

**Solapur University, Solapur**  
**Third Year B. Pharmacy**  
(w.e.f. June 2012)  
**Semester-V**

Sub Code	Subject	Teaching scheme (Hours/week)	Semester Examination			Sessional examination		Maximum marks for the subject	Minimum marks for Passing the subject
			Duration (Hours)	Maximum marks	Minimum marks for passing	Duration (Hours)	Maximum marks		
3.5.1	Solid Dosage Forms	3	3	80	32	1	20	100	40
3.5.2	Biopharmaceutics	3	3	80	32	1	20	100	40
3.5.3	Medicinal Chemistry-I	3	3	80	32	1	20	100	40
3.5.4	Pharmaceutical Analysis-III	3	3	80	32	1	20	100	40
3.5.5	Pharmacology-I	3	3	80	32	1	20	100	40
3.5.6	Biotechnology	3	3	80	32	1	20	100	40
<b>Practical</b>									
3.5.7	Solid Dosage Forms	3	4	80	32	3	20	100	40
3.5.8	Medicinal Chemistry-I	3	4	80	32	3	20	100	40
3.5.9	Pharmaceutical Analysis-III	3	4	80	32	3	20	100	40
3.5.10	Biotechnology	3	4	80	32	3	20	100	40
3.5.11	Project*	3							
Maximum Marks for the Semester - 1000									
Minimum marks for passing the semester - 500									

**Semester-VI**

Sub Code	Subject	Teaching scheme (Hours/week)	Semester Examination			Sessional examination		Maximum marks for the subject	Minimum marks for Passing the subject
			Duration (Hours)	Maximum marks	Minimum marks for passing	Duration (Hours)	Maximum marks		
3.6.1	Semisolid Dosage Forms	3	3	80	32	1	20	100	40
3.6.2	Medicinal Chemistry-II	3	3	80	32	1	20	100	40
3.6.3	Pharmaceutical Analysis-IV	3	3	80	32	1	20	100	40
3.6.4	Pharmacology-II	3	3	80	32	1	20	100	40
3.6.5	Clinical Pharmacology	3	3	80	32	1	20	100	40
3.6.6	Pharmacognosy-II	3	3	80	32	1	20	100	40
<b>Practical</b>									
3.6.7	Semisolid Dosage Forms	3	4	80	32	3	20	100	40
3.6.8	Medicinal Chemistry-II	3	4	80	32	3	20	100	40
3.6.9	Pharmaceutical Analysis-IV	3	4	80	32	3	20	100	40
3.6.10	Pharmacognosy-II	3	4	80	32	3	20	100	40
3.6.11	Project*	3	4	80	32	3	20	100	40
Maximum Marks for the Semester - 1000									
Minimum marks for passing the semester - 500									

\*The project for Semester-V will be continued in Semester-VI. The Project examination will be conducted by the colleges at the end of Semester-VI and the list of successful candidates shall be submitted to the University.

## **Third Year B. Pharmacy**

### *Semester-V*

#### **3.5.1 Solid Dosage Forms**

##### **1 Tablets:**

Introduction, advantages & disadvantages, types of tablets.

Formulation development: Preformulation of drugs and additives, introduction to tablet additives, need of granulation, mechanisms, manufacturing processes and equipments for wet granulation and dry granulation processes, characterization and evaluation of granules, mechanism, manufacturing process and equipments for Direct compression technique, Tablet compression machines, types of press tooling, manufacturing problems and remedies thereof, evaluation of tablets as per IP.

Tablet Coating: introduction and concept of tablet coating, types of tablet coating including Sugar, film and enteric coating, materials, processes employed and equipments for tablet coating, manufacturing problems during tablet coating and remedies, evaluation of coated tablets

Layouts of tablet manufacturing section

##### **2 Capsules:**

Introduction to capsule as a dosage form and concept of size selection of capsules

Hard gelatin capsules: Preparation of hard gelatin capsule shell, standards and defects thereof, Formulation, filling, processing and capsule filling equipments, problems in capsule filling and remedies thereof, in-process quality control and quality control parameters.

Soft gelatin capsules: formulation and development, manufacturing, processing and equipments, in-process quality control and quality control parameters.

##### **3 Microcapsules/Microspheres (Microencapsulation):**

Importance of microcapsule and microsphere in pharmacy, methods of preparation: Phase separation, coacervation, multi-orifice centrifugal methods, spray congealing, polymerization and Air suspension technique, pan coating and other techniques, evaluation of microcapsules.

