		
4.	**Individualization of therapy and variability**	4	15 – 20
	Variability and it causes variability due to age, weight, sex, diseases (renal, cardio vascular, hepatic, genetics and metabolic disorders). Kinetics of drug interaction		
5.	**Concepts and derivations**	6	10 – 15
	Assessment of AUC, estimation of half life, estimation of absorption kinetics, Mean residence Time, Blood to plasma ratio, drug accumulation, creatinine clearance.		
6.	**Compartment modelling**	8	20 – 25
	Various types of physiological compartment models, perfusion and distribution, volume of distribution, one compartment and multi compartment models for intra venous and extra vascular administration		
7.	**Nonlinear pharmacokinetics**	7	10 – 15
	Non linear pharmacokinetics of absorption, saturation in transport carriers, dose dependent absorption, nonlinear protein binding, drug elimination by capacity limited pharmacokinetics		
8.	**Special topics in pharmacokinetics**	5	05 – 10
	Dosage adjustment for renal, hepatic and metabolic failure patients, adjustment of dose based on age and body weight, dialysis and turnover concepts.		
	Application of pharmacokinetics in designing and development of novel dosage forms		
9.	**Problems based on the above chapters**		15 – 20

Reference Books:

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

Journal References

10. Clinical pharmacokinetics
11. Clinical pharmacology
12. Journal of pharmacy and pharmacology
13. European Journal of pharmaceutics and Biopharmaceutics

PK Pr **PHARMACOKINETICS** **Practical (6 hrs/wk.)**

1. Study of permeation of drug using in situ rat model
2. Study the metabolism of drug using rat liver slice model
3. Estimation of elimination rate constant of aspirin
4. Effect of food products on metabolism of drugs
5. Determination of logP value of drug
6. Dissolution studies of 2 to 3 marketed formulations
7. Measurement of bioavailability based on urinary data of rifampicin, pyridoxine, nitrofurantoin and the drugs excreted through urine
8. Practicals based on biopharmaceutical aspects of drug formulations
9. Study of protein binding of drugs on serum

BAB **BIOPHARMACEUTICS (BIOAVAILABILITY AND BIOEQUIVALENCE)** **Theory** **(3 hrs/wk.)**

		Hrs	Marks
1.	**Introduction** Definition of Bioavailability, bioequivalence, generic drugs, types of BA, methods to determine BA, Hatch max-man act 1971.	4	05 – 05
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,	18	30 – 40
3.	**Protocol in BA/BE studies** Designing of protocol, rationale of the research, selection of subjects. Construction, role and responsibilities of IRB/IEC	6	20 – 30
4.	**Conduct of Study** Design of the study, inclusion and exclusion criteria, sampling point, sampling volume, treatment groups	6	20 – 30
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**.**	5	15 – 20
6.	**Documentation in BA/BE** Formation of investigator's information brochure, Case Record Form (CRF), presentation of Results and conclusion.	6	10 – 15

Reference 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

Web resources

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

NDDS **NOVEL DRUG DELIVERY SYSTEMS** **Theory** **(3 hrs/wk.)**

		Hrs	Marks
1.	**Introduction** Various types of novel drug delivery, classes, objective, rationale, merits and demerits of NDDS, need of pharmacokinetic optimization. Strategies to improve the pharmacokinetic properties of drug.	2	05 – 05
2.	**Pharmaceutical product development** Selection of drug candidates, authentication of drugs, preformulation testing (solubility studies, drug excipients interaction, solid state optimization and crystallinity, analytical method development), selection of route of administration and dosage form, stability of drug products, Regulatory submission	3	05 – 10
3.	**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,	5	05 – 10
4.	**Fundamentals polymer science** Introduction, classification, physicochemical and biological properties of polymers. application and invivo fate of polymers	3	05 – 10
5.	**Biopharmaceutical classification system and its implication in NDDS** Solubility, permeability and other physicochemical properties influencing bioavailability, Mathematical modeling of drug release, Biopharmaceutical classification system and its applications, Invitro dissolution testing, various dissolution improvement technologies, different class of dissolution media, IVIVC	4	10 – 15
6.	**Mucosal drug delivery system** Buccal, vaginal, rectal and GI mucoadhesive drug delivery system, Bioadhesion, Bioadhesive polymer, mechanism of bioadhesion, preformulation, formulation and evaluation of mucosal drug delivery system	3	10 – 15
7.	**Ocular drug delivery** Ocular availability, mechanism of drug transport, Factors influencing ocular bioavailability, method of enhancement, selection of excipients, formulation development and invitro and invivo evaluation.	3	10 – 15
8.	**Transdermal drug delivery** Physiology of skin, various pathways permeation, permeation enhancement, types of transdermal therapeutic system, formulation strategies, and evaluation procedures	3	10 – 15

9.	**Oral and parental controlled release** Scope, terminologies, types and techniques, mechanism of drug release, gastric emptying time and its importance, influence of diseases state, selection drug candidates, preformulation, formulation development and evaluation.	8	15 – 20
10.	**Site specific drug delivery system** Colon targeting, Brain targeting, tumor targeting and other specific site targeting, types of targeting, carriers and its importance, method of preparation, evaluation, limitation in marketability, liposomes, microspheres, nanoparticles, monoclonal antibodies, resealed erythrocytes, niosomes,	5	10 – 15
11.	**Nasal drug delivery** Introduction, types, merits and demerits of nasal drug delivery, barriers in nasal drug delivery, strategies to improve the nasal bioavailability, various dosage forms and its formulation development. Pharmacokinetics, invtro and invivo evaluation of nasal formulations	4	10 – 15
12.	**Regulatory consideration in novel drug delivery** Bioavailability studies and USFDA, MCA, ICMR, WHO guidelines for ANDA and NDA of novel dosage forms	4	05 – 10

Reference Books:

1. Alfonso R. Gennaro. Remington: The Science and Practice of Pharmacy. Mack Publishing Company
2. Y. W. Chen Novel Drug Delivery System. Marcel Dekker Inc.
3. Vicent H.L., Controlled Drug Delivery System. Marcel Dekker Inc.
4. Abu K. Treatise in Controlled Drug Delivery. Marcel Dekker Inc.
5. N.K. Jain Novel and Controlled Drug Delivery Systems, CBS publications
6. Vyas, R. K. Khar Novel Carriers for Controlled Drug Delivery. CBS Publications
7. Vyas, R. K. Khar Controlled Drug Delivery Concepts And Applications. CBS Publications

Journal References

8. Journal of controlled release
9. Journal of microencapsulation
10. International journal of pharmaceutics
11. American journal of drug delivery
12. Advances in drug delivery review

NDDS Pr	**NOVEL DRUG DELIVERY SYSTEM**	**Practical**	**(6 hrs/wk.)**

1. Preparation and evaluation of Transdermal patches
2. Preparation and in-vitro evaluation of ophthalmic gels
3. Influence of disintegrant on HPMC based matrix tablets
4. Optimization of drug dissolution time of IR dosage form
5. Nasal diffusion studies of microspheres in goat mucosa
6. Chitosan based insitu gels for tumour targeting: Invitro evaluation
7. Preparation of solid dispersions for controlled oral delivery
8. Effect of chitosan on drug release and its mathematical modelling

SYLLABUS FOR M. PHARM (PHARMACEUTICS)

MAT MODERN ANALYTICAL TECHNIQUES Theory (3 hrs/wk.)

		Hrs	Marks
1.	Biostatistics and Computer Application: Introduction to and pharmaceutical applications of Student's t-test, F test, Chi-square test, Analysis of variance (ANOVA), correlation and regression analysis, Factor analysis, Time series analysis and Multidimensional scaling. Applications of computers related to quantitative and statistical pharmaceutical analysis.	3	10-15
2.	Sample Preparation for Analysis: Different techniques of sample preparation from body fluids, tissue extracts, cell culture extracts and phyto-chemical extracts.	5	10-15
3.	Structural Elucidation by Spectroscopic Methods: UV-Visible, IR, NMR and Mass with examples.	5	15-20
4.	Applications of DSC and XRD: Analysis of raw material (APIs and excipients), packaging material and finished products.	4	10-15
5.	Reference Standards: Introduction, preparation, types, storage, record keeping and validation.	5	10-15
6.	ESR Spectroscopy: Introduction, calibration, validation and application (in brief). Circular Dicorism and ORD: Introduction, calibration, validation and application (in brief).	5	10-15
7.	Particle Size Analysis: Introduction, significance, methods used in particle size analysis. Gel Permeation Chromatography (GPC): Introduction, instrumentation (Stationary phases and Detectors) and its application (particle size analysis).	4	15-20
8.	Immunochemical Techniques: ELISA, Immuno- precipitation, Radio immuno assays and Radio-labeling.	5	20-25

Reference Books

1. Introduction To Biostatistics & Computer Science, Mr. Y. I. Shah Dr. A. R. Paradkar, Mr. Y. I. Shah, Mr. M. G. Dhayagude
2. Pharmaceutical statistics using SAS: a practical Guide, Ralph B. D'Agostino
3. Introduction to Pharmaceutical Calculations, Judith A. Rees
4. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.

5. Practical Method Development, Snyder, L. R., Kirkland, J. J. and Glajch, J. L.
6. Principles of Instrumental Analysis, Skoog.
7. Textbook of Practical Biotechnology, C.R. Kokare.
8. Organic Spectroscopy, William Kemp
9. Physical Pharmacy – Martin, Swarbrick and Commarata
10. Physical Chemistry – Bahl and Tuli
11. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
12. I. P., B.P. and U.S.P.
13. Instrumental Methods of Analysis, Chatwal & Anand,
14. A Textbook of pharmaceutical analysis, K. A. Connors.
15. Pharmaceutical Analysis, Ashutosh Kar.
16. Instrumental and Chemical Analysis, B.K. Sharma.

MAT Pr **MODERN ANALYTICAL TECHNIQUES** **Practical (6 hrs/wk.)**

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. ED_{50} and LD_{50} Estimation and probit analysis

Reference Books

1. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.
2. Textbook of Pharmacognosy, Kokate C. K. Purohit A. P. and Gokhale S. B.
3. Pharmacognosy and Phytochemistry, Vol. I & II, V.D.Rangari.
4. Natural products Chemistry Practical Manuals, A.A.Siddiqui.
5. Indian Pharmacopoeia.
6. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
7. Harry's cosmetology, J. B. Wilkinson and R. J. Moore.
8. Textbook of Practical Biotechnology, C.R. Kokare.
9. Research Articles on Analytical Method Development in Journals
10. Physical Pharmacy – Martin, Swarbrick and Commarata
11. Physical Chemistry – Bahl and Tuli

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

		Hrs	Marks
	Physical pharmaceutics covering the following aspects		
1.	**Solids :**	07	17 – 24
	Particle characterisation 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, characterisation of granules and compacts.		
2.	**Dissolution :**	08	20 – 28
	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. Enhancement of dissolution rate.		
3.	**Surfactant System :**	10	23 – 30
	Phase behaviour of surfactant in binary and ternary systems. Factors affecting phase behaviour; Micellization; micelle structure, shape, size factors affecting CMC and micelle size, thermodynamics and kinetics of micelle formation. Pharmaceutical aspects of Solubilization, Solubilization in non-aqueous system, interactions with polymers and oppositely charged species. Hydrotrophy in pharmaceuticals, surfactants in emulsions and suspensions. Biological implications of surfactants; Effect on: dissolution of drugs, permeability of membranes, drug absorption, antibacterial activity. Cyclodextrin inclusion complexes and co-solvents.		
4.	**Polymer science :**	06	10 – 16
	Types and applications of polymers, polymerization reactions, methods of polymerization and characterization of polymers, thermodynamics of polymer solutions.		
5.	**Solid dispersions :**	06	10 – 16
	Types, methods of preparation, selection of carrier, characterization and applications.		
6.	**Stability studies :**	08	20 – 26
	Kinetics activation energy calculations, accelerated stability studies, factors responsible for destabilization of pharmaceutical products and techniques to improve, shelf life calculations. Physical testing of solution, suspension, emulsion, aerosol, powder, tablet and sustained release products.		

Reference Books:

1. A. Kitahard and A. Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
2. A. Martin, P. Bustamante and A. H. Chun; Physical Pharmacy; Waverly.
3. D. M. Parikh; Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
4. G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
5. H. G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
6. J. T. Cartensen; Drug Stability; Marcel Dekker.
7. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
8. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
9. M. N. Rubinstein; Pharmaceutical Technology, Drug stability, John Wiley and sons.
10. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.
11. N. G. Stanley – Wooed; Enlargement and compaction of particle solids; Butterworths.
12. P. H. List and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
13. P. J. Tarcha; Polymer for Controlled Drug Delivery, CRC Press.
14. Robinson; Novel Drug Delivery Systems, Marcel Dekker.

AP-I Pr **ADVANCED PHARMACEUTICS – I** **Practical (6 hrs/wk.)**

1. **Experiments based on following concepts.**
2. **Powder characterization:**
   - Microscopy – Particle size analysis, calculation of shape factors.
   - Compression and compaction – Huckel plot studies, tensile strength.
3. **Solubilization :**
   - Effect of dielectric constant on solubility
   - Complexation
   - Ternary phase diagram.
   - Solid dispersion
4. **Stability of multiple emulsions**
5. **Polymer science :**
   - Rheological and thermal characterization of polymers.
6. **Stability studies :**
   - Degradation kinetic study of a drug in a solution.
   - Accelerated stability studies of a formulation.
7. **Dissolution studies of various dosage forms.**

Recommended books

1. A. Kitahard and A. Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
2. A. Martin, P. Bustamante and A. H. Chun; Physical Pharmacy; Waverly.
3. D. M. Parikh; Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
4. G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
5. H. G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
6. J. T. Cartensen; Drug Stability; Marcel Dekker.
7. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
8. Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
9. M. N. Rubinstein; Pharmaceutical Technology, Drug stability, John Wiley and sons.
10. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.
11. N. G. Stanley – Wooed; Enlargement and compaction of particle solids; Butterworths.
12. P. H. List and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
13. P. J. Tarcha; Polymer for Controlled Drug Delivery, CRC Press.
14. Robinson; Novel Drug Delivery Systems, Marcel Dekker.

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

		Hrs	Marks
1.	Fundamental concepts of controlled release including Biopharmaceutical consideration of controlled release dosage forms.	03	05 – 10
2.	**Modified release oral drug delivery systems:**	06	20 – 26
	Principle, 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.		
3.	**Mucosal Drug delivery:**	05	10 – 14
	Mechanism of mucoadhesion, bioadhesive polymers, penetration enhancers. Development of buccal, nasal, pulmonary, rectal and vaginal drug delivery system. In vitro, ex-vivo and in-vivo evaluation techniques.		
4.	**Ocular drug delivery:**	05	10 – 14
	Ocular delivery mechanism, factors affecting ocular drug absorption and development of ocular drug delivery systems, mucoadhesive polymers, ocular inserts, iontophoresis, delivery of peptides and proteins.		
5.	**Transdermal drug delivery:**	05	10 – 14
	Permeation through skin, physicochemical factors in drug permeation, permeation enhancers, iontophoresis drug delivery, approaches and technologies for developing Transdermal drug delivery systems and their evaluation.		
6.	**Parenteral drug delivery :**	06	15 – 20
	• Implants and implantable devices: Types, release mechanism, fabrication, biocompatibility and performance evaluation. • 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. • Microspheres: Biodegradable polymers, drug entrapment technique and targeting. Evaluation of the formulation.		
7.	**Colon specific drug delivery:**	05	10 – 14
	Advantages of colon specific drug delivery, diseases 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.		

8. Pulsatile Drug Delivery: 05 10 – 14

Chronobiology, 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 Polymeric devices, TDDS , Floating pulsatile drug delivery system(DDS), Chronotherapy in cancer treatment.

9. Protein and peptide drug delivery: 05 10 – 14

Structural complexity of protein and peptide drugs. Routes for peptide delivery, Physiological barriers in bioavailability of such molecules, Formulation considerations, immunogenicity, stability in delivery of insulin, regulatory perspectives for such drugs.

Reference Books:

1. A. F. Kydonieus; Controlled Release Technologies, methods, theory and applications, Vol. I and II, CRC Press Inc.
2. A. J. Hickey; Pharmaceutical Inhalation Aerosol Technology, Marcel Dekker.
3. Barry; Dermatological Formulation, Marcel Dekker.
4. C. G. Wilson and N. Washington; Physiological Pharmaceutics, Ellis Horwood Limited.
5. D. W. Osborne, A. H. Amann; Topical drug delivery formulations, Marcel Dekker.
6. H. S. Bean, A. H. Becket and J. E. Carless; Advances in Pharmaceutical Sciences, Vol. 5, Academic Press.
7. J. Kreuter; Controlled Drug Delivery Systems, Marcel Dekker.
8. K. S. E. Su and S. F. Chang; Nasal Systemic Drug Delivery, Marcel Dekker.
9. Morton Rosoff; Controlled release of drugs, VCH Publishers.
10. N. K. Jain; Novel and Drug Delivery systems, CBS Publishers, New Delhi.
11. N. K. Jain. Progress in controlled and novel drug delivery systems, CBS publishers.
12. P. B. Deasy; Micro encapsulation and release drug processes, Marcel Dekker.
13. P. Johnson and J. G. lioyd- Jones; Drug Delivery Systems, VCH Publishers.
14. P. Tyle and B. P. Ram; Targetted Therapeutic systems, Marcel Dekker.
15. P. Tyle; Drug Delivery Devices, fundamental applications, Marcel Dekker.
16. R. O. Potts and R. H. Guy; Mechanism of Transdermal Drug Delivery, Marcel Dekker.
17. Robinson; Novel Drug Delivery systems. Marcel Dekker.
18. T. J. Roseman and S. Z. Mansdorf; Controlled release delivery Systems, Marcel Dekker.
19. Wise Donald L. , Handbook of pharmaceutical controlled release technology, Marcel Dekker Inc.
20. Y. W. Chein; Transdermal Controlled Systemic Medication, Marcel Dekker.

AP-II Pr **ADVANCED PHARMACEUTICS – II** **Practical (6 hrs/wk.)**

Experiments based on following concepts

1. Formulation of sustained release tablet formulation.
2. Preparation and characterization of Microcapsules/Microspheres.
3. Preparation and evaluation of Transdermal films.
4. In-vitro permeation studies across skin and nasal mucosa.
5. Bioavailability study of nasal mucosa.
6. Formulation design and evaluation of
    - Liposomes
    - Multiple emulsions.

