



★★★★★B+
Accredited By NAAC

SHIVAJI UNIVERSITY, KOLHAPUR-416 004. MAHARASHTRA

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शिवाजी विद्यापीठ, कोल्हापूर - ४१६ ००४.

दुरध्वनी : (ईपीएबीएक्स) २६०९००० (अभ्यास मंडळे विभाग- २६०९०९४) तार : युनिशिवाजी

फॅक्स : ००९१-०२३१-२६९१५३३ व २६९२३३३.e-mail:bos@unishivaji.ac.in

SU/BOS/Engg./Pharm/833

Date: 27/4/2009

To,
The Principal,
All Affiliated Pharmacy Colleges.

Subject: Revised syllabi of B.Pharmacy (Sem.-I to VIII) & M. Pharmacy (Sem. I to IV) course under the Faculty of Engineering.

Sir/Madam,

With reference to the subject mentioned above, I am directed to inform you that the university authorities have accepted and granted approval to the revised syllabi of B. Pharmacy (Sem.-I to VIII) & M. Pharmacy (Sem. I to IV) course under the Faculty of Engineering & Technology. This syllabi will be implemented from the academic year 2009-10 i.e. from June 2009 onwards, gradually. A soft copy (C.D.) containing the said syllabi is enclosed herewith.

Further, it is hereby informed that the question papers on the pre-revised syllabi for repeater candidates, if any will be set as mentioned below :-

Sr.No.	Examinations	Two Chances for the examinations to be held in
1	First year B. Pharmacy Sem.I & II	Oct.-2009 & April -2010
2	Second year B. Pharmacy Sem.III& IV	Oct.-2010 & April -2011
3	Third Year B. Pharmacy Sem.IV & V	Oct.-2011 & April -2012
4	Final Year B. Pharmacy Sem.V& VI	Oct.-2012 & April -2013

Sr.No.	Examinations	Two Chances for the examinations to be held in
1	First year M. Pharmacy Sem.I & II	Oct.-2009 & April -2010
2	Second year M. Pharmacy Sem.III& IV	Oct.-2010 & April -2011

You are therefore, requested to bring this to the notice of all students and teachers concerned.

Thanking you,

Yours faithfully,

Sd/-

Dy. Registrar

Enclosed:- As above

Copy f.w.c.s. to -

- 1)The Dean, Faculty of Engg.& Tech.
- 2)The Chairman, B.O.S in Pharmacy.

- 1) Appointment Section .
- 2) Other Exam.- 3

Copy for information and necessary action

SHIVAJI UNIVERSITY KOLHAPUR

**AN ORDINANCE TO PROVIDE FOR THE EXAMINATION LEADING
TO THE DEGREE OF MASTER OF PHARMACY
IN THE FACULTY OF ENGINEERING & TECHNOLOGY
IMPLEMENTED FROM JUNE 2009 ONWARDS**

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.

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 statutory/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 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
			Lectures	Practical	Theory		Practical		
					Hours	Marks	Hours	Marks	
Sem - I	APA	Advanced Pharmaceutical Analysis	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
			Lectures	Practical	Theory		Practical		
					Hours	Marks	Hours	Marks	
Sem - I	APA	Advanced Pharmaceutical Analysis	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
			Lectures	Practical	Theory		Practical		
					Hours	Marks	Hours	Marks	
Sem - I	APA	Advanced Pharmaceutical Analysis	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
			Lectures	Practical	Theory		Practical		
					Hours	Marks	Hours	Marks	
Sem - I	APA	Advanced Pharmaceutical Analysis	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
			Lectures	Practical	Theory		Practical		
					Hours	Marks	Hours	Marks	
Sem - I	APA	Advanced Pharmaceutical Analysis	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
			Lectures	Practical	Theory		Practical		
					Hours	Marks	Hours	Marks	
Sem - I	APA	Advanced Pharmaceutical Analysis	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

SYLLABUS FOR M. PHARM (PHARMACEUTICAL CHEMISTRY)

APA	ADVANCED PHARMACEUTICAL ANALYSIS	Theory	(3 hrs/wk.)		
				Hrs	Marks
1.	Spectroscopic Methods: Introduction application and Structure Elucidation using UV, IR, NMR, Mass Spectroscopy with examples. Electron Spin Resonance (ESR) Spectroscopy: Introduction, principles, instrumentation and application in detection of free radical reactions in chemical and biological systems.			10	20-25
2.	Separation Techniques: Theory, instrumentation, Applications of GLC, HPLC, HPTLC, Chiral Chromatography, Ion Pair Chromatography, Affinity chromatography, Electro kinetic chromatography & Capillary Electrophoresis.			10	20-25
3.	Thermal Analysis: Theory, Instrumentation and Applications of Thermogravimetric Analysis, Differential Thermal Analysis, Differential Scanning Calorimeter.			04	10-15
4.	Immunochemical Techniques: Immuno-electrophoresis, Immuno-precipitation, ELISA, Radioimmuno assays.			05	10-15
5.	X-Ray diffraction: Introduction, Principle, instrumentation and pharmaceutical applications.			05	10-15
6.	Basic principles, classification of laser.			03	10-15
7.	Reference standards: Source, preparation, characterization, usage, storage and records preparation of reference standards of diclofenac sodium, losartan and chloramphenicol.			05	10-15
8.	Introduction to Quality Assurance Techniques: Validation of equipments, processes, products, etc.			03	10-15