Reference Books:

1. A. F. Kydonieus; Controlled Release Technologies, methods, theory and applications, Vol. I and II, CRC Press Inc.
2. A. J. Hickey; Pharmaceutical Inhalation Aerosol Technology, Marcel Dekker.
3. Barry; Dermatological Formulation, Marcel Dekker.
4. C. G. Wilson and N. Washington; Physiological Pharmaceutics, Ellis Horwood Limited.
5. D. W. Osborne, A. H. Amann; Topical drug delivery formulations, Marcel Dekker.
6. H. S. Bean, A. H. Becket and J. E. Carless; Advances in Pharmaceutical Sciences, Vol. 5, Academic Press.
7. J. Kreuter; Controlled Drug Delivery Systems, Marcel Dekker.
8. K. S. E. Su and S. F. Chang; Nasal Systemic Drug Delivery, Marcel Dekker.
9. Morton Rosoff; Controlled release of drugs, VCH Publishers.
10. N. K. Jain; Novel and Drug Delivery systems, CBS Publishers, New Delhi.
11. P. B. Deasy; Micro encapsulation and release drug processes, Marcel Dekker.
12. P. Johnson and J. G. lioyd- Jones; Drug Delivery Systems, VCH Publishers.
13. P. Tyle and B. P. Ram; Targetted Therapeutic systems, Marcel Dekker.
14. P. Tyle; Drug Delivery Devices, fundamental applications, Marcel Dekker.
15. R. O. Potts and R. H. Guy; Mechanism of Transdermal Drug Delivery, Marcel Dekker.
16. Robinson; Novel Drug Delivery systems. Marcel Dekker.
17. T. J. Roseman and S. Z. Mansdorf; Controlled release delivery Systems, Marcel Dekker.
18. Y. W. Chein; Transdermal Controlled Systemic Medication, Marcel Dekker.

AP-III **ADVANCED PHARMACEUTICS – III** **Theory** **(3 hrs/wk.)**

		Hrs	Marks
1.	**Absorption:**	08	20 – 26
	Cell membrane, absorption mechanism, oral drug absorption, pHpartition 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.		
2.	**Distribution:**	06	15 – 20
	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-protein binding, significance of drug protein binding.		
3.	**Metabolism:**	08	20 – 26
	Drug metabolism, organs and enzymes, chemical pathways, Phase I and Phase II reactions. First pass effect, factors affecting.		
4.	**Excretion:**	05	10 – 14
	Renal and nonrenal routes of drug excretion.		
5.	**Integration of kinetics:**	03	05 – 10
	Interrelationships between pharmacokinetic parameters and physiological variables.		
6.	**Pharmacokinetics:**	06	15 – 20
	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	05 – 10
	Multiple dosing controlled release dosage form, dose adjustment in renal failure, haemodialysis, individualization, monitoring drug therapy, chronopharmacokinetics.		
8.	**Bio-availabilty and bioequavalence:**	05	10 – 14
	Study design protocols, regulatory requirements and statistical consideration in data analysis.		

Reference Books:

1. B. Testa; Advances in drug research; Vol. 19; Academic Press.
2. D. M. Bramhankar and S. B. Jaiswal; Biopharmaceutics and Pharmacokinetics A Treatise; Vallabh Prakashan.
3. J. B. Blanchard, R. J. Sawchul and B. B. Brodie; Principle and perspectives in drug bioavailabilty; K. Karger Publication.
4. Jean- Pierre Labaune; Handbook of Pharmacokinetics; John Wiley Sons.
5. M. Gibaldi and Perrier; Pharmacokinetics; Marcel Dekker.
6. M. Rawland and T. N. Tozer; Clinical Pharmacokinetics; Waverly Publications.
7. P. G. Welling and F. L. S. Tse; Pharmacokinetics, Regulatory- Industrial - Academic perspectives; Marcel Dekker.
8. P. Jenner and B. Testa; Concept in drug metabolism; Marcel Dekker.

SYLLABUS FOR M. PHARM (QUALITY ASSURANCE)

MAT MODERN ANALYTICAL TECHNIQUES Theory (3 hrs/wk.)

		Hrs	Marks
1.	Biostatistics and Computer Application: Introduction to and pharmaceutical applications of Student's t-test, F test, Chi-square test, Analysis of variance (ANOVA), correlation and regression analysis, Factor analysis, Time series analysis and Multidimensional scaling. Applications of computers related to quantitative and statistical pharmaceutical analysis.	3	10-15
2.	Sample Preparation for Analysis: Different techniques of sample preparation from body fluids, tissue extracts, cell culture extracts and phyto-chemical extracts.	5	10-15
3.	Structural Elucidation by Spectroscopic Methods: UV-Visible, IR, NMR and Mass with examples.	5	15-20
4.	Applications of DSC and XRD: Analysis of raw material (APIs and excipients), packaging material and finished products.	4	10-15
5.	Reference Standards: Introduction, preparation, types, storage, record keeping and validation.	5	10-15
6.	ESR Spectroscopy: Introduction, calibration, validation and application (in brief). Circular Dicorism and ORD: Introduction, calibration, validation and application (in brief).	5	10-15
7.	Particle Size Analysis: Introduction, significance, methods used in particle size analysis. Gel Permeation Chromatography (GPC): Introduction, instrumentation (Stationary phases and Detectors) and its application (particle size analysis).	4	15-20
8.	Immunochemical Techniques: ELISA, Immuno- precipitation, Radio immuno assays and Radio-labeling.	5	20-25

Reference Books

1. Introduction To Biostatistics & Computer Science, Mr. Y. I. Shah Dr. A. R. Paradkar, Mr. Y. I. Shah, Mr. M. G. Dhayagude
2. Pharmaceutical statistics using SAS: a practical Guide, Ralph B. D'Agostino
3. Introduction to Pharmaceutical Calculations, Judith A. Rees
4. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.

5. Practical Method Development, Snyder, L. R., Kirkland, J. J. and Glajch, J. L.
6. Principles of Instrumental Analysis, Skoog.
7. Textbook of Practical Biotechnology, C.R. Kokare.
8. Organic Spectroscopy, William Kemp
9. Physical Pharmacy – Martin, Swarbrick and Commarata
10. Physical Chemistry – Bahl and Tuli
11. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
12. I. P., B.P. and U.S.P.
13. Instrumental Methods of Analysis, Chatwal & Anand,
14. A Textbook of pharmaceutical analysis, K. A. Connors.
15. Pharmaceutical Analysis, Ashutosh Kar.
16. Instrumental and Chemical Analysis, B.K. Sharma.

MAT Pr **MODERN ANALYTICAL TECHNIQUES** **Practical (6 hrs/wk.)**

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. ED_{50} and LD_{50} Estimation and probit analysis

Reference Books

1. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.
2. Textbook of Pharmacognosy, Kokate C. K. Purohit A. P. and Gokhale S. B.
3. Pharmacognosy and Phytochemistry, Vol. I & II, V.D.Rangari.
4. Natural products Chemistry Practical Manuals, A.A.Siddiqui.
5. Indian Pharmacopoeia.
6. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
7. Harry's cosmetology, J. B. Wilkinson and R. J. Moore.
8. Textbook of Practical Biotechnology, C.R. Kokare.
9. Research Articles on Analytical Method Development in Journals
10. Physical Pharmacy – Martin, Swarbrick and Commarata
11. Physical Chemistry – Bahl and Tuli

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

		Hrs	Marks
1.	**Introduction :**	08	15 – 25
	An understanding of the concepts of Quality Assurance, Good Manufacturing Practice and Quality Control as applied to the pharmaceutical Industry.		
2.	**Documentation related to Pharmaceutical Industry :**	20	45 – 65
	• New application : NDA and ANDA requirements, Data presentation , verification and grant by FDA		
	• Manufacturing documents: BMR, routine records, downtime records, calibration and validation records.		
	• Quality Assurance documents: validation and types of validation, protocols methodology and related GMP /ICH guidelines.		
	• Quality Assurance documents: Internal audits SOP documents security and storage related issue.		
	• Store management documents: Stock reconciliation records for raw material, finished products and packaging materials.		
	• Maintenance and Environment control related documents.		
	• Consumer related documents: Product recall, complaint traceability printed packing, preventive maintenance records.		
3.	**Good laboratory Practices (GLP)**	10	25 – 30
	Regulations , 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.		
4.	**Related quality systems :**	07	15 – 20
	ISO, WHO etc, and their applications in pharmaceutical industry.		

RECOMMENDED BOOKS

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.

QAT-I Pr **QUALITY ASSURANCE TECHNIQUES – I** **Practical (6 hrs/wk.)**

EXPERIMENTS BASED ON FOLLOWING

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 following key documents
    a. SOP on SOP
    b. IPQC document
    c. Material receipt, sampling, dispensing & storage document
7. Experiment & documentation of dissolution test
8. IPQC tests for Tablets / Capsules / Injections / Liquid / Ointment

RECOMMENDED BOOKS

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.

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

		Hrs	Marks
1.	**Rules and Regulations :**	07	15 – 22
	Rules governing manufacturing of drugs in India. Drug and Cosmetic Act and rules. Narcotic drugs and Psychotropic substances Act and Rules. Magic Remedies and Objectionable Advertisement Act, Consumer protection Act, Factory Act and intellectual Property Right.		
2.	**Process validation :**	07	18 – 25
	Differences and similarities between process qualification and process validation, protocols, methodology and interpretation of data. Validation of process like mixing, granulation, drying, compression filling and water process system.		
3.	**Equipment Validation :**	07	18 – 25
	Installation qualification and operational qualification for sterilization equipments like autoclave, oven and membrane filter.		
4.	**Cleaning methods:**	06	12 – 17
	Analytical method validation requirements and validation of effective cleaning.		
5.	**Vendor validation :**	06	12 – 17
	Vendor audit, sample testing and trend analysis.		
6.	**Validation of service :**	06	12 – 17
	Training, maintenance and packing.		
7.	**Validation of electronic data processing :**	06	12 – 17
	Software validation methodology.		

RECOMMENDED BOOKS

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.

QAT-II Pr **QUALITY ASSURANCE TECHNIQUES – II** **Practical** **(6 hrs/wk.)**

EXPERIMENTS BASED ON FOLLOWING CONCEPTS

1. Validation of equipments, Autoclave, hot air oven, membrane filter.
2. Validation of process, Mixing drying and compression.
3. Validation of an analytical method.

RECOMMENDED BOOKS

1. J. F. Despautz, Automation and validation of information in Pharmaceutical Processing Marcel and Dekker.
2. F.J. Carleton and J.P. Agalloco validation of aseptic Pharmaceutical processes 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 Pharmaceuticals Marcel and Dekker.
5. R.F. Brewer, Design of Experiments for process improvement and quality Assurance, Narosa.
6. S. N. Katju Law and drugs, Law Publishers (I) Pvt. Ltd.

QAT-III QUALITY ASSURANCE TECHNIQUES – III Theory (3 hrs/wk.)

		Hrs	Marks
1.	**Validation of instruments :**	08	20 – 28
	HPLC, UV and IR spectrophotometer and dissolution test apparatus.		
2.	**Validation of Analytical Method :**	08	20 – 28
	Validation parameters, accuracy, precision, ruggedness, statistical design and statistical consideration.		
3.	**Current good manufacturing Practices.**	08	20 – 28
4.	**Biostatistics :**	15	30 – 40
	Probability distribution, normal, binomial and polynomial distributions, continuous data distribution, fiducial limits, probit and logit analysis. Linear regression and correlation, method of least squares, significance of correlation and regression. Parametric tests, testing hypothesis, types of errors test of significance based on normal distribution, test of significance for correlation coefficients. Non parametric test. Experimental Designs. Randomization completely randomized and Latin square designs, and factorial design. Statistical Quality Control.		
5.	**Guidelines and technique for experiments on animals.**	06	10 – 16

RECOMMENDED BOOKS

1. D.A. Berry, statistical methodology in the Pharmaceutical Science: Marcel and Dekker Vol.104.
2. S.W. Bergman and JC Gittins statistical methods for Pharmaceutical Research and planning Marcel and Dekker.
3. S. C. Chowand J.P. Liu statistical Design and Analysis in Pharmaceutical Sciences. Marcel, Dekker.

SYLLABUS FOR M. PHARM (PHARMACOLOGY)

MAT MODERN ANALYTICAL TECHNIQUES Theory (3 hrs/wk.)

		Hrs	Marks
1.	Biostatistics and Computer Application: Introduction to and pharmaceutical applications of Student's t-test, F test, Chi-square test, Analysis of variance (ANOVA), correlation and regression analysis, Factor analysis, Time series analysis and Multidimensional scaling. Applications of computers related to quantitative and statistical pharmaceutical analysis.	3	10-15
2.	Sample Preparation for Analysis: Different techniques of sample preparation from body fluids, tissue extracts, cell culture extracts and phyto-chemical extracts.	5	10-15
3.	Structural Elucidation by Spectroscopic Methods: UV-Visible, IR, NMR and Mass with examples.	5	15-20
4.	Applications of DSC and XRD: Analysis of raw material (APIs and excipients), packaging material and finished products.	4	10-15
5.	Reference Standards: Introduction, preparation, types, storage, record keeping and validation.	5	10-15
6.	ESR Spectroscopy: Introduction, calibration, validation and application (in brief). Circular Dicorism and ORD: Introduction, calibration, validation and application (in brief).	5	10-15
7.	Particle Size Analysis: Introduction, significance, methods used in particle size analysis. Gel Permeation Chromatography (GPC): Introduction, instrumentation (Stationary phases and Detectors) and its application (particle size analysis).	4	15-20
8.	Immunochemical Techniques: ELISA, Immuno- precipitation, Radio immuno assays and Radio-labeling.	5	20-25

Reference Books

1. Introduction To Biostatistics & Computer Science, Mr. Y. I. Shah Dr. A. R. Paradkar, Mr. Y. I. Shah, Mr. M. G. Dhayagude
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9. Physical Pharmacy – Martin, Swarbrick and Commarata
10. Physical Chemistry – Bahl and Tuli
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12. I. P., B.P. and U.S.P.
13. Instrumental Methods of Analysis, Chatwal & Anand,
14. A Textbook of pharmaceutical analysis, K. A. Connors.
15. Pharmaceutical Analysis, Ashutosh Kar.
16. Instrumental and Chemical Analysis, B.K. Sharma.

MAT Pr **MODERN ANALYTICAL TECHNIQUES** **Practical (6 hrs/wk.)**

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. ED_{50} and LD_{50} Estimation and probit analysis

Reference Books

1. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.
2. Textbook of Pharmacognosy, Kokate C. K. Purohit A. P. and Gokhale S. B.
3. Pharmacognosy and Phytochemistry, Vol. I & II, V.D.Rangari.
4. Natural products Chemistry Practical Manuals, A.A.Siddiqui.
5. Indian Pharmacopoeia.
6. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
7. Harry's cosmetology, J. B. Wilkinson and R. J. Moore.
8. Textbook of Practical Biotechnology, C.R. Kokare.
9. Research Articles on Analytical Method Development in Journals
10. Physical Pharmacy – Martin, Swarbrick and Commarata
11. Physical Chemistry – Bahl and Tuli

APCOL-I ADVANCED PHARMACOLOGY – I Theory (3 hrs/wk.)

		Hrs	Marks
1.	**Care, handling and breeding techniques** of laboratory animals, Regulations for Laboratory animal care and ethical requirements. Knowledge of the CPCSEA Proforma for performing experiments on animals. Alternative to animal studies.	3	10-10
2.	**Organization of preclinical screening** programme and safety assessment tests.	3	10-10
3.	**Preclinical evaluation** of following categories of drugs. ➢ Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotics, nootropics, antiparkinsonian agents, analgesics, antipyretics. ➢ Anti-inflammatory agents, anticonvulsants, local aneasthetics, CNS stimulants, ➢ Cardiac glycosides, antiarrhythmic, antihypertensive, anti-anginal, anti-atherosclerotic, ➢ Antiulcer agents, Laxatives, Bronchodilators, antitussives, ➢ Diuretics, ➢ Histamine antagonists. ➢ Muscle relaxants, Anticholinesterases, anticholinergics, adrenolytics. ➢ Hypoglycemics, antifertility agents, androgens. ➢ Anti-thyroid agents, Dermatological agents, Antitumor agents. ➢ Anthelmintics, Antimalarials, Antileprotics.	27	70-110
4.	**In vitro testing of drugs.** Animal cell lines and their uses. Limitations of in vitro testing of drugs.	3	10-10

Reference Books:

1. Kulkarni, S. K. Handbook of Experimental Pharmacology, (Vallabh Prakashan, Delhi)
2. Sheth, U. K. Dadkar, N. K. and Kamat, U. G. Selected Topics in Experimental Pharmacology (Kothari book Depot, Bombay).
3. Perry, W. L. M. Pharmacological Experiments on Isolated preparations (E & S Livingstone, London).
4. Ghosh, M. N.: Fundamentals of Experimental Pharmacology, (Scientific book Agency, Calcutta).
5. Jaju, B. P. Pharmacology Practical Exercise book (Jaypee Brothers, New Delhi).
6. Burn J. H. Practical Pharmacology (blackwell Scientific Co. oxford).
7. Lawrence, D. R. & Bacharach, A. L.: Evaluation of Drug Activities: Pharmacometrics (Academic press, London).
8. Turner R. A.: Screening Methods in Pharmacology (Academic Press, London).

9. Thompson E. B. Drug bioscreening VCH New York.
10. Vogel H. G. and Vogel W. H. Drug Discovery and Evaluation Pharmacological Assays Springer.

APCOL-I Pr **ADVANCED PHARMACOLOGY – I** **Practical (6 hrs/wk.)**

1. Preparation of vaginal smears of mice & rat and examination under microscope.
2. Methods of handling experimental animals.
3. Standard techniques for injection of drugs, collection of blood samples and feeding of animals.
4. Use of aneasthetics and cannulation of veins, arteries, and trachea. Working of physiographs (Students and Biopac) setting dog / rat / rabbit B. P., ECG recording.
5. Screening of analgesics, anti-inflammatory drugs and anti-anxietic drugs.
6. Determination of PA_2 Value of atropine
7. Forced swim test, animal model of depression, assessment of nootropic activity.
8. Effect of d-tubocurarine and physostigmine on conc. response curve of acetyl choline using rectus abdominis muscle preparation of frog & determination of dose ratio (EC50) of acetyl choline in the presence and absence of d-tubocurarine and physostigmine

Recommended books

1. Kulkarni, S. K. Handbook of Experimental Pharmacology, (Vallabh Prakashan, Delhi)
2. Ghosh, M. N.: Fundamentals of Experimental Pharmacology, (Scientific book Agency, Calcutta).
3. Sheth, U. K. Dadkar, N. K. and Kamat, U. G. Selected Topics in Experimental Pharmacology (Kothari book Depot, Bombay).
4. Perry, W. L. M. Pharmacological Experiments on Isolated preparations (E & S Livingstone, London).
5. Jaju, B. P. Pharmacology Practical Exercise book (Jaypee Brothers, New Delhi).
6. Burn J. H. Practical Pharmacology (blackwell Scientific Co. Oxford).
7. Lawarence, D. R. & Bacharach, A. L.: Evaluation of Drug Activities: Pharmacometrics (Academic press, London).
8. Turner R. A.: Screening Methods in Pharmacology (Academic Press, London).
9. Thompson E. B. Drug bioscreening VCH New York.
10. Vogel H. G. and Vogel W H. Drug Discovery and Evaluation Pharmacological Assays Springer.