Reference Books:

1. Skoog : Principles of Instrumental Analysis (Saunders College Publishing Philadelphia)
2. M.Orchin and H.H-Jaffe - Theory and applications of ultra violet spectroscopy (John Wiley Md Sons, N.Y.)
3. Silverstein. Basseler, Moiril – Spectrometric identification of organic compounds (John Wiley and Sons, N.Y.)
4. Willard, Merritt, Dean - Instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi)
5. J. R. Dyer - Applications of Absorption Spectroscopy of Organic compounds (Prentice Hall, London)

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

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

1. Asymmetric synthesis.
2. Application of partition coefficient, pKa, Steric 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. I. Vogel, Practical Qualitative and Quantitative Organic Chemistry (Orient Longman)

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

	Hrs	Marks
<p>1. Drug Discovery:</p> <p>1. Historical perspective.</p> <p>2. Drug Discovery Strategies in Direct Drug Design (Structure based) and indirect drug design. advantages and limitations of both.</p> <p>3. Target selection and lead identification</p> <p> i. Natural product sources</p> <p> ii. Fermentation / Microbial sources</p> <p> iii. Synthetic</p> <p>4. Structure activity relationships - Binding role of -OH groups, -NH₂ groups, aromatic rings, double bonds, ketones and amides.</p> <p>5. Bioinformatics in drug discovery.</p>	09	20-28
<p>2. Pharmacogenomics and informatics: Genomics – types of genomics, bioinformatics, chemoinformatics, proteomics, barriers to progress of pharmacogenomics progress.</p>	09	20-28
<p>3. QSAR:</p> <p>1. Parameters - Lipophilicity, electronic, Steric factors.</p> <p>2. Quantitative Models:</p> <p> i. Hansch analysis.</p> <p> ii. Free Wilson Analysis.</p> <p> iii. Mixed approach.</p> <p>3. Other QSAR Approaches.</p> <p>4. Applications of Hansch Analysis, Free Wilson Analysis.</p>	09	20-28
<p>4. Molecular Modeling in Drug Design: Introduction to Molecular Modeling: Concepts and Methods.</p> <p>1. Molecular Mechanics - force fields (Potential energy function).</p> <p>2. Energy Minimization Methods - Steepest, descent. Conjugate gradients, Newton methods (Non mathematical).</p> <p>3. Conformational Analysis</p> <p> i) Systematic search.</p> <p> ii) Monte Carlo simulations.</p> <p> iii) Molecular dynamics simulations.</p> <p>4. Ligand design based on 3D structure of receptor /enzyme.</p> <p>5. Computer assisted drug design.</p>	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 Kubing - QSAR, Hansch Analysis and Related approaches Vol I.
3. Poul Krogsgaard 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)

APA	ADVANCED PHARMACEUTICAL ANALYSIS	Theory	(3 hrs/wk.)		
				Hrs	Marks
1.	Spectroscopic Methods: Introduction application and Structure Elucidation using UV, IR, NMR, Mass Spectroscopy with examples. Electron Spin Resonance (ESR) Spectroscopy: Introduction, principles, instrumentation and application in detection of free radical reactions in chemical and biological systems.			10	20-25
2.	Separation Techniques: Theory, instrumentation, Applications of GLC, HPLC, HPTLC, Chiral Chromatography, Ion Pair Chromatography, Affinity chromatography, Electro kinetic chromatography & Capillary Electrophoresis.			10	20-25
3.	Thermal Analysis: Theory, Instrumentation and Applications of Thermogravimetric Analysis, Differential Thermal Analysis, Differential Scanning Calorimeter.			04	10-15
4.	Immunochemical Techniques: Immuno-electrophoresis, Immuno-precipitation, ELISA, Radioimmuno assays.			05	10-15
5.	X-Ray diffraction: Introduction, Principle, instrumentation and pharmaceutical applications.			05	10-15
6.	Basic principles, classification of laser.			03	10-15
7.	Reference standards: Source, preparation, characterization, usage, storage and records preparation of reference standards of diclofenac sodium, losartan and chloramphenicol.			05	10-15
8.	Introduction to Quality Assurance Techniques: Validation of equipments, processes, products, etc.			03	10-15

Reference Books:

1. Skoog : Principles of Instrumental Analysis (Saunders College Publishing Philadelphia)
2. M.Orchin and H.H-Jaffe - Theory and applications of ultra violet spectroscopy (John Wiley Md Sons, N.Y.)
3. Silverstein. Basseler, Moiril – Spectrometric identification of organic compounds (John Wiley and Sons, N.Y.)
4. Willard, Merritt, Dean - instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi)
5. J. R. Dyer - Applications of Absorption Spectroscopy of Organic compounds (Prentice Hall, London)