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

		Hrs	Marks
1.	**Clinical evaluation of new drugs.** Organization, Ethics and protocol for clinical trials.	2	10-10
2.	**Clinical pharmacology** of drugs used in the treatment of Hypertension, Congestive cardiac failure, Angina pectoris, Acute myocardial infarction, Cardiac arrhythmia, Atherosclerosis, Peripheral vascular disorders, Coagulation disorders.	6	10-20
3.	**Pain management,** pain pathways, NSAIDs analgesics, local anesthetics, prostaglandins, Leukotrienes and platelet activating factor.	3	10-10
4.	**Immunopharmacology:** current concepts in theory and research of drugs for AIDS. Vaccines and sera, Drug allergy, Tissue transplantation, Immunostimulants, Immunomodulaters Immunosuppressant. Knowledge of various in vitro and in vivo tests carried out in immunological investigation.	4	10-10
5.	**Pharmacotherapy of Gastrointestinal diseases:** Peptic ulcer, Nausea and vomiting, Diarrhoea and constipation.	3	10-10
6.	**Pharmacotherapy of Renal diseases:** Acute and chronic renal failure, Renal dialysis and transplantation. Drugs doses in renal impairment.	2	10-10
7.	**Pharmacotherapy of Respiratory diseases:** Asthma, Chronic obstructive pulmonary oedema. Pulmonary embolism.	3	10-10
8.	Pharmacotherapy of Hepatic disorders: Cirrhosis, hepatitis.	2	10-10
9.	**Pharmacotherapy of Infectious diseases:** General guidelines for rational use of antibiotics. Resistance to antibiotics Respiratory tract infections, Meningitis, Gastroenteritis, Pneumonia, bacterial, endocarditis, Septicemia, Otitis media, Urinary tract infection, Tuberculosis, Leprosy, Protozoal infection and helminthiasis. HIV and opportunistic infections, fungal infections.	7	10-20
10.	**Pharmacotherapy of Neoplastic disorders:** General principles of cancer chemotherapy commonly used cytotoxic drugs. Chemotherapy of lung, breast, head and neck cancer, leukemia, liver, and prostrate cancer. Note: For individual classes of drugs mechanism of action at molecular level will be emphasized.	4	10-10

Reference Books:

1. Clinical Pharmacy and Therapeutics: Roger and Walkar, Churchill Livingston Publication.
2. Pharmacotherapy: A Pathophysiological approach: Joseph L. Dipiro Elsevier.
3. Pathology and Therapeutics for Pharmacists: A basis for clinical Pharmacy Practice – Russle. T. G. Chapman and Hall Publication.
4. Clinical Pharmacy and Therapeuitics – E. T. Herfindal and J. L. Hirschman.
5. Applied Therapeutics: The clinical Uses of Drugs: Koda- Kimble M. A. et.al.
6. Relevant review articles from recent medical and Pharmaceutical literature.
7. Basic skills in interpreting Laboratory data : Scott LT. American Society of health System Pharmacists Inc.
8. Davidson's Principal and Practice of Medicine. Churchill Livingston Eighteenth Edition.
9. Harrisons Principles of Internal Medical. Vol. I & II 14th Edn. Int. Edn. McGraw Hill.
10. Choudhari Quintessence of Medical pharmacology Central.
11. Kundu A. K. Bedside clinics in medicine. Academic publisher part I & II.
12. Balakrishnan K. V. Komar's Manual of Medical prescriptions. Paras publishers.
13. Axford Medicine, Blackwell science.
14. Panda U. N. Textbook of Medicine, CBS.
15. Jambur Ananth Treatment of Psychiatric Disorders Jaypee.
16. Patten J. Neurolgical Differential Diagnosis 2nd Ed.
17. Misbahuddin M. Chaowdhary M. A. Jalil. Community Pharmacology Jaypee.
18. Bickley L. S. Bate's Guide to physical examination and history jaking. Lippincoft.
19. Walton J. Boain's Diseases of the nervous system. Tenth edn.

APCOL-II Pr ADVANCED PHARMACOLOGY – II Practical (6 hrs/wk.)

1. Screening of hypnotics, muscle relaxants.
2. Evaluation of local anaesthetics, anticonvulsants, antiparkinsonian agents, diuretic.
3. Screening of Antiulcer agents.
4. Pyrogen testing, LAL Test.
5. LD 50 determination.
6. Bioassays of Ach, Histamine, Oxytocin, Adrenaline, pancuronium.
7. Monitoring of some basic drugs in biological fluids.
8. Use of HPLC, Spectrofluorometer in estimation of drugs.

Reference Books:

1. Kulkarni, S. K. Handbook of Experimental Pharmacology, (Vallabh Prakashan, Delhi)
2. Ghosh, M. N: Fundamentals of Experimental Pharmacology, (Scientific book Agency, Calcutta).
3. Sheth, U. K. Dadkar, N. K. and Kamat, U. G. Selected Topics in Experimental Pharmacology (Kothari book Depot, Bombay).
4. Perry, W. L. M. Pharmacological Experiments on Isolated preparations (E & S Livingstone, London).
5. Jaju, B. P. Pharmacology Practical Exercise book (Jaypee Brothers, New Delhi).
6. Burn J. H. Practical Pharmacology (blackwell Scientific Co. Oxford).
7. Lawarence, D. R. & Bacharach, A. L. :Evaluation of Drug Activities : Pharmacometrics (Academic press, London).
8. Turner R. A.: Screening Methods in Pharmacology (Academic Press, London).
9. Thompson E. B. Drug bioscreening VCH New Yourk..
10. Vogel H. G. and Vogel W H. Drug Discovery and Evaluation Pharmacological Assays Springer.

APCOL-III ADVANCED PHARMACOLOGY – III Theory (3 hrs/wk.)

		Hrs	Marks
1.	**Molecular mechanisms of drug action:** Receptor occupancy and cellular signaling systems such as G-proteins, cyclic nucleotides, calcium and phosphatidyl inositol. Ionic channels and their modulators.	05	10-20
2.	**Endogenous bioactive molecules** as TNF-∝ , Interleukins, process of apoptosis, arachidonic acid metabolites, COX-2 regulators and their role in inflammation.	03	10-10
3.	**Recent trends on different classes of receptors and drugs acting on them.** ➢ Cholinergic receptors. ➢ Dopamine receptors. ➢ Serotonin receptors. ➢ Hormone receptors. ➢ GABA receptors. ➢ Opioid receptors. ➢ Purinergic receptors. ➢ Glutamate receptors.	20	50-80
4.	**Neurosteroids, Nitric oxide.**	02	10-10
5.	**Endothelium derived vascular substances** (NO, endothelins) and their modulators, Pharmacology of atrial peptides, reactive oxygen intermediates, antioxidants and their therapeutic implications.	03	10-10
6.	**Concept of gene therapy and recent development** in the treatment of various hereditary diseases. Transgenic mouse and its applications. Human genome mapping and its potential in drug research.	03	10-10

Reference Books:

1. Katzung B. G. Basic and clinical pharmacology (Lange Medical Publication, California).
2. Barar F. S. K. Essentials of pharmacotherapeutics. (S. Chand & C. New Delhi).
3. Bow man W. C. and Rand M. J. Text book of Pharmacology (Blackwell Oxford).
4. Melmon K. L. and Morelli. Clinical pharmacology Basic principles of Therapeutics. (Macmillan New York).
5. Craig C. R. and Stitzel B. E. Modern Pharmacology (Little Brown & Co. Bostom).
6. Drill V. A. Pharmacology in medicine. (Mc Graw Hill Co. New York).
7. Grollman Pharmacology & Therapeutics. (Lea and Febiger Philadephia).
8. Bacq Z. M. Capek. Fundamentals of Biochemical Pharmacology.
9. Avery G. S. Drug tratment (Adis Press, Sydney).
10. Goodman and Gilman Pharmacological Basis of Therapeuties (McGraw Hill).
11. Rang H. P. and Dale M. M. Pharmacology (Churchill Livingston, U.K.)

SYLLABUS FOR M. PHARM (PHARMACOGNOSY)

MAT MODERN ANALYTICAL TECHNIQUES Theory (3 hrs/wk.)

		Hrs	Marks
1.	Biostatistics and Computer Application: Introduction to and pharmaceutical applications of Student's t-test, F test, Chi-square test, Analysis of variance (ANOVA), correlation and regression analysis, Factor analysis, Time series analysis and Multidimensional scaling. Applications of computers related to quantitative and statistical pharmaceutical analysis.	3	10-15
2.	Sample Preparation for Analysis: Different techniques of sample preparation from body fluids, tissue extracts, cell culture extracts and phyto-chemical extracts.	5	10-15
3.	Structural Elucidation by Spectroscopic Methods: UV-Visible, IR, NMR and Mass with examples.	5	15-20
4.	Applications of DSC and XRD: Analysis of raw material (APIs and excipients), packaging material and finished products.	4	10-15
5.	Reference Standards: Introduction, preparation, types, storage, record keeping and validation.	5	10-15
6.	ESR Spectroscopy: Introduction, calibration, validation and application (in brief). Circular Dicorism and ORD: Introduction, calibration, validation and application (in brief).	5	10-15
7.	Particle Size Analysis: Introduction, significance, methods used in particle size analysis. Gel Permeation Chromatography (GPC): Introduction, instrumentation (Stationary phases and Detectors) and its application (particle size analysis).	4	15-20
8.	Immunochemical Techniques: ELISA, Immuno- precipitation, Radio immuno assays and Radio-labeling.	5	20-25

Reference Books

1. Introduction To Biostatistics & Computer Science, Mr. Y. I. Shah Dr. A. R. Paradkar, Mr. Y. I. Shah, Mr. M. G. Dhayagude
2. Pharmaceutical statistics using SAS: a practical Guide, Ralph B. D'Agostino
3. Introduction to Pharmaceutical Calculations, Judith A. Rees
4. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.

5. Practical Method Development, Snyder, L. R., Kirkland, J. J. and Glajch, J. L.
6. Principles of Instrumental Analysis, Skoog.
7. Textbook of Practical Biotechnology, C.R. Kokare.
8. Organic Spectroscopy, William Kemp
9. Physical Pharmacy – Martin, Swarbrick and Commarata
10. Physical Chemistry – Bahl and Tuli
11. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
12. I. P., B.P. and U.S.P.
13. Instrumental Methods of Analysis, Chatwal & Anand,
14. A Textbook of pharmaceutical analysis, K. A. Connors.
15. Pharmaceutical Analysis, Ashutosh Kar.
16. Instrumental and Chemical Analysis, B.K. Sharma.

MAT Pr **MODERN ANALYTICAL TECHNIQUES** **Practical (6 hrs/wk.)**

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. ED_{50} and LD_{50} Estimation and probit analysis

Reference Books

1. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.
2. Textbook of Pharmacognosy, Kokate C. K. Purohit A. P. and Gokhale S. B.
3. Pharmacognosy and Phytochemistry, Vol. I & II, V.D.Rangari.
4. Natural products Chemistry Practical Manuals, A.A.Siddiqui.
5. Indian Pharmacopoeia.
6. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
7. Harry's cosmetology, J. B. Wilkinson and R. J. Moore.
8. Textbook of Practical Biotechnology, C.R. Kokare.
9. Research Articles on Analytical Method Development in Journals
10. Physical Pharmacy – Martin, Swarbrick and Commarata
11. Physical Chemistry – Bahl and Tuli

APCOG-I **ADVANCED PHARMACOGNOSY - I** **Theory** **(3 hrs/wk.)**

		Hrs	Marks
1.	General Research Methodology	06	14 – 20
2.	Herbal drug Industry	07	16 – 24
3.	Herbal drug Regulatory affairs.	06	14 – 20
4.	Information Retrieval systems of Herbal Drugs.	16	32 – 44

Literature survey of following therapeutic groups

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
- Valeriana wallichi

vii) Anti-AIDS

- Areca catechu
- Thea sinensis

5.	Volatile oil of commercial significance	05	12 – 16
6.	Review of Natural sweeteners : Dyes and Pigments, Preservatives	05	12 – 16

Reference Books:

1. Ayurvedic formulary of India, Govt.of India, 1962.
2. British Herbal Pharmacopoia, (vol.I, II & III) Her majestys Services , U.K.
3. Cultivation and Utilization of aromatic plants : Atal & Kapoor, RRL, Jammu
4. Cultivation and Utilization of medicinal plants: Atal & Kapoor, RRL, Jammu.
5. Drug and Cosmatic act, (with latest amendments including Ayurvedic GMP), Govt. of India.
6. Herbal Drug industry: R.D. Chudhary, Eastern Publishers, New Delhi 1996.
7. Introduction to spices, plantation crops, medicinal and aromatic plants: N.Kumar et al , Oxford & IBH Publishing Co. Pvt. Ltd., New Delhi,1997.
8. Pharmacognosy: Trease W.C., Evans G.E. Bailliere and Tindall, Londan, 14th edtn.
9. Research in Education : John w. Best & James V. Kahn, Practice Hall of India Pvt. Ltd., New Delhi,1996.
10. Various journals related to medicinal plants.
11. Various journals related to spices, perfumes, food and nutrition.
12. Various Research Journals on Medicinal natural products.
13. Wealth of India , CSIR, New Delhi (Related Volumes)

APCOG-I Pr **ADVANCED PHARMACOGNOSY - I** **Practical (6 hrs/wk.)**

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 sena 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

Reference 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.

APCOG-II ADVANCED PHARMACOGNOSY - II Theory (3 hrs/wk.)

		Hrs	Marks
1.	Cultivation and post harvest technology of Opium, Solanum Kharsium, Ashwagandha, Aloe, Senna	08	20 – 28
2.	Isolation and Estimation of Clove oil, Atropine, Curcumin, Vinca alkaloids, Quinidine, Taxol, Emetine, Sennoside, Glycerrhizin, Starch, Microcrystalline cellulose	12	28 – 40
3.	Structural Elucidation of Citral, Nicotine, Atropine, Amygdaline, Caffeine, Morphine	07	16 – 24
4.	Chemotaxonomy of Flavonoids and Terpenoids.	06	12 – 16
5.	Marine drugs.	06	12 – 16
6.	Pest control	06	12 – 16

Reference Books:

1. Cultivation of medicinal plants: Kokate, Purohit, Gokhale, , Nirali Prakashan . Pune
2. Introduction to flavonoids: Bruce A .Bohm, harwood academic 1998.Amsterdam.
3. Herbal Drug industry: R.D. Chudhary, Eastern Publishers, New Delhi 1996.
4. Wealth of India , CSIR, New Delhi (Related Volumes)
5. Cultivation and Utilization of medicinal plants: Atal & Kapoor, RRL, Jammu.
6. Cultivation and Utilization of aromatic plants : Atal & Kapoor, RRL, Jammu
7. Various journals related to medicinal plants.
8. Pharmacognosy: Trease W.C., Evans G.E. Bailliere and Tindall, Londan, 14th edtn.
9. British Herbal Pharmacopoia, (vol.I, II & III) Her majestys Services , U.K.
10. Phytochemical methods : J.B.Harborne
11. Various Research Journals on Medicinal natural products.

APCOG-II Pr **ADVANCED PHARMACOGNOSY - II** **Practical (6 hrs/wk.)**

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
3. Study of UV and Visible spectra data of some natural products.
4. Study of IR spectra of some natural products.
5. Preparation of Traditional drug formulation mentioned in the Advanced Pharmacognosy theory and their standardization.

Reference Books:

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.

APCOG-III ADVANCED PHARMACOGNOSY – III Theory (3 hrs/wk.)

		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.	11	24 – 32
2.	**Traditional drug formulations** Ayurveda (Asava, Arista, Bhasma, Kwatha, Ghruta, Avalcha) Homoeopathy Siddha Unani Aromatherapy	08	16 – 24
3.	**Herbal drug formulations** Therapeutic drugs used Cosmetics: Skin, Hair.	07	16 – 20
4.	Agroproducts of economic significance – Cornoil, Soybean, Spirulina, pectin, Papain.	05	12 – 16
5.	Standardization of phyto-pharmaceuticals by HPTLC technique Bacoside.Andrographolide, solasodine, Glycerrhetinic acid, Vasicine, Sennosides	07	16 – 24
6.	Standardization of phyto-pharmaceuticals by HPLC technique Amarogention Asiaticoside Cardifoloside Lupeol Solasodine Vasicine	07	16 – 24

Reference Books:

1. Ayurvedic formulary of India, Govt. of India, 1962
2. British Herbal Pharmacopoeia, (Vol. I, II & III) Her Majestys Services , U.K.
3. Cultivation and Utilization of aromatic plants : Atal & Kapoor, RRL, Jammu
4. Cultivation and Utilization of medicinal plants: Atal & Kapoor, RRL, Jammu.
5. Herbal Drug industry: R.D. Chudhary, Eastern Publishers, New Delhi 1996.
6. HPLC methods of drug analysis: Mantu k.Ghosh
7. Pharmacognosy: Kokate, Purohit, Gokhale, 15th edition, Nirali Prakashan, Pune.
8. Pharmacognosy: Trease W.C., Evans G.E. Bailliere and Tindall, Londan, 14th edtn.
9. Phytochemical methods : J. B. Harborne
10. Various journals related to medicinal plants.
11. Various Research Journals on Medicinal natural products.
12. Wealth of India , CSIR, New Delhi (Related Volumes)

SYLLABUS FOR M. PHARM (PHARMACEUTICAL TECHNOLOGY)

MAT MODERN ANALYTICAL TECHNIQUES Theory (3 hrs/wk.)

		Hrs	Marks
1.	Biostatistics and Computer Application: Introduction to and pharmaceutical applications of Student's t-test, F test, Chi-square test, Analysis of variance (ANOVA), correlation and regression analysis, Factor analysis, Time series analysis and Multidimensional scaling. Applications of computers related to quantitative and statistical pharmaceutical analysis.	3	10-15
2.	Sample Preparation for Analysis: Different techniques of sample preparation from body fluids, tissue extracts, cell culture extracts and phyto-chemical extracts.	5	10-15
3.	Structural Elucidation by Spectroscopic Methods: UV-Visible, IR, NMR and Mass with examples.	5	15-20
4.	Applications of DSC and XRD: Analysis of raw material (APIs and excipients), packaging material and finished products.	4	10-15
5.	Reference Standards: Introduction, preparation, types, storage, record keeping and validation.	5	10-15
6.	ESR Spectroscopy: Introduction, calibration, validation and application (in brief). Circular Dicorism and ORD: Introduction, calibration, validation and application (in brief).	5	10-15
7.	Particle Size Analysis: Introduction, significance, methods used in particle size analysis. Gel Permeation Chromatography (GPC): Introduction, instrumentation (Stationary phases and Detectors) and its application (particle size analysis).	4	15-20
8.	Immunochemical Techniques: ELISA, Immuno- precipitation, Radio immuno assays and Radio-labeling.	5	20-25

Reference Books

1. Introduction To Biostatistics & Computer Science, Mr. Y. I. Shah Dr. A. R. Paradkar, Mr. Y. I. Shah, Mr. M. G. Dhayagude
2. Pharmaceutical statistics using SAS: a practical Guide, Ralph B. D'Agostino

3. Introduction to Pharmaceutical Calculations, Judith A. Rees
4. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.
5. Practical Method Development, Snyder, L. R., Kirkland, J. J. and Glajch, J. L.
6. Principles of Instrumental Analysis, Skoog.
7. Textbook of Practical Biotechnology, C.R. Kokare.
8. Organic Spectroscopy, William Kemp
9. Physical Pharmacy – Martin, Swarbrick and Commarata
10. Physical Chemistry – Bahl and Tuli
11. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
12. I. P., B.P. and U.S.P.
13. Instrumental Methods of Analysis, Chatwal & Anand,
14. A Textbook of pharmaceutical analysis, K. A. Connors.
15. Pharmaceutical Analysis, Ashutosh Kar.
16. Instrumental and Chemical Analysis, B.K. Sharma.