PK	PHARMACOKINETICS	Theory	(3 hrs/wk.)
		Hrs	Marks
1.	Introduction Introduction to pharmacokinetics, mathematical fundamentals, Pharmacokinetic models, application of pharmacokinetics in clinics and drug product development, toxicokinetics and its application.	3	05 - 10
2.	Therapeutic regimen Therapeutic response and toxicity, constant rate regimen and multiple dose regimens	4	10 - 10
3.	Physiological concepts and kinetics Zero order and first order kinetics, movement of drug through membrane, absorption kinetics (intravascular and extravascular), distribution and elimination kinetics, integration with kinetics.	8	10 - 15
4.	Individualization of therapy and variability Variability and it causes variability due to age, weight, sex, diseases (renal, cardio vascular, hepatic, genetics and metabolic disorders). Kinetics of drug interaction	4	15 - 20
5.	Concepts and derivations Assessment of AUC, estimation of half life, estimation of absorption kinetics, Mean residence Time, Blood to plasma ratio, drug accumulation, creatinine clearance.	6	10 - 15
6.	Compartment modelling 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	8	20 - 25
7.	Nonlinear pharmacokinetics Non linear pharmacokinetics of absorption, saturation in transport carriers, dose dependent absorption, nonlinear protein binding, drug elimination by capacity limited pharmacokinetics	7	10 - 15
8.	Special topics in pharmacokinetics 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	5	05 - 10
9.	Problems based on the above chapters		15 - 20

Reference Books:

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

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-demanded/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 in vivo 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 in vivo 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
8. Journal of microencapsulation
9. International journal of pharmaceutics
10. American journal of drug delivery
11. 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)

APA	ADVANCED PHARMACEUTICAL ANALYSIS	Theory	(3 hrs/wk.)	
			Hrs	Marks
1.	Spectroscopic Methods: Introduction application and Structure Elucidation using UV, IR, NMR, Mass Spectroscopy with examples. Electron Spin Resonance (ESR) Spectroscopy: Introduction, principles, instrumentation and application in detection of free radical reactions in chemical and biological systems.		10	20-25
2.	Separation Techniques: Theory, instrumentation, Applications of GLC, HPLC, HPTLC, Chiral Chromatography, Ion Pair Chromatography, Affinity chromatography, Electro kinetic chromatography & Capillary Electrophoresis.		10	20-25
3.	Thermal Analysis: Theory, Instrumentation and Applications of Thermogravimetric Analysis, Differential Thermal Analysis, Differential Scanning Calorimeter.		04	10-15
4.	Immunochemical Techniques: Immunoelectrophoresis, Immuno-precipitation, ELISA, Radioimmuno assays.		05	10-15
5.	X-Ray diffraction: Introduction, Principle, instrumentation and pharmaceutical applications.		05	10-15
6.	Basic principles, classification of laser.		03	10-15
7.	Reference standards: Source, preparation, characterization, usage, storage and records preparation of reference standards of diclofenac sodium, losartan and chloramphenicol.		05	10-15
8.	Introduction to Quality Assurance Techniques: Validation of equipments, processes, products, etc.		03	10-15

Reference Books:

1. Skoog : Principles of Instrumental Analysis (Saunders College Publishing Philadelphia)
2. M.Orchin and H.H-Jaffe - Theory and applications of ultra violet spectroscopy (John Wiley Md Sons, N.Y.)
3. Silverstein. Basseler, Moiril – Spectrometric identification of organic compounds (John Wiley and Sons, N.Y.)
4. Willard, Merritt, Dean - instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi)
5. J. R. Dyer - Applications of Absorption Spectroscopy of Organic compounds (Prentice Hall, London)
6. CN. R. Rao - Chemical applications of IR spectroscopy (Academic press, N.Y.)

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 - Wood; *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.

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 – Wood; 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: 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.	06	20 - 26
3.	Mucosal Drug delivery: 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.	05	10 - 14
4.	Ocular drug delivery: 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.	05	10 - 14
5.	Transdermal drug delivery: 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.	05	10 - 14
6.	Parenteral drug delivery : <ul style="list-style-type: none"> • 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. 	06	15 - 20
7.	Colon specific drug delivery: 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.	05	10 - 14

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.

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.

	Hrs	Marks
<p>1. Absorption:</p> <p>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.</p>	08	20 - 26
<p>2. Distribution:</p> <p>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.</p>	06	15 - 20
<p>3. Metabolism:</p> <p>Drug metabolism, organs and enzymes, chemical pathways, Phase I and Phase II reactions. First pass effect, factors affecting.</p>	08	20 - 26
<p>4. Excretion:</p> <p>Renal and nonrenal routes of drug excretion.</p>	05	10 - 14
<p>5. Integration of kinetics:</p> <p>Interrelationships between pharmacokinetic parameters and physiological variables.</p>	03	05 - 10
<p>6. Pharmacokinetics:</p> <p>Pharmacokinetics in drug discovery and development, pharmacokinetic models, Laplace transformations and concept of compartment modeling.</p> <ul style="list-style-type: none"> • 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. 	06	15 - 20

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|--|------------|
| 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 bioequivalence: | 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)