MAT Pr **MODERN ANALYTICAL TECHNIQUES** **Practical (6 hrs/wk.)**

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. ED_{50} and LD_{50} Estimation and probit analysis

Reference Books

1. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.
2. Textbook of Pharmacognosy, Kokate C. K. Purohit A. P. and Gokhale S. B.
3. Pharmacognosy and Phytochemistry, Vol. I & II, V.D.Rangari.
4. Natural products Chemistry Practical Manuals, A.A.Siddiqui.
5. Indian Pharmacopoeia.
6. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
7. Harry's cosmetology, J. B. Wilkinson and R. J. Moore.
8. Textbook of Practical Biotechnology, C.R. Kokare.
9. Research Articles on Analytical Method Development in Journals
10. Physical Pharmacy – Martin, Swarbrick and Commarata
11. Physical Chemistry – Bahl and Tuli

ADVANCED PHARMACEUTICAL TECHNOLOGY-I (THEORY)

No.	Chapter	Hrs/wk	Marks
1.	**Pre-Formulation Technology**	**4**	**10-15**
	Organoleptic properties of drug powder, purity of drug substances, particle size, shape and surface area, porosity, solubility, pKa and partition coefficient. Crystallinity, amorphism, and drug-excipient interaction studies by X ray diffraction, DSC, and TGA. Hygroscopicity, flowability and compressibility of powders.		
2.	**Optimization Techniques in Product Development Technology**	**4**	**10-15**
	Optimization techniques, Quality by design (QbD), Experimental designs like factorial, artificial neural network (ANN). Identifying formulation and process variables, formulation optimization, response surface methodology, in-vitro test systems to evaluate and monitor the performance of different types of dosage forms.		
3.	**Tablet Technology**	**8**	**25-30**
	Systematic and modern approach to tablet components and production designs. Process of compression and physics of tablet compression, effect of additives on tablet strength, crushing strength, tensile strength, friability. Press design and layout, press control (off line and online) and automization, trouble shooting, recent tablet technologies.		
	Tablet coating theory, techniques of coating, mechanism of coat formation (aqueous and nonaqueous coat), coating compositions, physico–mechanical properties of polymer films, coating of single unit and multi-particulate systems. Industrial coaters, process atomization and optimization, coating problems and troubleshooting.		
4.	**Polymer Technology**	**4**	**10-15**
	Introduction, classification, properties and characterization of polymers. Biodegradable polymers, thermodynamics of polymer solution, phase separation, polymers in solid state, polymer properties crucial in drug delivery and formulation design.		
5.	**Pelletisation Technology**	**2**	**10-15**
	Techniques of pelletisation and advantages of pellets. Extrusion-sphernoisation process, process controls and formulation variables in Extrusion-spheronisation. Hot melt extrusion: On line, in line and off line process controls. Applications of both processes in dosage form design.		

6.	**Dissolution Technology and IVIVC**	**4**	**10-15**

Historical Development, Compendial and noncompendial dissolution methodologies; US FDA Guidance; Techniques of dissolution enhancement; in vitro drug release kinetics, Introduction to BCS & IVIVC; Levels of correlation , 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.

7.	**Stability Testing**	**6**	**15-20**

Predicting shelf life and half-life of pharmaceutical formulations. 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. Photostability testing of new drug substances and products. Bracketing and matrixing designs for stability testing of new drug substances and products. Evaluation of stability data.

8.	**Process Analytical Technology (PAT)**	**4**	**10-15**

Introduction and applications to 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.

Reference books:

1. Fundamentals of Applied Statistics, S. C. Gupta, V. K. Kapoor, S. Chand and Sons, 2008.
2. Introduction to probability and Statistics, Henry L. Alder and Edward B. Roessler.
3. Mathematics and Statistics for use in Pharmacy, Biology, Chemistry, Saunders and Flemming.
4. B. K. Mahajan. Methods in Biostatistics (for Medical students and Research worker), 6th Ed, 1997, Jaypee Brothers Medical publishers (P) Ltd., New Delhi.
5. Theory and Practice of Industrial Pharmacy, Lachmann and Lieberman, Varghese, Publishing House, Bombay, 3rd Ed. – 1991
6. Physical Pharmacy, A. Martin, Lippincott Williams and Wilkins, London, 4th Ed. – 2001.

7. Drug stability: Principles and practices. Jens T. Carstensen
8. Stability Testing of Drug Products. W. Grimm.
9. Stability of Drugs and Dosage Forms by Yoshioka and Stella.
10. Pharmaceutical Dosage Form Tablets, Vol-I, II, III, Lieberman, Lachman and IB Schwartz, Marcel Dekker, New York, 2nd Ed. – 2008.
11. Pharmaceutical preformulation by J.T. Cartensen.
12. P. J. Tarcha; Polymers for controlled Drug Delivery; CRC Press
13. Tablet Machine instrumentation in pharmaceuticals, PR Watt, Ellis Horwoods, UK.
14. Swarbrick J and Boylon J.C., Encyclopedia of Pharmaceutical Technology, Vol. 1-3, Mercel Decker Inc.
15. Pharmaceutical Dissolution Testing; Ed by Jennifer Dressman and Johannes Kramer; Taylor & Francis.

ADVANCED PHARMACEUTICAL TECHNOLOGY-I (Practicals)

Minimum 12 experiments from the list given below should be completed.

1. To study of effect of particle size, moisture content and lubricants on flowability and compressibility of powders.
2. To study of effect of various 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 behaviour of three component system and construct ternary phase diagram.
13. Preparation and evaluation of pellets using certain techniques like extrusion

spheronisation, etc.

14. To perform an experiment demonstrating IVIVC studies.
15. Development of formulation and determination of its shelf life and half life.
16. Process controls and analysis of the output for certain products.

Reference books:

1. Practical Manual of Pharmaceutical Engineering. Munira Momin, Tejal A. Mehta, B. S. Shah Prakashan, Ahmedabad. Second Edition: 2009
2. Pharmaceutical Engineering: Practical Manual 2/ed Sudhakara Reddy Pondugula, M. Gopal Rao, Govinda Rajan Gudala, R. Vamsi Krishna
3. Practical Physical Pharmacy, H. N. More and A. A. Hajare; Third Edition, Career Publications, Nashik.
4. Practical Physical Pharmacy. Gaud and Gupta; 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
7. Novel Drug Delivery Systems, Y. W. Chein, Marcel Dekker, Inc
8. Microencapsulation, Simon Benita, Pub. Marcel Dekker Inc.
9. Specialized Drug Delivery Systems, Praveen Tyle, Pub. Marcel Dekker Inc.
10. Controlled and Novel Drug delivery, N. K. Jain, 1st Ed. CBS Publisher and Distributor.
11. Controlled release of drugs; Morton Rosoff; VCH Publishers.
12. Topical drug delivery formulations; Osborne, and Amann; Marcel Dekker.
13. Dermatological formulation; Barry: Marcel Dekker
14. Pharmaceutical Inhalation Aerosol Technology; A. J. Hickey; Marcel, Dekker.
15. Targeted and Controlled drug delivery- Novel Career System. Vyas S. P. and Khar R. K., CBS Publications, New Delhi..
16. Encyclopedia of Pharmaceutical Technology. Swarbrick J and Boylon J. C., Vol. 1-3, Marcel Decker Inc.
17. Nanoparticles. Ram, Marcel Dekker.
18. Microcapsules and Microencapsulation Techniques. M. I. Gutcho, Noyes Data, Corporation, 1976.
19. Introduction to Chemical Engineering, W.L.Badger & J. T. Banthero.

20. Unit Process in Pharmacy, David Ganderton. Medical Books Ltd. London

21. Unit Operations, G.G. Brown; CBS Publishers and Distributors, New Delhi.

22. Perry's Chemical Engineering Hand Book, Robbert H. Perry, Don W, Green; 7th edition, International Edition, McGraw Hill

23. Industrial Instrumentation, Donald P. Eckman Seventh Wiley Eastern, Reprint, 1983, Wiley Eastern Ltd, 4835/24, Ansari Road, Daryaganj, New Delhi 110 002

ADVANCED PHARMACEUTICAL TECHNOLOGY-II (THEORY)

No.	Chapter	Hrs/wk	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 targetting, design of targetting compounds and devices.	2	10-15
2.	**Oral controlled drug delivery system (OCDDS):** 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.	5	15-20
3.	**Ocular Drug Delivery Systems:** Drug absorption in eye, formulation consideration and evaluation of ophthalmic products, contact lenses, occuserts, container and closures, safety.	4	10-15
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 transdermal devices and osmotic pumps.	4	10-15
5.	**Drug Targeting Technologies:** Need, fundamentals and techniques of targeting. A) Physical Targeting Approaches like- Enteric/colonic Targeting Through Coating, Lipid-Based Formulations for Oral Administration for Bioavailability Enhancement and Lipoprotein Targeting of Lipophilic Drugs, B) 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 and prodrugs, C) Biological Targeting Approaches- Gene Delivery with Artificial Viral Envelopes, Evolution of Viral Liposomes: Improvements and Applications, Targeting of Viral Vectors for Cancer Gene Therapy.	4	10-15
6.	**Lipid vesicle based drug delivery systems:** Liposomes: Structure, classification, methods of preparation,	5	10-15

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.

7. Micro and nano technology: **4** **10-15**

Design and evaluation of microcapsules. Release kinetics, applications, and recent advances. Nanotechnology and nanomedicine, merits and demerits. Techniques of nanonisation (top-down and bottom up approach). Nano-technological products: nano-devices, nano-robotics for surgery, cancer detection and diagnosis, gold nanoparticles. Nanomaterials: dendrimers, nanotubes, nanofibres, nanowires and quantum dots.

8. Aerosols: **4** **10-15**

Advances in metered dose inhaler designs and dry powder inhalers. Respules for inhalation. Particle engineering techniques to improve inhalable fraction and evaluation thereof.

Reference books:

1. Dermatological Formulation – Percutaneous Absorption. Srian W. Berry, Marcel Dekker Inc. New York.
2. Lee and Robinson, Controlled Drug Delivery, Second Edition, Marcel Decker Inc
3. Novel Drug Delivery Systems, Y. W. Chein, Marcel Dekker, Inc
4. Microencapsulation, Simon Benita, Pub. Marcel Dekker Inc.
5. Specialized Drug Delivery Systems, Praveen Tyle, Pub. Marcel Dekker Inc.
6. Controlled and Novel Drug delivery, N. K. Jain, 1st Ed. CBS Publisher and Distributor.
7. Drug Delivery Devices, fundamental and applications; P. Tyle; Marcel Dekker.
8. Controlled release of drugs; Morton Rosoff; VCH Publishers.
9. Topical drug delivery formulations; Osborne, and Amann; Marcel Dekker.
10. Barry: Dermatological formulation; Marcel Dekker
11. Mechanisms of Transdermal drug delivery; R. O. Potts, and R.H. Guy; Marcel Dekker.
12. Nanotechnology in Drug Delivery (Biotechnology: Pharmaceutical Aspects) by Melgardt M. de Villiers

13. Pharmaceutical Inhalation Aerosol Technology; A. J. Hickey; Marcel, Dekker.

14. Targeted and Controlled drug delivery- Novel Career System. Vyas S. P. and Khar R. K., CBS Publications, New Delhi..

15. Encyclopedia of Pharmaceutical Technology. Swarbrick J and Boylon J. C., Vol. 1-3, Marcel Decker Inc.

16. Nanoparticles. Ram, Marcel Dekker.

17. Microcapsules and Microencapsulation Techniques. M. I. Gutcho, Noyes Data, Corporation, 1976.

18. Nanoparticulate drug delivery systems. Thassu

ADVANCED PHARMACEUTICAL TECHNOLOGY-II (Practicals)

Minimum 12 experiments from the list given below should be completed.

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 system.
4. Preparation and evaluation of hydrogel.
5. Study of Mier's super solubility curve for the given samples.
6. Determine the effect of various factors on the rate of filtration.
7. To determine overall heat transfer coefficient of drying process.
8. To determine moisture content in a given sample by Karl Fischer Titrator or IR moisture balance.
9. To study effect of filter aid concentration on rate of filtration.
10. Preparation of polymer films containing different drugs and study of film characteristics and release patterns.
11. Preparation and study on invitro evaluation of mucoadhesive system.
12. Preparation and evaluation for ocusert.
13. Formulation and characterization of liposomes.
14. Preparation of nanoparticles using some solvent based techniques
15. Use of spray drying technique to generate DPI.
16. Demonstration of design of targetted drug delivery system.

Reference books:

1. Practical Manual of Pharmaceutical Engineering. Munira Momin, Tejal A. Mehta, B. S. Shah Prakashan, Ahmedabad. Second Edition: 2009
2. Pharmaceutical Engineering: Practical Manual 2/ed Sudhakara Reddy Pondugula, M. Gopal Rao, Govinda Rajan Gudala, R. Vamsi Krishna
3. Practical Physical Pharmacy, H. N. More and A. A. Hajare; Third Edition, Career Publications, Nashik.
4. Practical Physical Pharmacy. Gaud and Gupta; 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
7. Novel Drug Delivery Systems, Y. W. Chein, Marcel Dekker, Inc
8. Microencapsulation, Simon Benita, Pub. Marcel Dekker Inc.
9. Specialized Drug Delivery Systems, Praveen Tyle, Pub. Marcel Dekker Inc.
10. Controlled and Novel Drug delivery, N. K. Jain, 1st Ed. CBS Publisher and Distributor.
11. Controlled release of drugs; Morton Rosoff; VCH Publishers.
12. Topical drug delivery formulations; Osborne, and Amann; Marcel Dekker.
13. Dermatological formulation; Barry: Marcel Dekker
14. Pharmaceutical Inhalation Aerosol Technology; A. J. Hickey; Marcel, Dekker.
15. Encyclopedia of Pharmaceutical Technology. Swarbrick J and Boylon J. C., Vol. 1-3, Marcel Decker Inc.
16. Microcapsules and Microencapsulation Techniques. M. I. Gutcho, Noyes Data, Corporation, 1976.
17. Unit Process in Pharmacy, David Ganderton. Medical Books Ltd. London
18. Unit Operations, G.G. Brown; CBS Publishers and Distributors, New Delhi.

BIOPHARMACEUTICS AND BIOMEDICAL ENGINEERING (THEORY)

No.	Chapter	Hrs/wk	Marks
1.	**Concepts of Compartment models**:	**8**	**20-25**
	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 pertaining to absorption rate constant, absorption half life, lag time and extent of absorption, AUC. Apparent volume of distribution and its determination, apparent elimination rate constant, and half life under the conditions, Intravenous bolus injection, Intravenous infusion, Single dose oral administration, multiple dosage oral administration. 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 novel drug delivery systems)		
2.	**Bioavailability (BA) and bioequivalence (BE):**	**4**	**10-15**
	Definition of Bioavailability, bioequivalence, generic drugs; parameters of bioavailability, criteria for BE; Statistical aspects; study design and conduct 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; biotechnology products.		
3.	**Bioprocess Technology:**	**4**	**10-15**
	Introduction to bioprocess technology, fermenter design, types of Fermentation, downstream processing.		
4.	**Formulation of Biologicals:**	**6**	**15-20**
	Formulation of recombinant proteins like erythropoietin, interferons, insulin, growth hormones, follicle stimulating hormone (FSH). Biophysical aspects of protein formulations, Stabilization aspect of biologicals. Drying techniques like spray drying, freeze drying, vacuum foam drying, zero-vac drying, supercritical fluid drying.		
5.	**Biomedical applications in Drug Delivery:**	**6**	**15-20**
	Introduction to molecular electronics- field emission and shielding-microelectromechanical systems (MEMS), molecular and supramolecular switches for intracellular drug delivery, bionsensors,		

microfabricated nanochannels (new tool for molecular motion control), plasma assisted immobilization of bioactive molecules for biomedical and biotechnological applications, introduction to macromolecular crystallography and review of crystallographic concepts.

6.	**Informatics and database management:**	**2**	**10-15**

Fundamentals and applications of predictive pharmaceutics, chemico-pharmaceutics, cheminformatics, bioinformatics and data mining.

7.	**Pilot Plant and scale up technology:**	**3**	**10-15**

Pilot plant and scale up technique, introduction to Scale-Up and Post-Approval Changes (SUPAC) guidelines. Preparation of technology transfer protocol. Effect of scale up on formulation, process parameters like mixing, granulation, drying, tablet compression, coating, packaging, stability, selection and evaluation of suitable equipments.

8.	**Regulation of product development and marketing:**	**3**	**10-15**

Pharmaceutical, medical and health-related government and regulatory bodies at national and international level. Their guidelines for biopharmaceuticals and nonbiopharmaceuticals. 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), he Food and Drug Administration (FDA), Therapeutic Goods Administration (TGA).

Reference books:

1. Modern Pharmaceutics. Gilbert S Banker, Christophex, T Rhodes 4th edition-2008, Marcel Dekker
2. Biopharmaceutics and Pharmacokinetics. Robert E. Notari, Marcel Dekker, Inc.4th Ed. 2008.
3. Biopharmaceutics and Clinical Pharmacokinetics. Milo Gibaldi, Marcel Dekker, Inc., 2nd Ed. – 2006.
4. Biopharmaceutics and Clinical Pharmacokinetics. D. M. Brahmankar, Vallabh, Delhi.
5. AI Brody and K.S. Marsh, "The Wiley Encyclopedia of Packaging Technology", John Wiley and Sons, New York.
6. Applied Biopharmaceutics and Pharmacokinetics by Leon. Shargel, Andrew B. C.

Yes.

7. Pharmaceutical Biotechnology; S. P. Vyas and V. K. Dixit, 2005, CBS Publishers.

8. Pharmaceutical Biotechnology – An Introduction for Pharmacists and Pharmaceutical Scientists – D.J.A. Crommelin and R.D. Sindelar (Eds.), 2002, Routledge (Pub.).

9. Freeze drying / Lyophilization of Pharmaceuticals and Biological Products. L. Ray, Vol. 96, Marcel Dekker, NY, New York, 2005.

10. International stability testing. Mazzo D J. Eastern Press Pvt. Ltd., Bangalore, 1999.

11. Encyclopedia of Pharmaceutical Technology, Swarbrick J and Boylon J.C., Vol. 1-3, Mercel Decker Inc

12. Theory and Practice of Industrial Pharmacy. Lachmann and Lieberman, 3rd Ed. – 1991, Varghese, Publishing House, Bombay,

13. A.K.Sawhney, "A Course in Electrical and Electronic measurements and Instruments", Dhanpat Rai and Sons, 2000. (UNIT I, II)

14. Leshie Cromwell, Fred. J. Weibell and Erich. A. Pfeiffer, "Biomedical

Instrumentation and Measurements", 2nd Edition, PHI, 2003. (UNIT III, IV)

15. John G. Webster, Medical Instrumentation: Application and Design, 3rd edition, John Wiley & Sons, New York, 1998. (UNIT V)

16. Biomembrane-Active Molecular Switches as Tools for Intracellular Drug Delivery Volga Bulmus, *Australian Journal of Chemistry* 58(6) 411–422

17. Principles of Protein X-ray Crystallography, J Derenth, Springer

18. Practical Protein Crystallography, Duncan E.Mc Ree, Elsevier Crystallography made crystal Clear, Gale Rhodes, Wiley

19. Outline of Crystallography for Biologists, David Blow, Oxford University Press

SYLLABUS FOR M.PHARM. (PHARMACEUTICAL ANALYSIS)

MAT MODERN ANALYTICAL TECHNIQUES Theory (3 hrs/wk.)

		Hrs	Marks
1.	Biostatistics and Computer Application: Introduction to and pharmaceutical applications of Student's t-test, F test, Chi-square test, Analysis of variance (ANOVA), correlation and regression analysis, Factor analysis, Time series analysis and Multidimensional scaling. Applications of computers related to quantitative and statistical pharmaceutical analysis.	3	10-15
2.	Sample Preparation for Analysis: Different techniques of sample preparation from body fluids, tissue extracts, cell culture extracts and phyto-chemical extracts.	5	10-15
3.	Structural Elucidation by Spectroscopic Methods: UV-Visible, IR, NMR and Mass with examples.	5	15-20
4.	Applications of DSC and XRD: Analysis of raw material (APIs and excipients), packaging material and finished products.	4	10-15
5.	Reference Standards: Introduction, preparation, types, storage, record keeping and validation.	5	10-15
6.	ESR Spectroscopy: Introduction, calibration, validation and application (in brief). Circular Dicorism and ORD: Introduction, calibration, validation and application (in brief).	5	10-15
7.	Particle Size Analysis: Introduction, significance, methods used in particle size analysis. Gel Permeation Chromatography (GPC): Introduction, instrumentation (Stationary phases and Detectors) and its application (particle size analysis).	4	15-20
8.	Immunochemical Techniques: ELISA, Immuno- precipitation, Radio immuno assays and Radio-labeling.	5	20-25

Reference Books

1. Introduction To Biostatistics & Computer Science, Mr. Y. I. Shah Dr. A. R. Paradkar, Mr. Y. I. Shah, Mr. M. G. Dhayagude
2. Pharmaceutical statistics using SAS: a practical Guide, Ralph B. D'Agostino
3. Introduction to Pharmaceutical Calculations, Judith A. Rees
4. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.

5. Practical Method Development, Snyder, L. R., Kirkland, J. J. and Glajch, J. L.
6. Principles of Instrumental Analysis, Skoog.
7. Textbook of Practical Biotechnology, C.R. Kokare.
8. Organic Spectroscopy, William Kemp
9. Physical Pharmacy – Martin, Swarbrick and Commarata
10. Physical Chemistry – Bahl and Tuli
11. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
12. I. P., B.P. and U.S.P.
13. Instrumental Methods of Analysis, Chatwal & Anand,
14. A Textbook of pharmaceutical analysis, K. A. Connors.
15. Pharmaceutical Analysis, Ashutosh Kar.
16. Instrumental and Chemical Analysis, B.K. Sharma.

MAT Pr **MODERN ANALYTICAL TECHNIQUES** **Practical (6 hrs/wk.)**

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. ED_{50} and LD_{50} Estimation and probit analysis

Reference Books

1. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.
2. Textbook of Pharmacognosy, Kokate C. K. Purohit A. P. and Gokhale S. B.
3. Pharmacognosy and Phytochemistry, Vol. I & II, V.D.Rangari.
4. Natural products Chemistry Practical Manuals, A.A.Siddiqui.
5. Indian Pharmacopoeia.
6. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
7. Harry's cosmetology, J. B. Wilkinson and R. J. Moore.
8. Textbook of Practical Biotechnology, C.R. Kokare.
9. Research Articles on Analytical Method Development in Journals
10. Physical Pharmacy – Martin, Swarbrick and Commarata
11. Physical Chemistry – Bahl and Tuli

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

	Hrs	Marks
1. **UV-Visible Spectroscopy:** Introduction, calibration, validation and applications of Woodward-Fisher rule.	**5**	**15-20**
2. **IR-Spectroscopy:** Introduction, calibration, validation and applications of IR and FT-IR spectroscopy.	**6**	**15-20**
3. **NMR Spectroscopy:** Introduction, calibration, validation and applications of P-NMR and C-NMR.	**5**	**15-20**
4. **Mass Spectroscopy:** Introduction, calibration, validation and applications.	**4**	**15-20**
5. **Atomic Absorption and Atomic Emission spectroscopy:** Introduction, calibration, validation and application.	**4**	**10-15**
6. **Thermal Analysis:** Theory and applications of Thermo gravimetric Analysis, Differential Thermal Analysis, Differential Scanning Calorimeter.	**6**	**15-20**
7. **Named Reactions**: Mechanism and applications in drug analysis: Grignard, Perkin, Darzen, Mannich and Merrifield solid phase synthesis.	**3**	**10-15**
8. **Karl- Fischer Titration:** Introduction, reagents instrumentation, calibration, validation and applications of Karl- Fischer Titration.	**3**	**05-10**

Reference Books

1. Instrumental and Chemical Analysis, B.K. Sharma.
2. Organic spectroscopy, William Kemp
3. UV-Visible Sectrophotometry in Pharmaceutical Analysis, Sandor Gorog
4. Handbook of Instrumental Techniques for Analytical Chemistry, Settle.

5. Text Book of Pharmaceutical analysis, Vol. I & II, Kasture, Wadodkar, Mahadik and More.
6. A Textbook of pharmaceutical analysis, K. A. Connors.
7. Principles of Instrumental Analysis, Skoog.
8. Instrumental methods of analysis, Hobart. H. Willard.
9. Instrumental Methods of Analysis, Chatwal & Anand,
10. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.
11. Capillary Electrophoresis: Instrumentation and Operation, Wim Kok.
12. Pharmaceutical Analysis, Ashutosh Kar.
13. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
14. Instrumental methods of chemical analysis, Ewing, GW.

APA – I Pr **ADVANCED PHARMACEUTICAL ANALYSIS – I** **Practical (6 hrs/wk.)**

Carry out analysis of at 2-3 samples under each experiment.

1. Estimation of partition and distribution coefficient of drugs by electrochemical methods. Determination of pKa & pKb of acidic and basic drugs by electrochemical methods.
2. In-vitro protein binding assay of some drugs.
3. To formulate and perform IPQC tests for solid, liquid, ointment dosage form as per IP, BP and USP.
4. Separation of serum protein, amino acid mixture and saccharides by electrophoresis.
5. Biochemical analysis using Auto-analyzer.

Reference Books

1. Physical Pharmacy – Martin, Swarbrick and Commarata
2. Practical Pharmaceutics (Physical Pharmacy), H. N. More, Ashok Hajare
3. Theory & Practice of Industrial Pharmacy, Lachman Liebermann & Kanig
4. I. P., B.P. and U.S.P.
5. Textbook of Practical Biotechnology, C.R. Kokare.
6. Capillary Electrophoresis: Instrumentation and Operation, Wim Kok.
7. Physical Chemistry – Bahl and Tuli

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

		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.	**6**	**20-25**
2.	**Methods for Sensitivity and Selectivity Enhancement in HPLC:** Pre-column Derivatization, Post-column Derivatization, Ion Suppression and Ion Pair chromatography.	**5**	**10-15**
3.	**HPTLC:** Introduction, principle, Instrumentation, calibration, validation and applications.	**5**	**20-25**
4.	**Hyphenated Techniques:** GC-MS, LC-MS, LC-MS-MS, LC-NMR and their application in structural elucidation and quantitative analysis of complex mixtures.	**5**	**10-15**
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.	**4**	**10-25**
6.	**Validation:** Guidelines for analytical and bio-analytical methods validation as per ICH, AOAC and USFDA guidelines.	**3**	**10-15**
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.	**4**	**10-15**
8.	**Electrophoresis:** Introduction stationary phases, mobile phases and application of paper, starch, agarose gel, acrylamide and Capillary electrophoresis.	**4**	**10-15**

Reference Books:

1. Instrumental and Chemical Analysis, B.K. Sharma.
2. Practical Method Development, Snyder, L. R., Kirkland, J. J. & Glajch, J. L
3. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
4. Instrumental methods of chemical analysis, Ewing, GW.
5. European Pharmacopoeia
6. ICH Q2A. (1994). Text on Validation of Analytical Procedures.
7. ICH Q2B. (1996). Validation of Analytical Procedures: Methodology.
8. USFDA guidelines for Bio-analytical method validation.
9. Bioavailabity and Bioequivalence in Pharmaceutical Technology, Pal, P.K. and Ganesan, M.
10. A Textbook of pharmaceutical analysis, K. A. Connors.
11. Instrumental methods of analysis, Hobart. H. Willard.
12. Instrumental Methods of Analysis, Chatwal & Anand,
13. An Introduction to HPLC for Pharmaceutical Analysis, Oona McPolin
14. Analytical Chemistry by open learning series.
15. Introduction to High Performance Liquid chromatography, R. J. Hamilton.

APA-II Pr **ADVANCED PHARMACEUTICAL ANALYSIS – II** **Practical** **(6 hrs/wk.)**

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.

Reference Books

1. Analytical Chemistry by Open Learning: fluorescence and phosphorescence, Rendell and David.
2. Organic spectroscopy, William Kemp.
3. Instrumental Methods of Analysis, Chatwal & Anand,
4. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
5. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.
6. ICH Q2A. (1994). Text on Validation of Analytical Procedures.
7. ICH Q2B. (1996). Validation of Analytical Procedures: Methodology.
8. Research articles on analytical method development in Journals.

FBCA FOOD, BIOLOGICALS AND COSMETIC ANALYSIS Theory (3 hrs/wk.)

		Hrs	Marks
	Analysis of food:		
1.	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, microbial analysis and toxicological testing (NELA and FDA).	**6**	**15-20**
	Analytical Methods for milk products:		
2.	Methods for analysis of milk, milk constituents and milk products like ice products, milk powder, butter, cheese including adulterants and contaminants of milk. Microbial testing of milk and milk products.	**5**	**15-20**
3.	**Analysis of fermentation products like wine, spirits, beer and vinegar:** Analysis of the above fermentation products and the containers and packaging material for the same.	**3**	**10-15**
	Analysis of Cosmetics:		
4.	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.	**6**	**20-25**
5.	**Safety legislations related to cosmetic products and different toxicity tests for cosmetics.**	**3**	**5-10**
	Nutraceuticals:		
6.	Concept, use and testing as per USP-NF, guidelines for analysis and testing of raw material and final products of various nutra-ceuticals.	**4**	**10-15**
	Analytical Techniques used in Food, Cosmetic and Nutra-ceutical analysis:		
7.	Principle and applications of Near IR, SP Radio-immuno assays, Raman spectroscopy, X ray fluorescence, Particle size analysis, ICP in Analysis of Food, Cosmetic and Nutra-ceuticals.	**5**	**15-20**
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	**4**	**10-15**

Reference Books:

1. The Chemical Analysis of Foods and Food Products
2. Hand book of Analysis and Quality Control for Fruit and Vegetables Products
3. Handbook of cosmetic sciences and technology
4. Modern Cosmetics
5. Harry's cosmetology
6. The Chemical Analysis of Food
7. Introduction To Chemical Analysis of Food
8. Official Methods of Analysis
9. Analysis of Food Constituents
10. Ayurvedic formulary of India, Govt.of India, 1962.
11. British Herbal Pharmacopoia, (vol.I, II & III) Her majestys Services , U.K.
12. Drug and Cosmatic act, (with latest amendments including Ayurvedic GMP), Govt. of India.
13. Herbal Drug industry: R.D. Chudhary, Eastern Publishers, New Delhi 1996.

SYLLABUS FOR M. PHARM (QUALITY ASSURANCE TECHNIQUES)

MAT MODERN ANALYTICAL TECHNIQUES Theory (3 hrs/wk.)

		Hrs	Marks
1.	Biostatistics and Computer Application: Introduction to and pharmaceutical applications of Student's t-test, F test, Chi-square test, Analysis of variance (ANOVA), correlation and regression analysis, Factor analysis, Time series analysis and Multidimensional scaling. Applications of computers related to quantitative and statistical pharmaceutical analysis.	3	10-15
2.	Sample Preparation for Analysis: Different techniques of sample preparation from body fluids, tissue extracts, cell culture extracts and phyto-chemical extracts.	5	10-15
3.	Structural Elucidation by Spectroscopic Methods: UV-Visible, IR, NMR and Mass with examples.	5	15-20
4.	Applications of DSC and XRD: Analysis of raw material (APIs and excipients), packaging material and finished products.	4	10-15
5.	Reference Standards: Introduction, preparation, types, storage, record keeping and validation.	5	10-15
6.	ESR Spectroscopy: Introduction, calibration, validation and application (in brief). Circular Dicorism and ORD: Introduction, calibration, validation and application (in brief).	5	10-15
7.	Particle Size Analysis: Introduction, significance, methods used in particle size analysis. Gel Permeation Chromatography (GPC): Introduction, instrumentation (Stationary phases and Detectors) and its application (particle size analysis).	4	15-20
8.	Immunochemical Techniques: ELISA, Immuno- precipitation, Radio immuno assays and Radio-labeling.	5	20-25

Reference Books

1. Introduction To Biostatistics & Computer Science, Mr. Y. I. Shah Dr. A. R. Paradkar, Mr. Y. I. Shah, Mr. M. G. Dhayagude
2. Pharmaceutical statistics using SAS: a practical Guide, Ralph B. D'Agostino
3. Introduction to Pharmaceutical Calculations, Judith A. Rees

4. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.
5. Practical Method Development, Snyder, L. R., Kirkland, J. J. and Glajch, J. L.
6. Principles of Instrumental Analysis, Skoog.
7. Textbook of Practical Biotechnology, C.R. Kokare.
8. Organic Spectroscopy, William Kemp
9. Physical Pharmacy – Martin, Swarbrick and Commarata
10. Physical Chemistry – Bahl and Tuli
11. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
12. I. P., B.P. and U.S.P.
13. Instrumental Methods of Analysis, Chatwal & Anand,
14. A Textbook of pharmaceutical analysis, K. A. Connors.
15. Pharmaceutical Analysis, Ashutosh Kar.
16. Instrumental and Chemical Analysis, B.K. Sharma.

MAT Pr **MODERN ANALYTICAL TECHNIQUES** **Practical (6 hrs/wk.)**

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. ED_{50} and LD_{50} Estimation and probit analysis

Reference Books

1. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.
2. Textbook of Pharmacognosy, Kokate C. K. Purohit A. P. and Gokhale S. B.
3. Pharmacognosy and Phytochemistry, Vol. I & II, V.D.Rangari.
4. Natural products Chemistry Practical Manuals, A.A.Siddiqui.
5. Indian Pharmacopoeia.
6. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
7. Harry's cosmetology, J. B. Wilkinson and R. J. Moore.
8. Textbook of Practical Biotechnology, C.R. Kokare.
9. Research Articles on Analytical Method Development in Journals
10. Physical Pharmacy – Martin, Swarbrick and Commarata
11. Physical Chemistry – Bahl and Tuli

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

		Hrs	Marks
1.	**Introduction :**	08	15 – 25
	An understanding of the concepts of Quality Assurance, Good Manufacturing Practice and Quality Control as applied to the pharmaceutical Industry.		
2.	**Documentation related to Pharmaceutical Industry :**	20	45 – 65
	• New application : NDA and ANDA requirements, Data presentation , verification and grant by FDA		
	• Manufacturing documents: BMR, routine records, downtime records, calibration and validation records.		
	• Quality Assurance documents: validation and types of validation, protocols methodology and related GMP /ICH guidelines.		
	• Quality Assurance documents: Internal audits SOP documents security and storage related issue.		
	• Store management documents: Stock reconciliation records for raw material, finished products and packaging materials.		
	• Maintenance and Environment control related documents.		
	• Consumer related documents: Product recall, complaint traceability printed packing, preventive maintenance records.		
3.	**Good laboratory Practices (GLP)**	10	25 – 30
	Regulations , 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.		
4.	**Related quality systems :**	07	15 – 20
	ISO, WHO etc, and their applications in pharmaceutical industry.		

RECOMMENDED BOOKS

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.

QAT-I Pr **QUALITY ASSURANCE TECHNIQUES – I** **Practical (6 hrs/wk.)**

EXPERIMENTS BASED ON FOLLOWING

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 following key documents
    d. SOP on SOP
    e. IPQC document
    f. Material receipt, sampling, dispensing & storage document
7. Experiment & documentation of dissolution test
8. IPQC tests for Tablets / Capsules / Injections / Liquid / Ointment

RECOMMENDED BOOKS

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.

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

		Hrs	Marks
1.	**Rules and Regulations :**	07	15 – 22
	Rules governing manufacturing of drugs in India. Drug and Cosmetic Act and rules. Narcotic drugs and Psychotropic substances Act and Rules. Magic Remedies and Objectionable Advertisement Act, Consumer protection Act, Factory Act and intellectual Property Right.		
2.	**Process validation :**	07	18 – 25
	Differences and similarities between process qualification and process validation, protocols, methodology and interpretation of data. Validation of process like mixing, granulation, drying, compression filling and water process system.		
3.	**Equipment Validation :**	07	18 – 25
	Installation qualification and operational qualification for sterilization equipments like autoclave, oven and membrane filter.		
4.	**Cleaning methods:**	06	12 – 17
	Analytical method validation requirements and validation of effective cleaning.		
5.	**Vendor validation :**	06	12 – 17
	Vendor audit, sample testing and trend analysis.		
6.	**Validation of service :**	06	12 – 17
	Training, maintenance and packing.		
7.	**Validation of electronic data processing :**	06	12 – 17
	Software validation methodology.		

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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.