APA	ADVANCED PHARMACEUTICAL ANALYSIS	Theory	(3 hrs/wk.)		
				Hrs	Marks
1.	Spectroscopic Methods: Introduction application and Structure Elucidation using UV, IR, NMR, Mass Spectroscopy with examples. Electron Spin Resonance (ESR) Spectroscopy: Introduction, principles, instrumentation and application in detection of free radical reactions in chemical and biological systems.	10	20-25	10	20-25
2.	Separation Techniques: Theory, instrumentation, Applications of GLC, HPLC, HPTLC, Chiral Chromatography, Ion Pair Chromatography, Affinity chromatography, Electro kinetic chromatography & Capillary Electrophoresis.	10	20-25	10	20-25
3.	Thermal Analysis: Theory, Instrumentation and Applications of Thermogravimetric Analysis, Differential Thermal Analysis, Differential Scanning Calorimeter.	04	10-15	04	10-15
4.	Immunochemical Techniques: Immuno-electrophoresis, Immuno-precipitation, ELISA, Radioimmuno assays.	05	10-15	05	10-15
5.	X-Ray diffraction: Introduction, Principle, instrumentation and pharmaceutical applications.	05	10-15	05	10-15
6.	Basic principles, classification of laser.	03	10-15	03	10-15
7.	Reference standards: Source, preparation, characterization, usage, storage and records preparation of reference standards of diclofenac sodium, losartan and chloramphenicol.	05	10-15	05	10-15
8.	Introduction to Quality Assurance Techniques: Validation of equipments, processes, products, etc.	03	10-15	03	10-15

Reference Books:

1. Skoog : Principles of Instrumental Analysis (Saunders College Publishing Philadelphia)
2. M.Orchin and H.H-Jaffe - Theory and applications of ultra violet spectroscopy (John Wiley Md Sons, N.Y.)
3. Silverstein. Basseler, Moiril – Spectrometric identification of organic compounds (John Wiley and Sons, N.Y.)
4. Willard, Merritt, Dean - instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi)
5. J. R. Dyer - Applications of Absorption Spectroscopy of Organic compounds (Prentice Hall, London)
6. CN. R. Rao - Chemical applications of IR spectroscopy (Academic press, N.Y.)

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

	Hrs	Marks
<p>1. Introduction :</p> <p>An understanding of the concepts of Quality Assurance, Good Manufacturing Practice and Quality Control as applied to the pharmaceutical Industry.</p>	08	15 - 25
<p>2. Documentation related to Pharmaceutical Industry :</p> <ul style="list-style-type: none"> • 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. 	20	45 - 65
<p>3. Good laboratory Practices (GLP)</p> <p>Regulations , biological evaluation microbiological limit tests, sterility tests for effectiveness of antimicrobial preservative , LD 50 ED 50 teratogenicity , mutagenicity , clinical trials , Bioassays, pyrogens and pyrogen testing safely testing presentation of related data and supporting raw data.</p>	10	25 - 30
<p>4. Related quality systems :</p> <p>ISO, WHO etc, and their applications in pharmaceutical industry.</p>	07	15 - 20

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.

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
<p>1. Rules and Regulations :</p> <p>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.</p>	07	15 - 22
<p>2. Process validation :</p> <p>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.</p>	07	18 - 25
<p>3. Equipment Validation :</p> <p>Installation qualification and operational qualification for sterilization equipments like autoclave, oven and membrane filter.</p>	07	18 - 25
<p>4. Cleaning methods:</p> <p>Analytical method validation requirements and validation of effective cleaning.</p>	06	12 - 17
<p>5. Vendor validation :</p> <p>Vendor audit, sample testing and trend analysis.</p>	06	12 - 17
<p>6. Validation of service :</p> <p>Training, maintenance and packing.</p>	06	12 - 17
<p>7. Validation of electronic data processing :</p> <p>Software validation methodology.</p>	06	12 - 17

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.

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 : HPLC, UV and IR spectrophotometer and dissolution test apparatus.	08	20 - 28
2. Validation of Analytical Method : Validation parameters, accuracy, precision, ruggedness, statistical design and statistical consideration.	08	20 - 28
3. Current good manufacturing Practices.	08	20 - 28
4. Biostatistics : 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.	15	30 - 40
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. Chow and J.P. Liu statistical Design and Analysis in Pharmaceutical Sciences. Marcel, Dekker.

SYLLABUS FOR M. PHARM (PHARMACOLOGY)

APA	ADVANCED PHARMACEUTICAL ANALYSIS	Theory	(3 hrs/wk.)	
			Hrs	Marks
1.	Spectroscopic Methods: Introduction application and Structure Elucidation using UV, IR, NMR, Mass Spectroscopy with examples. Electron Spin Resonance (ESR) Spectroscopy: Introduction, principles, instrumentation and application in detection of free radical reactions in chemical and biological systems.		10	20-25
2.	Separation Techniques: Theory, instrumentation, Applications of GLC, HPLC, HPTLC, Chiral Chromatography, Ion Pair Chromatography, Affinity chromatography, Electro kinetic chromatography & Capillary Electrophoresis.		10	20-25
3.	Thermal Analysis: Theory, Instrumentation and Applications of Thermogravimetric Analysis, Differential Thermal Analysis, Differential Scanning Calorimeter.		04	10-15
4.	Immunochemical Techniques: Immuno-electrophoresis, Immuno-precipitation, ELISA, Radioimmuno assays.		05	10-15
5.	X-Ray diffraction: Introduction, Principle, instrumentation and pharmaceutical applications.		05	10-15
6.	Basic principles, classification of laser.		03	10-15
7.	Reference standards: Source, preparation, characterization, usage, storage and records preparation of reference standards of diclofenac sodium, losartan and chloramphenicol.		05	10-15
8.	Introduction to Quality Assurance Techniques: Validation of equipments, processes, products, etc.		03	10-15

Reference Books:

1. Skoog : Principles of Instrumental Analysis (Saunders College Publishing Philadelphia)
2. M.Orchin and H.H-Jaffe - Theory and applications of ultra violet spectroscopy (John Wiley Md Sons, N.Y.)
3. Silverstein. Basseler, Moiril – Spectrometric identification of organic compounds (John Wiley and Sons, N.Y.)
4. Willard, Merritt, Dean - instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi)
5. J. R. Dyer - Applications of Absorption Spectroscopy of Organic compounds (Prentice Hall, London)
6. CN. R. Rao - Chemical applications of IR spectroscopy (Academic press, N.Y.)

	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.	27	70-110
➤ Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotics, nootropics, antiparkinsonian agents, analgesics, antipyretics.		
➤ Anti-inflammatory agents, anticonvulsants, local anaesthetics, 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.		
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
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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 anaesthetics 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-anxiotic drugs.
6. Determination of PA₂ 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. 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.

Reference Books:

1. Clinical Pharmacy and Therapeutics: Roger and Walkar, Churchill Livingstone 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 Therapeutics - 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 Livingstone 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. Neurological 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 taking. Lippincott.
19. Walton J. Boain's Diseases of the nervous system. Tenth edn.

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. 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 Yourk..
10. Vogel H. G. and Vogel W H. Drug Discovery and Evaluation Pharmacological Assays Springer.

	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- α , 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.	20	50-80
➤ Cholinergic receptors.		
➤ Dopamine receptors.		
➤ Serotonin receptors.		
➤ Hormone receptors.		
➤ GABA receptors.		
➤ Opioid receptors.		
➤ Purinergic receptors.		
➤ Glutamate receptors.		
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)

APA	ADVANCED PHARMACEUTICAL ANALYSIS	Theory	(3 hrs/wk.)		
				Hrs	Marks
1.	Spectroscopic Methods: Introduction application and Structure Elucidation using UV, IR, NMR, Mass Spectroscopy with examples. Electron Spin Resonance (ESR) Spectroscopy: Introduction, principles, instrumentation and application in detection of free radical reactions in chemical and biological systems.	10	20-25	10	20-25
2.	Separation Techniques: Theory, instrumentation, Applications of GLC, HPLC, HPTLC, Chiral Chromatography, Ion Pair Chromatography, Affinity chromatography, Electro kinetic chromatography & Capillary Electrophoresis.	10	20-25	10	20-25
3.	Thermal Analysis: Theory, Instrumentation and Applications of Thermogravimetric Analysis, Differential Thermal Analysis, Differential Scanning Calorimeter.	04	10-15	04	10-15
4.	Immunochemical Techniques: Immuno-electrophoresis, Immuno-precipitation, ELISA, Radioimmuno assays.	05	10-15	05	10-15
5.	X-Ray diffraction: Introduction, Principle, instrumentation and pharmaceutical applications.	05	10-15	05	10-15
6.	Basic principles, classification of laser.	03	10-15	03	10-15
7.	Reference standards: Source, preparation, characterization, usage, storage and records preparation of reference standards of diclofenac sodium, losartan and chloramphenicol.	05	10-15	05	10-15
8.	Introduction to Quality Assurance Techniques: Validation of equipments, processes, products, etc.	03	10-15	03	10-15

Reference Books:

1. Skoog : Principles of Instrumental Analysis (Saunders College Publishing Philadelphia)
2. M.Orchin and H.H-Jaffe - Theory and applications of ultra violet spectroscopy (John Wiley Md Sons, N.Y.)
3. Silverstein. Basseler, Moiril – Spectrometric identification of organic compounds (John Wiley and Sons, N.Y.)
4. Willard, Merritt, Dean - instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi)
5. J. R. Dyer - Applications of Absorption Spectroscopy of Organic compounds (Prentice Hall, London)
6. CN. R. Rao - Chemical applications of IR spectroscopy (Academic press, N.Y.)

7. Higuchi : Instrumental Methods of Analysis (CBS Publishers)
8. Analytical Chemistry by open learning series
9. Wim Kok : Capillary Electrophoresis : Instrumentation and Operation
10. R. J. Hamilton - Introduction to High Performance Liquid chromatography,
(Chapman and Hall, London)
11. Ewing - Instrumental Methods of Chemical Analysis (McGraw Hill Book Co. New York)

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

1. Experiments based on UV-Vis, FT-IR, HPLC, & GC.
2. Interpretation of UV & IR Spectra of some Chemicals & drugs.
3. ELISA Test / LAL Test.
4. Estimation of drugs in biological fluids.
5. Validation of analytical methods.
6. Analysis of OTC Analgesics by High Performance Chromatographic methods.
7. Demonstration of Reverse Phase HPLC by Internal standard method.