QAT-II Pr **QUALITY ASSURANCE TECHNIQUES – II** **Practical (6 hrs/wk.)**

EXPERIMENTS BASED ON FOLLOWING CONCEPTS

1. Validation of equipments, Autoclave, hot air oven, membrane filter.
2. Validation of process, Mixing drying and compression.
3. Validation of an analytical method.

RECOMMENDED BOOKS

1. J. F. Despautz, Automation and validation of information in Pharmaceutical Processing Marcel and Dekker.
2. F.J. Carleton and J.P. Agalloco validation of aseptic Pharmaceutical processes 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 Pharmaceuticals Marcel and Dekker.
5. R.F. Brewer, Design of Experiments for process improvement and quality Assurance, Narosa.
6. S. N. Katju Law and drugs, Law Publishers (I) Pvt. Ltd.

QAT-III QUALITY ASSURANCE TECHNIQUES – III Theory (3 hrs/wk.)

		Hrs	Marks
1.	**Validation of instruments :**	08	20 – 28
	HPLC, UV and IR spectrophotometer and dissolution test apparatus.		
2.	**Validation of Analytical Method :**	08	20 – 28
	Validation parameters, accuracy, precision, ruggedness, statistical design and statistical consideration.		
3.	**Current good manufacturing Practices.**	08	20 – 28
4.	**Biostatistics :**	15	30 – 40
	Probability distribution, normal, binomial and polynomial distributions, continuous data distribution, fiducial limits, probit and logit analysis. Linear regression and correlation, method of least squares, significance of correlation and regression. Parametric tests, testing hypothesis, types of errors test of significance based on normal distribution, test of significance for correlation coefficients. Non parametric test. Experimental Designs. Randomization completely randomized and Latin square designs, and factorial design. Statistical Quality Control.		
5.	**Guidelines and technique for experiments on animals.**	06	10 – 16

RECOMMENDED BOOKS

1. D.A. Berry, statistical methodology in the Pharmaceutical Science: Marcel and Dekker Vol.104.
2. S.W. Bergman and JC Gittins statistical methods for Pharmaceutical Research and planning Marcel and Dekker.
3. S. C. Chowand J.P. Liu statistical Design and Analysis in Pharmaceutical Sciences. Marcel, Dekker.

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

MAT MODERN ANALYTICAL TECHNIQUES Theory (3 hrs/wk.)

		Hrs	Marks
1.	Biostatistics and Computer Application: Introduction to and pharmaceutical applications of Student's t-test, F test, Chi-square test, Analysis of variance (ANOVA), correlation and regression analysis, Factor analysis, Time series analysis and Multidimensional scaling. Applications of computers related to quantitative and statistical pharmaceutical analysis.	3	10-15
2.	Sample Preparation for Analysis: Different techniques of sample preparation from body fluids, tissue extracts, cell culture extracts and phyto-chemical extracts.	5	10-15
3.	Structural Elucidation by Spectroscopic Methods: UV-Visible, IR, NMR and Mass with examples.	5	15-20
4.	Applications of DSC and XRD: Analysis of raw material (APIs and excipients), packaging material and finished products.	4	10-15
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9. Physical Pharmacy – Martin, Swarbrick and Commarata
10. Physical Chemistry – Bahl and Tuli
11. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
12. I. P., B.P. and U.S.P.
13. Instrumental Methods of Analysis, Chatwal & Anand,
14. A Textbook of pharmaceutical analysis, K. A. Connors.
15. Pharmaceutical Analysis, Ashutosh Kar.
16. Instrumental and Chemical Analysis, B.K. Sharma.

MAT Pr **MODERN ANALYTICAL TECHNIQUES** **Practical (6 hrs/wk.)**

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. ED_{50} and LD_{50} Estimation and probit analysis

Reference Books

1. Text book of Practical Pharmaceutical chemistry, Vol. I & II, AH Beckett & Stenlake.
2. Textbook of Pharmacognosy, Kokate C. K. Purohit A. P. and Gokhale S. B.
3. Pharmacognosy and Phytochemistry, Vol. I & II, V.D.Rangari.
4. Natural products Chemistry Practical Manuals, A.A.Siddiqui.
5. Indian Pharmacopoeia.
6. Spectrometric identification of organic compounds, Silverstein RM, Webstar FX.
7. Harry's cosmetology, J. B. Wilkinson and R. J. Moore.
8. Textbook of Practical Biotechnology, C.R. Kokare.
9. Research Articles on Analytical Method Development in Journals
10. Physical Pharmacy – Martin, Swarbrick and Commarata
11. Physical Chemistry – Bahl and Tuli

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

	Hrs	Marks
A. Research and Development:	25	50-65

a. Drug substances –

Identification, selection of chemical & solvents, lead compound development & optimization, HTS, combinational chemistry, SAR optimization,

Structure elucidation, process development, process validation, Demo batches, technology transfer – Analytical transfer.

b. Drug product –

Rational for 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,

Selection of Technology transfer - Process validation, optimization, packing development, requirement of exhibit batches.

c. Analytical Research:

Analytical API method development for reaction monitoring; KSM study method development for drug substance, structure determination

Impurity identification - Impure guideline ICH, Q2, A, B, C

Analytical method validation, which includes force degradation study, of essay and impurity methods. GLP,

Drug product :- Method development for in process control, In-vitro drug release method developments, essay method, Impurity methods, dissolution method, validation & force degradation study, Prefomulation methods, Quality by design, Pharmaceutical experimental design and optimization.

Analytical method transfer to locations exhibit base requirements

Specification preparation of API, R.M & Drug product.GLP,

Working standard preparations /Reference standard MFC, potency, cancellation, dissolution calculation,

B. Manufacturing: 10 25-35

1.GMP - CFR 210, 211

2.Schedule M

3.Process validation

4.BMR preparation, selection of equipments. In brief process flow chart for each dosage form.

5.Process analytical technology

C. Quality: 10 25-35

1. Quality control:-

Analysis of raw materials, In-process & finished goods. GLP of non clinical laboratories, Working standard preparation reference standard preparation, Quality Control responsibilities.

2. Quality Assurance:-

Change Control, cleaning validation, SOP preparation, quality assurance responsibilities, internal audit, quality guideline Validation & qualification of analytical labs and manufacturing equipments and GLP.

Reference books:

1. Martin, P. Bustamante and A. H. Chun; Physical Pharmacy; Waverly.
2. D. M. Parikh; Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
3. G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
4. H. G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
5. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
6. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
7. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.

8. N. G. Stanley – Wooed; Enlargement and compaction of particle solids; Butterworths.
9. P. H. List and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
10. Leon Shargel. 2003, Applied Biopharmaceutics & Pharmacokinetics, Prentice Hall International, London.
11. D.M. Brahmankar, S.B. Jaiswal. 1997, Biopharmaceutics & Pharmacokinetics - A treatise. CBS Publications, New Delhi.
12. S. Weinberg, Good laboratory practice Regulations, Marcel and Dekker.
13. J. Swarbrick Boylan, Encyclopedia of pharmaceutical technology, Marcel and Dekker.
14. J.R. Berry and R.A. Nash, Pharmaceutical process validation. Marcel and Dekker.
15. S.H. Will and J.R. Stoker, good manufacturing Practices for Pharmaceutics Marcel Dekker.
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21. R.F. Brewer, Design of Experiments for process improvement and quality Assurance, Narosa.
22. S. N. Katju Law and drugs, Law Publishers (I) Pvt. Ltd.

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

Experiments based on following concepts

1. Formulation of sustained release tablet formulation.
2. Preparation and characterization of Microcapsules/Microspheres.
3. Preparation and evaluation of Transdermal films.
4. In-vitro permeation studies across skin and nasal mucosa.
5. Bioavailability study of nasal mucosa.
6. Formulation design and evaluation of
    a. Liposomes
    b. Multiple emulsions.

Reference Books:

1. A. F. Kydonieus; Controlled Release Technologies, methods, theory and applications, Vol. I and II, CRC Press Inc.
2. A. J. Hickey; Pharmaceutical Inhalation Aerosol Technology, Marcel Dekker.
3. Barry; Dermatological Formulation, Marcel Dekker.
4. C. G. Wilson and N. Washington; Physiological Pharmaceutics, Ellis Horwood Limited.
5. D. W. Osborne, A. H. Amann; Topical drug delivery formulations, Marcel Dekker.
6. H. S. Bean, A. H. Becket and J. E. Carless; Advances in Pharmaceutical Sciences, Vol. 5, Academic Press.
7. J. Kreuter; Controlled Drug Delivery Systems, Marcel Dekker.
8. K. S. E. Su and S. F. Chang; Nasal Systemic Drug Delivery, Marcel Dekker.
9. Morton Rosoff; Controlled release of drugs, VCH Publishers.
10. N. K. Jain; Novel and Drug Delivery systems, CBS Publishers, New Delhi.
11. P. B. Deasy; Micro encapsulation and release drug processes, Marcel Dekker.
12. P. Johnson and J. G. lioyd- Jones; Drug Delivery Systems, VCH Publishers.
13. P. Tyle and B. P. Ram; Targetted Therapeutic systems, Marcel Dekker.
14. P. Tyle; Drug Delivery Devices, fundamental applications, Marcel Dekker.
15. R. O. Potts and R. H. Guy; Mechanism of Transdermal Drug Delivery, Marcel Dekker.
16. Robinson; Novel Drug Delivery systems. Marcel Dekker.
17. T. J. Roseman and S. Z. Mansdorf; Controlled release delivery Systems, Marcel Dekker.
18. Y. W. Chein; Transdermal Controlled Systemic Medication, Marcel Dekker.

AP **ADVANCED PHARMACEUTICS** **Theory** **(3 hrs/wk.)**

		Hrs	Marks
	Physical pharmaceutics covering the following aspects		
1.	**Solids :**	07	17 – 24
	Particle characterisation 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, characterisation of granules and compacts.		
2.	**Dissolution :**	08	20 – 28
	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. Enhancement of dissolution rate.		
3.	**Surfactant System :**	10	23 – 30
	Phase behaviour of surfactant in binary and ternary systems. Factors affecting phase behaviour; Micellization; micelle structure, shape, size factors affecting CMC and micelle size, thermodynamics and kinetics of micelle formation. Pharmaceutical aspects of Solubilization, Solubilization in non-aqueous system, interactions with polymers and oppositely charged species. Hydrotrophy in pharmaceuticals, surfactants in emulsions and suspensions. Biological implications of surfactants; Effect on: dissolution of drugs, permeability of membranes, drug absorption, antibacterial activity. Cyclodextrin inclusion complexes and co-solvents.		
4.	**Polymer science :**	06	10 – 16
	Types and applications of polymers, polymerization reactions, methods of polymerization and characterization of polymers, thermodynamics of polymer solutions.		
5.	**Solid dispersions :**	06	10 – 16
	Types, methods of preparation, selection of carrier, characterization and applications.		
6.	**Stability studies :**	08	20 – 26
	Kinetics activation energy calculations, accelerated stability studies, factors responsible for destabilization of pharmaceutical products and techniques to improve, shelf life calculations. Physical testing of solution, suspension, emulsion, aerosol, powder, tablet and sustained release products.		

Reference Books:

1. A. Kitahard and A. Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
2. A. Martin, P. Bustamante and A. H. Chun; Physical Pharmacy; Waverly.
3. D. M. Parikh; Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
4. G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
5. H. G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
6. J. T. Cartensen; Drug Stability; Marcel Dekker.
7. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
8. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
9. M. N. Rubinstein; Pharmaceutical Technology, Drug stability, John Wiley and sons.
10. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.
11. N. G. Stanley – Wooed; Enlargement and compaction of particle solids; Butterworths.
12. P. H. List and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
13. P. J. Tarcha; Polymer for Controlled Drug Delivery, CRC Press.
14. Robinson; Novel Drug Delivery Systems, Marcel Dekker.

AP-Pr ADVANCED PHARMACEUTICS Practical (6 hrs/wk.)

1. **Experiments based on following concepts.**
2. **Powder characterization:**
   - Microscopy – Particle size analysis, calculation of shape factors.
   - Compression and compaction – Huckel plot studies, tensile strength.
3. **Solubilization :**
   - Effect of dielectric constant on solubility
   - Complexation
   - Ternary phase diagram.
   - Solid dispersion
4. **Stability of multiple emulsions**
5. **Polymer science :**
   - Rheological and thermal characterization of polymers.
6. **Stability studies :**
   - Degradation kinetic study of a drug in a solution.
   - Accelerated stability studies of a formulation.
7. **Dissolution studies of various dosage forms.**

Recommended books

1. A. Kitahard and A. Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
2. A. Martin, P. Bustamante and A. H. Chun; Physical Pharmacy; Waverly.
3. D. M. Parikh; Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
4. G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
5. H. G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
6. J. T. Cartensen; Drug Stability; Marcel Dekker.
7. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
8. Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
9. M. N. Rubinstein; Pharmaceutical Technology, Drug stability, John Wiley and sons.
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11. N. G. Stanley – Wooed; Enlargement and compaction of particle solids; Butterworths.
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13. P. J. Tarcha; Polymer for Controlled Drug Delivery, CRC Press.
14. Robinson; Novel Drug Delivery Systems, Marcel Dekker.

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

	Hrs	Marks
A. Clinical Trials & Pre-Clinical trials:	12	25-30

a. Pre-clinical –
   1. Animal pharmacology, animal toxicity, animal models, correlation of animal pharmacology to human pharmacology.
      Solution - dose testing
      Efficacy – Invite animal study
   2. Regulatory requirements as per ICH, FDA, WHO, EMEA, IP, TGA etc.

b. Clinical Trials –
   1. Early clinical trials, clinical trial design statistical treatment of data,
   2. Clinical trial phases – I to IV, clinical trial requirement as per category.
   3. Regulation requirement as per ICH, FDA, WHO, EMEA, IP, TGA etc.
   4. BA/BE study requirements. – CFR314

B. Regularity Filling:	08	20-25

1. New drug application (NDA), ANDA, drug product application, Biopharmaceutical product application CTD, preparation – application through CDT, Supplemental application, Annual updates DMF, COS.
2. Regulation filling with different agencies- FDA, Atssa, MHRA, EDQM, TGA.
3. Overview of different regulation agencies.
   1. Guideline of different regulation agencies

C. Pharmaceutical excipient:	08	20-25

1. Excipient : Defination, selection, IIG data base
2. Requirement for excipient manufacturing as per International Pharmaceutical Excipients Council (IPEC)
3. Approval of new excipient
4. Excipients –Functionality specifications and monograph

D. Preparation of Regulatory Dossier for Following:	10	25-30

1. Generic product
2. Modified release product
3. Biological product
4. Device
5. Excipient

6. Investigation new drug application

E. Regularity requirements of medical devices: 07 10-15

1. Medical devices – Introductions,
2. Type of Medical devices,
3. Testing requirements for devices,
4. Regularity requirements of different agencies for medical devices.

Reference books:

1. Clinical Pharmacy and Therapeutics: Roger and Walkar, Churchill Livingston Publication.
2. Clinical Pharmacy and Therapeuitics – E. T. Herfindal and J. L. Hirschman.
3. Relevant review articles from recent medical and Pharmaceutical literature.
4. Davidson's Principal and Practice of Medicine. Churchill Livingston Eighteenth Edition.
5. Choudhari Quintessence of Medical pharmacology Central.
6. Bickley L. S. Bate's Guide to physical examination and history jaking. Lippincoft.
7. Malcohm Rowland C., Thomas N. Tozer. Clinical Pharmacokinetics – Concept & Application., 1987, Lea & Febiger Book
8. P. G. Welling and F. L. S. Tse; Pharmacokinetics, Regulatory- Industrial - Academic perspectives; Marcel Dekker.
9. D. M. Bramhankar and S. B. Jaiswal; Biopharmaceutics and Pharmacokinetics A Treatise; Vallabh Prakashan.
10. P.L. Madan. Biopharmaceutics & Pharmacokinetics, 2000, Jaypee publications, New Delhi.
11. Gibaldi & Pancot. Handbook of clinical pharmacokinetics. 1992, Marcel Dekker, New York.
12. Swarbrik. Biopharmaceutics. 1987, Lea & Febiger book publication. U. K
13. Wade A, Paul J. Weller. 1994. Handbook of pharmaceutical excipients.
14. S. Weinberg, Good laboratory practice Regulations, Marcel and Dekker.
15. J.R. Berry and R.A. Nash, Pharmaceutical process validation. Marcel and Dekker.
16. S.H. Will and J.R. Stoker, good manufacturing Practices for Pharmaceutics Marcel Dekker.
17. R.F. Brewer, Design of experiments for process improvement and quality Assurance Narrosa.
18. D.H. Stamatis, Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.
19. J. F. Despautz, Automation and validation of information in Pharmaceutical Processing Marcel and Dekker.
20. F.J. Carleton and J.P. Agalloco validation of aseptic Pharmaceutical processes Marcel and Dekker.
21. R.F. Brewer, Design of Experiments for process improvement and quality Assurance, Narosa.

List of Elective Subjects for Semester I

1. Drug Design
2. Bulk Drug Technology
3. Toxicology
4. Biopharmaceutics & Pharmacokinetics
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

Electives

1. DRUG DESIGN **Theory** **(3 hrs/wk.)**

		Hrs	Marks
1.	**Introduction to drug design:** Drug design, Molecular modification, Rational approach of drug design, QSAR and drug design, drug design methodologies, challenges of drug design.	06	15-20
2.	**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.	07	15-20
3.	**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**.** **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.	10	25-30
4.	**The basis of drug design and recent advances in Chemtherapeutic agents:** 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. **Chemistry of β-lactam antibiotics –** Design of β-lactamase resistant and acid resistant analogs.	08	15-25
5.	**Molecular modelling in Drug Design:** • Molecular mechanics and Quantum Mechanics • Known receptor sites: Defination, Characterisation of sites, design of ligands, manually assisted three dimentional databases & calculation of affinity. • Unknown receptor sites: Searching for similarity, Pharmacophore models, molecular comparisons, finding common patterns.	07	15-20

6. **Structural variations for drug design and drug target interactions:** 07 15-25

a. Drug design, variation of substituents.

b. Extention 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.

i. A case study of oxamniquine.

Reference Books:

1. Ariens – drug design Vol. – II.
2. Annual Reports in medicinal chemistry (Academic press Inc.).
3. Smith - William – Introduction to the principles of drug design.
4. Woodridge – Progress in pharmaceutical Research.
5. Medicinal Chemistry – Monographs series (Academic Press).
6. Burgers - Medicinal Chemistry & Drug Discovery.