Reference Books:

1. Analytical Chemistry by open learning series
2. C. N. R. Rao - Chemical applications of IR spectroscopy (Academic press, N.Y.)
3. Ewing - Instrumental Methods of Chemical Analysis (McGraw Hill Book Co. New York)
4. Higuchi : Instrumental Methods of Analysis (CBS Publishers)
5. J. R. Dyer - Applications of Absorption Spectroscopy of Organic compounds (Prentice Hall, London)
6. M. Orchin and H.H-Jaffe - Theory and applications of ultra violet spectroscopy (John Wiley Md Sons, N.Y.)
7. R. J. Hamilton - Introduction to High Performance Liquid chromatography, (Chapman and Hall, London)
8. Silverstein. Basseler, Moiril – Spectrometric identification of organic compounds (John Wiley and Sons, N.Y.)
9. Skoog: Principles of Instrumental Analysis (Saunders College Publishing Philadelphia)
10. Willard, Merritt, Dean - instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi)
11. Wim Kok : Capillary Electrophoresis : Instrumentation and Operation

	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		
• Ginger officinalis		
iii) Hepatoprotectives		
• Silibum marianum		
• Phyllanthus niruri		
• Picrorrhiza kurroa		
• Andrographis paniculata		
iv) Anticancer		
• Taxus species		
• Camptotheca acuminata		
v) Antifertility		
• Embelica ribes		
• Azadirachta indica		
• Gossypium species		
vi) Nervine Tonic		
• Centella asiatica		
• Acorus calamus		
• Valeriana wallichii		

- 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 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. 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, London, 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)

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 from *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.

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 corylifolia* 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. Pharmacopoeia of India, Ministry of Health, Govt. of India.1966.
3. Practical Pharmacognosy, Kokate C.K. Vallabh Prakashan, New Delhi.
4. Indian Herbal Pharmacopoeia, 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 Morrill T.C. 5th Ed., John Wiley and Sons Inc. 1991.

	Hrs	Marks
<p>1. Plant Extracts, Preparation and standardization Tinospora cardifolia, Curcuma longa, Solanum xanthocarpum, Ocimum santum, Adhatoda vasica, Emblica officinalis, Centella asiatica, Melia Azadirachta, withania somnifera.</p>	11	24 - 32
<p>2. Traditional drug formulations Ayurveda (Asava, Arista, Bhasma, Kwatha, Ghruta, Avalcha) Homoeopathy Siddha Unani Aromatherapy</p>	08	16 - 24
<p>3. Herbal drug formulations Therapeutic drugs used Cosmetics: Skin, Hair.</p>	07	16 - 20
<p>4. Agroproducts of economic significance - Cornoil, Soybean, Spirulina, pectin, Papain.</p>	05	12 - 16
<p>5. Standardization of phyto-pharmaceuticals by HPTLC technique Bacoside. Andrographolide, solasodine, Glycerrhetinic acid, Vasicine, Sennosides</p>	07	16 - 24
<p>6. Standardization of phyto-pharmaceuticals by HPLC technique Amarogention Asiaticoside Cardifoloside Lupeol Solasodine Vasicine</p>	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, London, 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)

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. Extension of structure, chain extensions / contraction.
 - c. Ring expansion / contractions.
 - d. Ring variations.
 - e. Ring fusions.
 - f. Isosters.
 - g. Simplification and rigidification of structures.
 - h. Conformation blockers.
 - 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, filtration 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:		08	20-20
<ul style="list-style-type: none"> • 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. 			
2. Molecular aspects of toxicology :- Cytotoxicity - Molecular Mechanism of cell death, Genetic toxicology		05	10-10
Introduction to carcinogenesis.			
3. Organ toxicology :-		32	70-110
<ul style="list-style-type: none"> • Cytopathology general response patterns and Morphological aspects Necrosis and apoptosis: irreversibility of cell damage and cell death. • Dermatotoxicology: Toxicological, pathology and methodological aspects. • Respiratory toxicology: Toxicological pathophysiology, toxicological pathology and mechanisms of toxicity. • Gastrointestinal toxicology: toxicological pathology and source of intestinal toxicity. • Hepatotoxicology: Mechanisms of liver toxicity and methodology aspects. • Nephrotoxicology : toxicological pathology and biochemical toxicology. • Cardiovascular toxicology; toxicological pathology and methodological aspects. • Toxicology of blood: Pathophysiology, Toxicological pathology and mechanisms of toxicity. • Immunotoxicology: determination of immunotoxic effects and immunotoxicity mechanisms. • Endocrine toxicology. • General reproductive toxicology. • Functional neurotoxicology. • Neurobehavioural toxicology. • Food, nutritional toxicology. • Medical and clinical toxicology. 			

- Ecotoxicology.
- Occupational toxicology.
- Carcinogenicity 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 Definition of Biopharmaceutics, Pharmacokinetic, clinical Pharmacokinetic and its importance	05	10 - 15
2.	Basic concepts 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.	06	15 - 20
3.	Compartment modelling: - <i>a. One compartment open model :</i> 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. <i>b. Multi compartment modeling :</i> 2 compartment and 3 compartment models, determination of compartment models.	08	20 - 30
4.	Absorption of drugs 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.	06	15 - 20
5.	Distribution of drugs :- <i>a) Factors affecting distribution of drugs.</i> 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)	05	10 - 15

b) *Volume of distribution*

Clinical concepts and kinetics of physiological parameters of distribution.