2. **BULK DRUG TECHNOLOGY** **Theory** **(3 hrs/wk.)**

		Hrs	Marks
1.	**Stoichiometry and its importance in the manufacture of drugs** **Discussion on the following processes** (reaction types in relation to manufacturing of drugs Acetylation, Nitration, Sulphonation, chlorosulphonation, Oxidation, Reduction, alkylation, Halogenation, Carboxylation, Decarboxylation, Esterification, Addition, epoxidation and important rearrangements.	07	16 – 24
2.	**Unit processes:** Study of the following chemical processes (with reference to reagents, mechanisms, equipments. and manufacture of drugs given below): Acylation, Esterification, alkylation, amination, Halogenation, hydrolysis, nitration, oxidation, reduction.	08	18 – 24
3.	**Further discussion on (unit operation important to drug synthesis)** e. g. mixing, distillation, drying, filteration and centrifugation, evaporation, crystallization, Counter current extraction, Effluent treatment and Pollution Control.	07	15 – 22
4.	**Principles and design of the reactors-** Factors to be considered (including material selection) construction of flow diagrams- selection of Equipment	08	18 – 24
5.	**Detailed manufacturing aspects, inclusive of processes and operations involved-for :** Aspirin, Adrenaline, Aneurine, Barbitones, Benzocaine, Chloramphenicol, Sulphathiazole	07	15 – 22
6.	Safety and Hazards concepts.	08	18 – 24

Reference Books:

1. M. Giarians : Fundamentals of Chemicals Engineering Operations
2. W. J. Badger and Banchero : Introduction to chemical engineering (McGraw Hill Services)
3. L. Lachman - the theory and practice of Industrial Pharmacy (Varghese Publishing)
4. Ganderton G ; Unit processes in Pharmacy
5. Groggin P. K. : Unit processes in Organic synthesis (McGraw Hill Publication London)
6. Marshall Sitting : Organic Chemical Processes
7. Dryden C. L.: Outlines of chemical Technology (Affiliated East-West Press Pvt. Ltd.)

3. TOXICOLOGY **Theory (3 hrs/wk.)**

		Hrs	Marks
1.	**Fundamental Principles:** • 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.	08	20-20
2.	Molecular aspects of toxicology :- Cytotoxicity – Molecular Mechanism of cell death, Genetic toxicology Introduction to carcinoensis.	05	10-10
3.	**Organ toxicology :-** • Cytopathology general response patterns and Morphological aspects Necrosis and apoptossis: irreversibility of cell damage and cell death. • Dermatotoxicology: Toxicological, pathology and methodological aspects. • Raspiratory toxicology: Toxicological pathophysilogy, toxicological pathology and mechanisms of toxicity. • Gastrointstinal toxicology: toxicological pathology and source of intestinal toxicity. • Hepatotoxicology: Mechanisms of liver toxicity and methodology aspects. • Nephotoxicology : toxicologycal pathology and biochemical toxicology. • Cardiovascular toxicology; toxicological pathology and methodological aspects. • Toxicology of blood: Pathophysiology, Toxicological pathology and mechanisms of toxicity. • Immunoxicology: determination of immunotoxic effects and immunotoxicity mechanisms. • Endocrine toxicology. • General reproductive toxicology. • Functional neurotoxicology. • Neurobehavioural toxicology. • Food, nutritional toxicology. • Medical and clinical toxicology.	32	70-110

- Ecotoxicology.
- Occupational toxicology.
- Carcinogencity mutagenicity ; Teratogenicity.

Reference Books:

1. Niesink R. J. M. de Vries J and Hollingers M. A. Toxicology, Principal and Applications, CRC Press 1996
2. Amdur M. O Doul J and Klassen C. D. Casarett and Doull's Toxicology
3. Gupta P, K and Salunkhe D. K. Modern toxicology Vol. -I, II and III (Metropolitan, New Delhi).

4. BIOPHARMACEUTICS & PHARMACOKINETICS Theory (3 hrs/wk.)

		Hrs	Marks
1.	**Introduction to Biopharmaceutics and clinical pharmacokinetics**	05	10 – 15
	Definition of Biopharmaceutics, Pharmacokinetic, clinical Pharmacokinetic and its importance		
2.	**Basic concepts**	06	15 – 20
	Definition and introduction to absorption rate constant, bioavailability, volume of distribution, elimination half-life, elimination rate constant. Clearance, extraction ratio, area under curve, protein binding and tissue binding.		
	Calculation of parameters from plasma and urine data.		
3.	**Compartment modelling: -**	08	20 – 30
	a. One compartment open model :		
	I. V. route of administration; Disposition viewed from plasma ($t_{1/2}$, V, 1st order examination, fraction of dose remaining) total clearance, renal clearance, disposition viewed from urine only and estimation of pharmacokinetic parameters.		
	E. V. route of administration, kinetics of absorption, body level time relationship and assessment of pharmacokinetic parameters.		
	b. Multi compartment modeling :		
	2 compartment and 3 compartment models, determination of compartment models.		
4.	**Absorption of drugs**	06	15 – 20
	a. GI absorption of drugs		
	b. Cell membrane structure and physiology		
	c. Mechanism of drug absorption		
	d. Factors influencing drug absorption and bioavailability.		
	e. Concepts and kinetics of physiological parameters of absorption.		
5.	**Distribution of drugs :-**	05	10 – 15
	a) Factors affecting distribution of drugs.		
	1) Tissue permeability of drugs		
	Physicochemical properties of drugs.		
	Physiological barriers to diffusion of drugs.		
	2) Organ / Tissue size and perfusion rate.		
	3) Binding of drugs to blood components and tissue. Factors affecting it.		
	4) Miscellaneous factors (Age, Pregnancy, Obesity etc)		

b) Volume of distribution

Clinical concepts and kinetics of physiological parameters of distribution.

6.	**Elimination of drug: -** a. Concept of clearance b. Hepatic metabolism: chemical pathways and factors affecting it c. Renal excretion: principle processes and factors affecting It d. Non renal excretion: e. Concepts and kinetics of physiological parameters of elimination	05	10 – 15
7.	**Bioavailability:** • Objective of bioavailability studies, determination bioavailability parameters of bioavailability rate of absorption extent of absorption, relative bioavailability, determination of AUC (using planimeter, counting squares trapezoidal rule and cutting and weighing studies) • Drug dissolution rate and bioavailability Theories of dissolution in-vitro drug dissolution testing models invitro - invivo correlation • Invitro and insitu absorption studies Various Invitro & insitu models – selection of animals Correlation between invitro & invivo studies.	06	15 – 20
8.	**Non linear Pharmacokinetics** Saturable enzymatic elimination process, drug elimination by capacity limited pharmacokinetics, mixed drug elimination, time dependent pharmacokinetics, bioavailability of drug that follow non linear pharmacokinetics, non linear pharmacokinetics due to protein binding (e. g. phenytoin)	06	15 – 20

Reference Books:

1. Applied Biopharmaceutics & Pharmacokinetics – Leon Shargel.
2. Biopharmaceutics - Swarbrick, Lea & Febiger book publication
3. Biopharmaceutics & P'cokinetics - an introduction - Robert E. Notary.
4. Biopharmaceutics & P'cokinetics - Milo Gibaldi , Lea & Febiger book publication
5. Biopharmaceutics & Pharmacokinetics - P. L. Madan
6. Biopharmaceutics & Pharmacokinetics. A treatise - D. M. Brahmankar S B. Jasiwal
7. Clinical Pharmacokinetics - concept & application - Malcolm Rowland & Thomas N. Tozer, Lea & Febiger book.
8. Handbook of clinical p'cokinetics- Gibaldi & Pancot
9. Introduction to Biopharmaceutics. - G. P. -Shriwastav
10. Pharmacokinetics - Milo Gibaldi & Donald Perrier
11. Remington's pharmaceutical sciences

5.	MEDICINAL PLANT BIOTECHNOLOGY	Theory	(3 hrs/wk.)
		Hrs	**Marks**
1.	**Introduction to plant Genetic structure & Molecular Biology**	05	10-16
2.	**Plant gene Mapping & molecular maps of plant genomes**	05	12-18
3.	**Methods of quality improvement of plants** a. Chemodemes b. Hybridization c. Mutation d. Polyploidy	05	12-18
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	06	14-20
5.	**Localization of transferred gene in genetically modified plants** a. Plant chromosome analysis b. Gene mapping c. Use of markers d. DNA hybridization	06	14-20
6.	**Applications of transgenic plants** a. Resistance to herbicides, insects, fungus and virus, physiological stress b. Edible vaccines	06	14-18
7.	**Plant tissue Culture** a. Totipotency b. Culture media c. Types of cultures d. Cell suspension, Organogenesis, Embryogenesis, Protoplast culture e. Cell Immobilization f. Biotransformation g. Generation and production of secondary metabolites h. Germplasm conservation	12	24-30

Reference Books:

1. Elements of Biotechnology: P. K. Gupta
2. Molecular biology and biotechnology: J. M. Walter, E. D. Gingo
3. Essentials of molecular biology: Dovid F. A. , George M . M.
4. An introduction to plant tissue culture : A. Razdan
5. Plant biotechnology: Samtel
6. Plant tissue culture: Narayanswamy, S. ; Tata McGraw-Hill Publishing Company, Ltd. , New Delhi
7. Plant tissue culture: Angela Stafford, Open University press, Buckingham. 1991.
8. Plant tissue culture: Dixon (47)
9. Pharmaceutical Biotechnology: Vyas, Dixit, CBS Publishers, New Delhi. 1998
10. Pharmacognosy: Trease W. C. , Evans G. E. , Baillerie & Tindall, 15th Edi.

6. CLINICAL RESEARCH Theory (3 hrs/wk.)

		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	4	05 – 10
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.	6	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	8	10 – 15
4.	**Phase studies** Introduction, study design, conduct, monitoring of phase I, II, III and IV studies	12	30 – 40
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	15	45 – 60

Reference 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. Cocchetto, Nardi. Managing the Clinical Drug Development Process, 1987, Marcel Dekker Inc.
5. Lelia Duley Barbara. Clinical Trials. 2002, Viva Books Pvt. Ltd.

Web resources

6. www.fda.gov/cder/handbook/preclin
7. www.cato.com/biotech/bio-prod-cro
8. www.niaid.nih.gov/hivvaccines/preclinrd
9. www.qservegroup.com/consulatancy/services/pre_clinical
10. www.pharmahungary.com

7. ADVANCES IN DRUG DELIVERY **Theory (3 hrs/wk.)**

		Hrs	Marks
1.	**Protein & peptide drug delivery system: -**	06	16-22
	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, practical considerations. Importance of Preformulation & formulation considerations, toxicity immunogenicity, 'stability & regulatory perspective.		
2.	**Mucosal drug delivery models: -**	04	08-14
	Buccal, rectal: & vaginal drug delivery. Mechanisms of transports of drugs trough mucosal routes		
3.	**Occular Drug Delivery: -**	04	08-14
	Occular delivery mechanisms & development of Occular controlled release system		
4.	**Transdermal drug delivery system: -**	05	12-14
	Permeation through skin including mechanism, permeation enhancers, invitro skin permeation, technologies for developing Transdermal drug delivery system & evaluation thereof.		
5.	**Oral & Parenteral controlled release system: -**	05	12-14
	Scope, terminology & techniques used, injectable controlled release formulation. Long acting contraceptive formulations. Implantable drug delivery, microspheres liposomes, & nanoparticles & quality control.		
6.	**Site specific drug delivery system: -**	05	12-14
	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.		
7.	**Intrauterine drug delivery system: -**	04	08-12
	Medicated IUDs,, 'Copper lUDs, Harmone released lUDs		
8.	**Regulatory considerations in controlled release modification: -**	04	08-12
	Requirements to demonstrate safety, efficiency & controlled release nature, Bioavailability, assurance, WHO & Indian condition.		
9.	**Methods of enhancing bioavailability: -**	04	08-12
	Solubilisation, Prodrugs, and enhancement of dissolution characteristics, bioavailability enhancer		
10.	**Fundamental polymer sciences: -**	04	08-12
	Use of polymers, hydrogels biodegradable & other polymers in preparation of NDDS		

Reference Books:

1. Remington's pharmaceuticals sciences
2. Novel drug delivery system – Marcel Dekker N. Y.
3. Controlled drug delivery system- Vincent H. L, Marcel Dekker
4. Bentley's textbook of pharmaceuticals – E. A. Rawlin
5. Novel and controlled drug delivery systems - N. K. Jain.

8. PRODUCT DEVELOPMENT **Theory (3 hrs/wk.)**

		Hrs	Marks
1.	**Preformulation studies:**	05	15 – 20
	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.		
2.	**Design of experiments and optimization:**	04	10 – 15
	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.		
3.	**Dosage form development:**	08	30 – 40
	Types, components, manufacturing and evaluation of tablets (coated, uncoated, layered and immediate release), capsules (HGC, SGC, microcapsules), liquids like suspension (coarse suspension, nano suspension), emulsion (conventional, multiple, microemulsion, nanoemulsion) and self emulsifying drug delivery system (SEDDS). cGMP as followed in the manufacturing of above dosage forms.		
4.	**Validation:**	04	10 – 15
	Concept and need of validation, types of validation, process validation, equipment validation and cleaning validation, validation master plan.		
5.	**5. Packaging of pharmaceuticals:**	04	15 – 20
	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.		
6.	**Basics of statistics in product development**	04	10 – 15
	Data collection, summarizing data, proposing hypothesis, 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)		
7.	**Drug regulatory affairs:**	04	10 – 15
	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.		

Reference Books:

1. N. G. Stanley – Wooed; Enlargement and compaction of particle solids; Butterworths.
2. D. M. Parikh; Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
3. H. G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
4. A. Kitahard and A. Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
5. J. T. Cartensen; Drug Stability; Marcel Dekker.
6. G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
7. A. Martin, P. Bustamante and A. H. Chun; Physical Pharmacy; Waverly.
8. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
9. M. N. Rubinstein; Pharmaceutical Technology, Drug stability, John Wiley and sons.
10. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.
11. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
12. P. J. Tarcha; Polymer for Controlled Drug Delivery, CRC Press.
13. P. H. List and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
14. Robinson; Novel Drug Delivery Systems, Marcel Dekker.
15. N. K. Jain; Pharmaceutical product development, CBS publishers and distributors.

9. INDUSTRIAL PHARMACY AND PRODUCTION MANAGEMENT Theory (3 hrs/wk.)

		Hrs	Marks
1.	**Pilot plant scale – up pilot plant design:** tablets, capsules, liquid orals. Parenterals and semisolid preparations. Basic requirements for design of product, facility, equipment selection. Personnel, Pharmaceutical process validation for various products.	5	10 – 15
2.	**Quality Assurance:** GMP considerations, quality assurance and process control. Total quality management and productivity. ISO 9000 Salient features.	6	15 – 20
3.	**Optimization Techniques:** Optimization parameters, classical optimization, statistical design and applied optimization methods.	6	10 – 15
4.	**Production Planning:** Plant site selection, layout and organization of pharmaceutical industrial. Vendor development capacity (plant, machine, human resources) assessment of production rate changes, inventory management costing of product and cost controls, planning product mix.	6	15 – 20
5.	**Drugs and Cosmetics Act:** Requirement related to manufacturing and sale of drugs.	4	10 – 15
6.	**Machinery Engineering:** Introduction to mechanical, electrical and electronic parts of pharmaceutical machinery, equipments. Material handing for various pharmaceutical products.	4	10 – 15
7.	**Safety:** Industrial hazards due to fire, accident, mechanical and electrical equipment, chemical and pharmaceuticals, monitoring and preventive system.	4	10 – 10
8.	**Effluent Testing and Treatment:** Pharmaceutical industry.	4	10 – 15
9.	**Automation:** Flexible manufacturing system. Computer control systems: data acquizition, distribution control and centralized control system. Typical models for solid and liquid manufacturing.	6	10 – 15

Reference Books:

1. A. Jaiswal: Management of quility control and standardization: Kanishka Pubisher, New Delhi.
2. B. Rothery: ISO 14000 and ISO 9000; Gower.
3. D. H. Stamatis: Understanding ISO 9000 and implementing the basics to quality: Marcel Dekker.
4. G. C. Cole: Pharmaceutical production facilities, design and application: Taylor and Francis.
5. J. F. Despautz: Automation and validation of information in Pharmaceutical processing: Marcel Dekker.
6. J. M. Juran and A. B. Godfrey: Juraris quality handbook: McGraw Hill.
7. J. R. Berry and R. A. Nashi Pharmaceutical process validation: Marcel Dekker.
8. P. Gilson. G. Green halgh and K. Kerr: Manufacturing management: Chapman and Hall.
9. P. R. Watt: Tablet machine instruments in pharmaceuticals; John Wiley and Sons.
10. R. F. Brewer: Design of Experiments for process improvement and quality Assurance: Narosa.
11. S. Bolton: Pharmaceutical statistical: Marcel Dekker.
12. S. H. Will and J. R. Stoker; Good Manufacturing Practices for Pharmaceutical: Marcel Dekker.
13. S. N. Katju's; Law and drugs: Law publishers (I) Pvt. Ltd.
14. S. S. Rao: Optimization theory and applications: Wiley Eastern Limited.

10. **QUALITY ASSURANCE** **Theory (3 hrs/wk.)**

		Hrs	Marks
1.	Interpretations of current good manufacturing regulations	4	08 – 10
2.	Auditing function in the Total control of Quality.	4	08 – 10
3.	Process validation and control of components, containers & closures.	5	10 – 15
4.	Production and process controls.	5	10 – 15
5.	Packaging & Labelling control.	3	07 – 10
6.	Laboratory controls.	3	07 – 10
7.	Records and reports.	3	07 – 10
8.	Returned and Salvaged Drug products.	3	07 – 10
9.	Repacking and Re-labeling.	3	07 – 10
10.	Recalls.	3	07 – 10
11.	Problem Analysis and Corrective action Report.	3	07 – 10
12.	Quality control of Biological -international Biological standards.	3	07 – 10
13.	Safety testing, of Pharmaceutical Quality control of Antibiotics, Evaluation of sustained release products.	3	07 – 10

Reference Books:

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

11. **COSMETICOLOGY** **Theory** **(3 hrs/wk.)**

		Hrs	Marks
1.	**Physiological Consideration:** Skin, hair, nail and eye- in relation to cosmetic application.	4	10 – 15
2.	**Rheology of cosmetics:** Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, hair products, creams and lotions.	4	10 – 15
3.	**Manufacturing techniques:** cosmetics creams, powders, compacts, sticks, liquids, foam and aerosol cosmetics.	8	15 – 20
4.	**Evaluation of cosmetics: Performance**, physicochemical, microbiological and psychometric evaluation of cosmetics. Design and Assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives. Testing of moisturizers, deodorants, antiperspirants, sunscreen and anti-aging products.	6	10 – 15
5.	**Clinical safety testing:** Irritation, sensitization, photoirritation, photoallergy, ocular irritation and protocols for the same.	3	10 – 15
6.	**Regulatory requirements: Manufacturing** and sale of cosmetics.	3	10 – 10
7.	**Herbal cosmetics:** Formulation development.	4	10 – 15
8.	**Packaging:** Package development and design for cosmetics including aerosol packs.	5	10 – 15
9.	**Advance in cosmetics:** Liposomes, multiple and micromulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses.	8	15 – 20

Reference Books:

1. J. Knowlton and S. Rearce; Handbook of cosmetic sciences and technology Elsevier science publisher.
2. J. B. Wilkinson and R. J. Moore; Harry's cosmetology; Longman science and Technical.
3. S. N. Katju's; Law of Drugs; Law Publishers (India) Pvt. Ltd.
4. E. G. Thomssen; Modern cosmetics; Universal Publishing Corporation.
5. M. S. Balsam and E. Sagarin; Cosmetics, science and technology; John Wiley and Sons.
6. R. L. Elder; Cosmetic Ingredients, their safety assessment; Pathotox.
7. H. R. Moskowitz; Cosmetic Product Testing; Marcel Dekker.
8. W. C. Waggoner; Clinical safety and efficacy testing of cosmetics; Marcel Dekker.
9. C. G. Gebelein, T. C. Cheng and V. C. Yang ; Cosmetic and pharmaceutical applications of polymers; Plenum.
10. L. Appell; The formulation and preparation of cosmetics, fragrances and flavours; Micelle Press.
11. W. A. Poucher; Poucher's Perfumes, cosmetics and soaps; vol. 3 Chapman and Hall
12. Dr. Laba; 'Rheological properties of cosmetics and toiletries; Marcel Dekker.