- | | | | |
|----|---|----|---------|
| 6. | Elimination of drug: - <ul style="list-style-type: none">a. Concept of clearanceb. Hepatic metabolism: chemical pathways and factors affecting itc. Renal excretion: principle processes and factors affecting Itd. Non renal excretion:e. Concepts and kinetics of physiological parameters of elimination | 05 | 10 – 15 |
| 7. | Bioavailability: <ul style="list-style-type: none">• 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<ul style="list-style-type: none">Theories of dissolution in-vitro drug dissolution testing models invitro - invivo correlation• Invitro and insitu absorption studies<ul style="list-style-type: none">Various Invitro & insitu models – selection of animalsCorrelation between invitro & invivo studies. | 06 | 15 – 20 |
| 8. | Non linear Pharmacokinetics <p>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)</p> | 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	05	12-18
	a. Chemodemes		
	b. Hybridization		
	c. Mutation		
	d. Polyploidy		
4.	Gene transfer in plants	06	14-20
	a. Using Vectors of <i>Agrobacterium</i>		
	Ti, co-integrative, Intermediate plasmid		
	b. DNA mediated gene transfer		
	Electroporation, Microprojectiles, Micro and macro injection, Liposomes		
	Ultrasonication		
5.	Localization of transferred gene in genetically modified plants	06	14-20
	a. Plant chromosome analysis		
	b. Gene mapping		
	c. Use of markers		
	d. DNA hybridization		
6.	Applications of transgenic plants	06	14-18
	a. Resistance to herbicides, insects, fungus and virus, physiological stress		
	b. Edible vaccines		
7.	Plant tissue Culture	12	24-30
	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		

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: David 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. , Bailliere & 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, Tuskegee 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/consultancy/services/pre_clinical
10. www.pharmahungary.com

7.	ADVANCES IN DRUG DELIVERY	Theory	(3 hrs/wk.)
		Hrs	Marks
1.	Protein & peptide drug delivery system: - Physical aspects, biochemistry of protein drug (structure, properties & stability) general methods of analysis of protein' & peptide drugs, barrier to transport & pharmacokinetics, different route of delivery, practical considerations. Importance of Preformulation & formulation considerations, toxicity immunogenicity, 'stability & regulatory perspective.	06	16-22
2.	Mucosal drug delivery models: - Buccal, rectal: & vaginal drug delivery. Mechanisms of transports of drugs trough mucosal routes	04	08-14
3.	Ocular Drug Delivery: - Ocular delivery mechanisms & development of Ocular controlled release system	04	08-14
4.	Transdermal drug delivery system: - Permeation through skin including mechanism, permeation enhancers, invitro skin permeation, technologies for developing Transdermal drug delivery system & evaluation thereof.	05	12-14
5.	Oral & Parenteral controlled release system: - Scope, terminology & techniques used, injectable controlled release formulation. Long acting contraceptive formulations. Implantable drug delivery, microspheres liposomes, & nanoparticles & quality control.	05	12-14
6.	Site specific drug delivery system: - Active & passive targeting, resealed erythrocyte, monoclonal antibodies drug targeting particulate carrier system, specific drug delivery to targeted organs like brain & colon, freeze drying of Parenteral, environmental controlled Parenteral manufacturing.	05	12-14
7.	Intrauterine drug delivery system: - Medicated IUDs,, 'Copper IUDs, Hormone released IUDs	04	08-12
8.	Regulatory considerations in controlled release modification: - Requirements to demonstrate safety, efficiency & controlled release nature, Bioavailability, assurance, WHO & Indian condition.	04	08-12
9.	Methods of enhancing bioavailability: - Solubilisation, Prodrugs, and enhancement of dissolution characteristics, bioavailability enhancer	04	08-12
10.	Fundamental polymer sciences: - Use of polymers, hydrogels biodegradable & other polymers in preparation of NDDS	04	08-12

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: 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.	05	15 - 20
2.	Design of experiments and optimization: Design of experiment, Terminologies in experimental design. Product, process and response variables. Optimization methodologies with special reference to factorial design, central composite design and mixture designs. Response surface analysis.	04	10 - 15
3.	Dosage form development: 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.	08	30 - 40
4.	Validation: Concept and need of validation, types of validation, process validation, equipment validation and cleaning validation, validation master plan.	04	10 - 15
5.	5. Packaging of pharmaceuticals: Types of primary and secondary packaging materials for pharmaceuticals. Studies on types and suitability evaluation of glass, plastic and rubber as a primary packaging for non-sterile and sterile dosage forms. Regulatory requirements for pharmaceutical packaging.	04	15 - 20
6.	Basics of statistics in product development 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)	04	10 - 15
7.	Drug regulatory affairs: Need of harmonization in pharmaceutical sector, Regulatory requirements of US, UK, domestic and other markets. Concept of NDA and ANDA with the process of patent filing.	04	10 - 15

Reference Books:

1. N. G. Stanley – Wood; 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 handling 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 acquisition, distribution control and centralized control system. Typical models for solid and liquid manufacturing.	6	10 - 15

Reference Books:

1. A. Jaiswal: Management of quality control and standardization: Kanishka Publisher, 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: Juran's quality handbook: McGraw Hill.
7. J. R. Berry and R. A. Nashi: Pharmaceutical process validation: Marcel Dekker.
8. P. Gilson, G. Greenhalgh 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 statistics: 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 Pharmaceuticals 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, Ginkgolides.	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:	10	25 – 30
<ul style="list-style-type: none"> • Antibiotic fermentation: Properties, Biosynthesis and Fermentation of Antibacterial antibiotics –Penicillin, tetracyclines, aminoglycosides, chloramphenicol and macrolides. • Antifungals – 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. 		
5. Downstream Processing : Unit operations in downstream processing	10	25 – 30
<ul style="list-style-type: none"> • Harvesting: Sedimentation, centrifugation, filtration. • Cell Disintegration: Nonmechanical method such as wet milling, high pressure homogenization, treatment extrusion and sonification. • Clarification of crude extract. • Product Enrichment: precipitation, ultrafiltration, extraction. • Chromatography: Gel filtration, ion exchange, hydrophobic and affinity type 		

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

- | | |
|---|-----------------|
| <p>5. Immuno assays</p> <ul style="list-style-type: none"> ➤ 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) | <p>08 20-30</p> |
| <p>6. FcReceptors</p> <ul style="list-style-type: none"> ➤ Introduction, structure and function of antibodies, conformation of antibodies, Fc8R family, ➤ Proteins, transcripts and genes: Gene, structure and actions of high affinity Fc receptor <i>for</i> immunoglobulin E. ➤ Fc - receptor mediated killing ➤ Fc - receptor on T and B lymphocytes ➤ Immunoglobulin binding factors | <p>05 10-10</p> |

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: 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.	10	25 - 35
2.	Evaluation of Polymers in Solution: 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.	05	15 - 25
3.	Therapeutic Applications of Polymers: Polymers for therapeutic applications, biocompatible and biodegradable polymers, biodegradability and biodegradability testing of polymers, applications of biodegradable polymers in parenterals and surgicals, polymer-drug conjugates, self-assembled polymeric carriers (polymeric micelles, polymer-coated liposomes, nanoparticles, microspheres, etc.)	07	20 - 25
4.	Biointeractions of Polymers: 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.	07	20 - 25
5.	Polymer Drugs Prospects of polymer drugs and challenges in polymer therapeutics	03	10 - 15
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
	<ul style="list-style-type: none"> • Scope objective & goals in healthcare • Practice of Clinical Pharmacy in hospitals & community 		
2.	FUNDAMENTALS OF DISEASES	5	10 – 15
	<ul style="list-style-type: none"> • 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
	<i>A. Drug Selection & Administration</i>		
	<ul style="list-style-type: none"> • Problems associated with concomitant therapy • Patient sensitivities, allergies. • Precautions during the use • Diet control 		
	<i>B. Reasons for noncompliance :-</i>		
	<ul style="list-style-type: none"> • Poor standards of labeling, social isolation, complex therapeutic regimens, nature of medication, side effects. • Lack of doctor / pharmacist / patient rapport • Inadequate patient education. 		
	<i>C. Strategies for Improving Compliance</i>		
	<ul style="list-style-type: none"> • Supplementary labeling, simplification of therapeutic regimens, patient counseling, use of warning cards, patient education, patient – package inserts. 		
	<i>D. Use of drugs in Geriatric, Pediatric patients & in Pregnancy.</i>		
4.	MONITORING THE PATIENT IN HEALTH & ILLNESS	5	10 – 15
	<i>A.</i>		
	<ul style="list-style-type: none"> • Fluid & electrolyte imbalance. • Cardio-pulmonary dysfunction • Metabolic disorders • Patient follow-up. 		

	<ul style="list-style-type: none"> • 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
	<ul style="list-style-type: none"> • 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
	<ul style="list-style-type: none"> a. <i>Cardiovascular diseases</i> <ul style="list-style-type: none"> i. Myocardial ischemia. ii. Miocardial infraction. iii. Conjestive cardiac failure iv. Cardiac arrhythmias v. Hypertension vi. Hyperlipidema b. <i>Renal disorders</i> <ul style="list-style-type: none"> i. Acute renal failure ii. Chronic renal failure c. <i>Respiratory disorders</i> <ul style="list-style-type: none"> 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		05	05 - 10
Symptoms and diseases identification, ADRs, prevention of communicable diseases, drug selection and administration, patient non compliance, strategy to improve the compliance			
2. Monitoring the patient in health and illness		04	10 - 15
Fluid and electrolyte imbalance, cardio-pulmonary dysfunction, metabolic disorders, precautions and directions during used of medication, pharmacological and biochemical examinations			
3. Therapeutic management of diseases		06	10 - 15
Cardiovascular, renal, respiratory and metabolic disorders			
4. INTRODUCTION TO THERAPEUTIC DRUG MONITORING		06	10 - 15
<ul style="list-style-type: none"> ➤ Definition & introduction. ➤ Indication for TDM & clinical applications. ➤ Monitoring plasma drug levels. ➤ Role of Clinical pharmacist in TDM. 			
5. TECHNIQUES USED IN TDM		05	10 - 15
a) Physical methods			
HPLC, HPTLC, GC			
b) Immuno assays.			
RIA, ELISA, EMITH, NIIA			
6. IMPORTANCE OF TDM WITH REFERENCE TO ADVERSE DRUG REACTION		03	10 - 10
7. VARIATION OF CLINICAL LABORATORY TESTS DUE TO DRUGS		06	10 - 15
TESTS: -			
Serum Creatinine, blood urea, nitrogen, plasma, glucose, creatine kinase, phosphatase, amylase, bilirubin, serum proteins, globulines, complete blood count & differential blood count			

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