12. **PHYTOPHARMACEUTICALS** **Theory** **(3 hrs/wk.)**

		Hrs	Marks
	Source, phytochemistry (isolation, identification, chemical nature) and physiological activities of following phytopharmaceuticals.		
1.	**Anticancer:** Taxol, other taxanes, Camptothecin, vinblastine, Genistein, Etoposide.	12	26 – 36
2.	**Nervous system activities:** Hypericin, Valepotriates, Gingkolides.	07	14 – 20
3.	**CVS activities:** Colenol, Streptokinase.	05	12 – 16
4.	**Anti-inflammatory:** Curcuminoids, Guggulipids, Boswellic acid, Serratioptidase.	08	18 – 24
5.	**Miscellaneous:** Silymarin, Artemisinin, Omega-3 fatty acids.	06	14 – 20
6.	Charantin and momordicosides, Resveretrol, Protamine sulphate, prostaglandins.	07	16 – 24

Reference Books:

1. Pharmacognosy : Trease and Evans, Bailliere & Tindall. 14th edth.
2. Pharmacognosy : Kokate, Puruhit, Gokhale, Nirali Prakashan, Pune, 15th edtn.
3. Biochemistry : Delvin.
4. Alkalods Edited by J. R. F. Manske.
5. Various Research Journals on Natural products and therapeutics.

13. STERILE PRODUCT FORMULATION AND TECHNOLOGY Theory (3 hrs/wk.)

		Hrs	Marks
A)	**FORMULATIONS:**		
1.	**Preformulation:** Physico-chemical properties of materials used in perenteral formulations. Selection of polymeric components. Selection of packaging components.	6	10 – 15
2.	**Formulation of SVP and LVP:** Requirement, components, materials, Pharmacopoeial requirements, special types of parenterals such as suspensions, emulsions, dried forms, sterile diagnostics and radiopharmaceuticals.	6	10 – 15
3	**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.	8	20 – 25
4	**Sustained Release Parenterals: -** Liposomes, and niosomes, nanoparticles, proteins and peptides, implants, loaded erythrocytes.	12	30 – 40
B.	**TECHNOLOGY:**		
	Manufacturing of Parenterals:		
5.	Environmental control: Temperature and humidity control, air handing systems and their validation.	4	10 – 15
6.	Industrial sterilization: Large scale sterilization processes, process selection, specifications, development and validation of process and equipment.	4	10 – 15
7.	Guidelines: Overview of GMP and regulatory guidelines.	5	10 – 15

Reference Books:

1. K. E. Avis, H. A. Liberman and Lanchman; Pharmaceutical dosage forms: Parenteral Medications: Vol. 1, 2, 3, Marcel Dekker.
2. S. J. Turco; Sterile dosage forms: their preparation and clinical application; Lee and Febiger.
3. N. K. Jain; Controlled and novel drug delivery: CBS Publication.
4. J. R. Robinson and H. L. Lee; Controlled drugs delivery: Fundamentals and Applications; Marcel Dekker.
5. F. J. Carleton and J. P. Agalloco; Validation of aseptic pharmaceutical processes: Marcel Dekker.
6. L. A. Trissel: Handbook on injectable drugs; American Society for Hospital Pharmacist Publication.
7. N. A. Halls; Achieving sterility in medical and pharmaceutical products; Marcel and Dekker.

14. **FERMENTATION TECHNOLOGY** **Theory** **(3 hrs/wk.)**

		Hrs	Marks
1.	**Industrial Microorganisms:** Source, characteristics, growth and genetics.	5	10 – 20
2.	**Development of Industrial Fermentation Processes:** Screening, detection and assay of fermentation products, stick cultures, fermentation media, inoculum preparation, scale up of fermentations, increasing product yields, fermentation economics.	10	20 – 30
3.	**Industrial Fermentor:** Batch and continuous operation, requirements and design of Fermentor, control mechanisms for temperature, pH and foam. Sterilization of fermentation equipment. Tank agitators, spargers, heating and cooling equipment. Materials for construction.	10	20 – 30
4.	**Typical Fermentation Processes:** • Antibiotic fermentation: Properties, Biosynthesis and Fermentation of Antibacterial antibiotics –Penicillin, tetracyclines, aminoglycosides, chloramphenicol and macrolides. • Antifugals – Griseofulvin. Antiviral – Bacitracin, hamycin. Antibiotic Production by immobilized living cells. • Enzyme Fermentation: Amylases, Proteolytic enzymes. Other Fermentation: Acetonebutanol, citric acid, glycerol, industrial alcohol, yeast and Vitamins.	10	25 – 30
5.	**Downstream Processing :** Unit operations in downstream processing • Harvesting: Sedimentation, centrifugation, filtration. • Cell Disintegration: Nonmechanical method such as wet milling, high pressure homogenization, treatment extrusion and sonification. • Clarification of crude extract. • Product Entrichment: precipitation, ultrafiltration, extraction. • Chromatography: Gel filtration, ion exchange, hydrophobic and affinity type	10	25 – 30

Reference Books:

1. E. J. Vandamme; Biotechnology of Industrial Antibiotics; Marcel and Dekker.
2. H. J. Rahm and G. Reed : Biotechnology : Verlag Chaemie.
3. L. E. Casida: Industrial Microbiology: Wiley Eastern Limited.
4. G. REED: Prescott and Dunn's Industrial Microbiology: The AVI Publications.
5. Petal: Industrial Microbiology.

15. **QUALITY CONTROL** **Theory** **(3 hrs/wk.)**

		Hrs	Marks
1.	Concept of Therapeutic equivalence and Pharmaceutical equivalence, General steps in Conduct and Analysis of Bioavailability and Bioequivalence Studies.	3	09 – 10
2.	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.	3	09 – 10
3.	Quality Risk Management: Introduction to Quality Risk Management (QRM), Scope, Principles of QRM, Risk management methodology, applications of QRM.	2	06 – 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.	5	15 – 20
5.	Stability testing of API and pharmaceutical products. Evaluation of stability data and stability data package for registration applications.	4	12 – 15
6.	General considerations for clinical trials, Protection of clinical trial subjects, Scientific approaches in design and analysis, development methodology.	3	09 – 10
7.	In-process quality control tests, introduction to Process Analytical Technology (PAT) as a framework for innovative pharmaceutical manufacturing and QA.	3	09 – 15
8.	Evaluation of pharmaceutical container closure systems. Labeling for Human Prescription Drugs and Biological Products. Prescribing information, information necessary for the safe and effective use of a prescription drugs. Development of 'Package inserts' and 'Drug information leaflets.	5	15 – 20
9.	Comparison of QC and QA aspects in International and National Pharmacopoeias.	3	09 – 15
10.	Statistics in drug product development and regulatory approval processes.	3	09 – 15

Reference Books:

1. Design and Analysis of Bioavailability and Bioequivalence studies by Shein-Chung Chow, Jen-Pei Liu, Biostatistics, New York, Marcel Dekker, 2000.
2. A WHO guide to good manufacturing practice (GMP) requirements, World Health Organization, Geneva, 1997.
3. Risk Assessment and Risk Management in the Pharmaceutical Industry Clear and Simple, James L. Vesper, PDA book store.
4. Pharmaceutical Quality Systems by Oliver Schmidt, Interpharm Press Inc, US.
5. Drug Stability: Principles and Practices (Drugs and the Pharmaceutical Sciences) by Jens T. Carstensen (Editor), Christopher Rhodes, M. Dekker, New York.
6. Principles of Clinical Research, by G. Ignazio, Routledge; 1 edition (March 30, 2001).
7. Guide to Clinical Trials, by Bert Spilker, Lippincott Williams & Wilkins; 1st edition 1991.
8. Process Analytical Technology: Books: Edited by Katherine A. Bakeev.
9. Introduction: Process Analytical Technology, http://www. fda. gov /cder/ OPS/PAT. htm.
10. Patient Package Insert as a Source of Drug Information Edited by M. Bogaert, R. v. d. Stichele, J. -M. Kaufman, R. Lefebvre, Excerpta Medica.
11. New Drug Approval Process, Fourth Edition, by Richard Guarino, Informa Healthcare, USA.

16. IMMUNOPHARMACOLOGY AND IMMUNOASSAYS Theory (3 hrs/wk.)

		Hrs	Marks
1.	**Basic Principles:** ➢ Cells of the immune system. ➢ Non specific immunity ➢ The specific immunologic response Antigens and antigen-body binding ➢ Immunologlobulines ➢ The humoral immune response ➢ The cellular immune response ➢ The control of immune response ➢ The complement system	04	10-10
2.	**Pharmacological aspects of clinical conditions involving immunological mechanism** ➢ Hypersensitivity ➢ Delayed hypersensitivity ➢ Immunomodulators	08	20-20
3.	**Current concepts in therapy and research of drugs for:** ➢ Acquired Immuno Deficiency Syndrome (AIDS) ➢ Tissue transplantation (Immunosuppresants and immunoenhancers) ➢ Cancer ➢ Vaccines and sera ➢ Antifertility drugs and vaccine ➢ Drug allergy	16	30-50
4.	**Methods for (invitro and invivo) evaluation of influencing immune system drugs**	04	10-20

5. Immuno assays 08 20-30

- 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)
- Immunomodulators of Indigenous origin (plants)

6. FcReceptors 05 10-10

- Introduction, structure and function of antibodies, conformation of antibodies, Fc8R family,
- Proteins, transcripts and genes: Gene, structure and actions of high affinity Fc receptor *for* immunoglobulin E.
- Fc - receptor mediated killing
- Fc - receptor on T and B lymphocytes
- Immunoglobulin binding factors

Reference Books:

1. Kirkwood E and Catriona L. Understanding Medical Immunology (John Wiley and Sons New York)
2. Humphrey J. H. and White R. G. Immunology for students of Medicine (Blackwell Scientific Publication London)
3. Goodman and Gilmans. The pharmacological Basis of Therapeutics (9th Ed) McGraw Hill 1996.

17. **POLYMER TECHNOLOGY** **Theory** **(3 hrs/wk.)**

		Hrs	Marks
1.	**General Study of Polymer Science:**	10	25 – 35
	Classification of polymers, Macromolecules: structure and properties (molecular mass, molecular weight distribution, conformation and configuration), Major strategies for synthesis of polymers, general methods of preparation of polymers like solution bulk, suspension and emulsions polymerizations with examples. Methods of polymer modification, Solid state properties of polymers, flow characteristics, crystallinity.		
2.	**Evaluation of Polymers in Solution**:	05	15 – 25
	Polymers in solutions: 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.		
3.	**Therapeutic Applications of Polymers:**	07	20 – 25
	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.)		
4.	**Biointeractions of Polymers:**	07	20 – 25
	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), functional excipients and biological response modifiers, polymeric immunoadjuvants and immunomodulators, stimuli responsive systems and intracellular drug delivery.		
5.	**Polymer Drugs**	03	10 – 15
	Prospects of polymer drugs and challenges in polymer therapeutics		
6.	**Regulatory Issues Of Polymer Therapeutics**	02	10 – 15

Reference Books:

1. J. Brandrup, E. H. Immergur; Polymer Handbook ;John wiley and Sons
2. L. H. Sperling, Introduction to Polymer Science, Wiley, NY, 1992.
3. H. Morawetz, Macromolecules in Solution (2nd ed.), Wiley-Interscience, NY, 1975
4. C. Tanford, Physical Chemistry of Macromolecules, John Wiley, NY, 1961.
5. F. W. Billmeyer, Jr. , Textbook of Polymer Science, 3rd Ed. , J. Wiley, New York, 1984.
6. 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.
7. Biomedical Polymers and Polymer Therapeutics, Eds. E. Chiellini et. al. , KluwerCharles G. Gebelein. T. C. Chin and V. C. Yang; Cosmetic and Pharmaceutical Applications of Polymers; Plenum Press, New work.
8. D. S. Soane; Polymer Applications for Biotechnology ; Prentice Hall Inc.
9. J. R. Robinson and V. H. Lee: Controlled Drug Delivery – Fundamentals and Application; Marcel Dekker.
10. N. K. Jain; Controlled and Novel Drug Delivery; CBS publications.
11. P. J. Tarcha; Polymers for controlled Drug Delivery; CRC Press.
12. A. F. Kydonieus; Controlled Release Technologies: Methods, Theory and Application, Vol-I & II; CRC Press Inc.
13. Academic/Plenum Publishers, NY, 2001.
14. Self-Assembling Complexes for Gene Delivery. From Laboratory to Clinical Trial. A. V. Kabanov,
15. P. L. Felgner, L. W. Seymour, Eds. , John Wiley & Sons: New York, 1998.

18. **CLINICAL PHARMACY** **Theory** **(3 hrs/wk.)**

		Hrs	Marks
1.	**Introduction to Clinical Pharmacy**	3	05 – 10
	• Scope objective & goals in healthcare		
	• Practice of Clinical Pharmacy in hospitals & community		
2.	**FUNDAMENTALS OF DISEASES**	5	10 – 15
	• Symptoms & disease identification		
	• General Systemic effects of disease.		
	• CVS & other systemic effects of disease & injury.		
	• Endocrine & metabolic responses to disease & trauma.		
	• Nervous system involvement in disease.		
	• Communicable disease prevention		
3.	**THERAPEUTIC USE OF MEDICINE**	10	20 – 25
	A. Drug Selection & Administration		
	• Problems associated with concomitant therapy		
	• Patient sensitivities, allergies.		
	• Precautions during the use		
	• Diet control		
	B. Reasons for noncompliance : -		
	• Poor standards of labeling, social isolation, complex therapeutic regimens, nature of medication, side effects.		
	• Lack of doctor / pharmacist / patient rapport		
	• Inadequate patient education.		
	C. Strategies for Improving Compliance		
	• Supplementary labeling, simplification of therapeutic regimens, patient counseling, use of warning cards, patient education, patient – package inserts.		
	D. Use of drugs in Geriatric, Pediatric patients & in Pregnancy.		
4.	**MONITORING THE PATIENT IN HEALTH & ILLNESS**	5	10 – 15
	A.		
	• Fluid & electrolyte imbalance.		
	• Cardio-pulmonary dysfunction		
	• Metabolic disorders		
	• Patient follow-up.		

- Discharge interview for hospitalized patients

B. Precautions & Directions during use of medication.

C. Pharmacological & biochemical examinations, their significance.

D. Supervision of therapeutic success, side effects & adverse effects.

5.	**DRUG INFORMATION**	5	10 – 10

- Introduction to information resources available, development of drug information services, drug literature utilization, selection, evaluation & immunization
- Physician - Pharmacist interaction
- Pharmacist - patient interaction

6.	**Therapeutic management of following diseases**	7	15 – 20

a. *Cardiovascular diseases*
   i. Myocardial ischemia.
   ii. Miocardial infraction.
   iii. Conjestive cardiac failure
   iv. Cardiac arrhythmias
   v. Hypertension
   vi. Hyperlipidema

b. *Renal disorders*
   i. Acute renal failure
   ii. Chronic renal failure

c. *Respiratory disorders*
   i. Bronchial asthma
   ii. Chronic obstructive lung disease

7.	**Clinical testing of drugs**	5	10 – 15

Introduction, various phases, ICH guidelines, regulatory affairs.

8.	**Statistical methods in pharmacy**	5	10 – 15

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.

9.	**Examples: Based on above**		10 – 15

Reference Books:

1. Clinical pharmacy practice; C.W. Blissit
2. Clinical pharmacy & therapeutics; Walker Edwards, Churchill Livingston
3. Analysis drug treatment
4. TB of clinical pharmacology; James M. Ritter, Lionel D.
5. Drugs in Pregnancy & lactation; 4th Ed; Gerald, G Briggs, Roger K. Freeman, Williams & Wilkins.
6. Pharmaceutical & Medicine Information Management; Principles & Practice; Andrew S. Robson, Churchill - Livingston.
7. Computer & bio statistics: Paradkar
8. Handbook of Pharmacy Healthcare Diseases & Patient Advice; Ed; R.J. Harman, Pharmaceutical Press; London.
9. Patient care in community practice; R.J. Harman; Pharmaceutical Press, London.
10. Applied therapeutics for clinical pharmacists; Koda Kimble M.N, Applied Therapeutic Inc. San, Fransico.

19. THERAPEUTIC DRUG MONITORING Theory (3 hrs/wk.)

		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	05	05 – 10
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 – 15
3.	**Therapeutic management of diseases** Cardiovascular, renal, respiratory and metabolic disorders	06	10 – 15
4.	**INTRODUCTION TO THERAPEUTIC DRUG MONITORING** ➢ Definition & introduction. ➢ Indication for TDM & clinical applications. ➢ Monitoring plasma drug levels. ➢ Role of Clinical pharmacist in TDM.	06	10 – 15
5.	**TECHNIQUES USED IN TDM** a) Physical methods HPLC, HPTLC, GC b) Immuno assays. RIA, ELISA, EMITH, NIIA	05	10 – 15
6.	**IMPORTANCE OF TDM WITH REFERENCE TO ADVERSE DRUG REACTION**	03	10 - 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, globulines, complete blood count & differential blood count	06	10 – 15

8. TDM OF SPECIFIC DRUGS 09 30 – 40

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

9. Futuristic application of TDM 02 05 – 10

TDM of antiretroviral and anti tubercular drugs

Reference Books:

1. Clinical pharmacy practice - C. W. Blissit.
2. Therapeutic drug monitoring - B. Widdop
3. TDM & Clinical biochemistry – Mike Hallworth
4. Textbook of therapeutics, Drug & disease management - 7th edition - Eric T. Herfindel, Dick. R. Gourley.
5. Recent developments in TDM & Clinical toxicology – I. Sunshine - Marcel – Dekker – 1992.
6. Handbook of TDM. – Simkin
7. TDM – Abbot

Journal references

8. Therapeutic drug monitoring
9. AIDS
10. Clinical pharmacology
11. New England Journal of Medicine