##### **References:**

1. Remington "The science and practice of pharmacy" 21st Ed., Mack publishing company, 2005.
2. James J.Wells " Pharmaceutical Preformulation: The physicochemical properties of drug substances " Ellis Horwood, Chichester, UK,1988
3. H.C.Ansel; N.G.Popovich; L.V.Allen "Pharmaceutical dosage forms and Drug Delivery systems" 9th edition, Wolters kluwer- Lippincott Williams and wilkins, 2009.
4. L.Lachman; H.A.Lieberman; J.L.Kanig "The Theory and Practice of Industrial Pharmacy" 3<sup>rd</sup> edition; Verghese publishing House, Mumbai 1991. Special Indian edition, 2009.
5. M.E.Aulton "Pharmaceutics: The design and manufacture of medicines" 3rd edition; Churchill livingstone, 2007.
6. Bentley's "Test book of Pharmaceutics" Bailliere Tindall; 8th edition; ELBS Publication, 1996.
7. G.S.banker, R.K.Chalmers "Pharmaceutics and Pharmacy Practice "J.B. Lippincott Company, Philadelphia, PA, 1982.
8. J.Swarbrick; J.C.Boylan "Encyclopedia of pharmaceutical technology" Marcel Dekker, 1998.
9. H.A.Lieberman, L.Lachman and J.B.Schwartz "Pharmaceutical dosage forms: Tablets" Marcel Dekker, Vol. I, II, III 1998.

### **3.5.7 Solid Dosage Forms**

#### **1. Tablets:**

Preparation and evaluation of tablets by direct compression.

Preparation and evaluation of tablets by wet granulation.

Preparation and evaluation of tablets by dry granulation.

Evaluation of granules- Carr's Index and Hausner's ratio.

Evaluation of Tablets: Hardness, Friability, Weight variation, Tablet porosity, Dimensions, Disintegration time, Dissolution time.

#### **2. Capsules:**

Filling of powder/granules in hard gelatin capsule and its evaluation as per official compendia.

#### **3. Tablet Coating (Demonstration)**

#### **4. Microencapsulation:**

Preparation and evaluation of microencapsulated products.

#### **5. Visit to Pharmaceutical Manufacturing Plant**

### 3.5.2 Biopharmaceutics

#### 1. Introduction to Biopharmaceutics, Pharmacokinetics:

Their role in drug and formulation development, Biopharmaceutical Classification System

#### 2. Biopharmaceutics:

**Absorption:** Mechanisms and factors affecting drug absorption, theories of dissolution

**Distribution:** Factors affecting distribution. binding of drugs to plasma and tissue components, miscellaneous factors, volume of distribution, distribution coefficient and effective partition coefficient.

**Elimination:** Routes of elimination, factors affecting elimination, enzyme induction and enzyme inhibition, clearance, extraction ratio, extra-hepatic circulation.

#### 3. Pharmacokinetics:

Significance of plasma drug concentration measurement.

Pharmacokinetic models - Definition and classification.

Compartment kinetics- One compartment model- I.V. Bolus Dosing, I.V. infusion and extra-vascular administration, multi-compartment models (No mathematical derivation).

#### 4. Non-linear pharmacokinetics:

Causes of Non-linearity, Michaelis Menten equation

#### 5. Bioavailability and bioequivalence:

Measures of bioavailability,  $C_{max}$ ,  $t_{max}$ , and Area Under-Curve (AUC).

Curve fitting (method of Residuals), regression procedures.

Design of single dose bioequivalence study and relevant statistics.

ICH guidelines and review of regulatory requirements for conduction of bioequivalent studies.

#### References:

1. Notari R.E. "Biopharmaceutics and Pharmacokinetics - An Introduction" Marcel Decker.
2. Lachman L., Lieberman H.A., Kanig J.L. "The Theory and Practice of Industrial Pharmacy". Varghese Publishing House.
3. Milo Gibaldi, "Biopharmaceutics & Clinical Pharmacokinetics" Lea & Febiger, Philadelphia.
4. Leon Shargel and Andrew B.C. "Applied Biopharmaceutics & Pharmacokinetics" Appleton Century-Crofts.
5. Swarbrick J. "Current Concepts in Pharmaceutical Sciences: Dosage form design and Bioavailability". Lea & Febiger, Philadelphia.
6. Brahmankar D.M, Jaiswal S.B, "Biopharmaceutics and Pharmacokinetics-A Treatise", Vallabh Prakashan, New Delhi.
7. Rowland and Tozer: "Textbook of clinical Pharmacokinetics", Walter-Kluwer (India) Ltd, New Delhi, 2007
8. Jambhekar S.S. and Breen P.J. "Basic Pharmacokinetics", Pharmaceutical Press, London, 2009
9. Bhise S.B., Dias R.J., Dhawale S.C. and Mali K.K. "Lab Manual of Biopharmaceutics and Pharmacokinetics, Trinity Publishing House, 2011
10. Niazi S. "Handbook of Bioequivalence Testing", Informa Healthcare, New-York, 2007
11. Dr. Shobha Rani H., Sehgal R. and Dr. Rajat Sethi. "Elements of Pharmacovigilance", Kongposh Publications, New Delhi
12. ICH Guidelines Website

### 3.5.3 Medicinal Chemistry-I

#### 1. Basic principles of medicinal chemistry:

Physiochemical properties of drug molecule and biological action (solubility, surface activity, dissociation constant, drug shape, bio-isosterism, molar refractivity, partition coefficient, hydrogen bonding, ionization, complexation protein binding).

#### 2. Introduction to receptor concept:

Introduction, affinity, receptor and biological response, drug-receptor interaction, forces involved in drug receptor interactions, receptor theories, conformational flexibility and multiple mode of action.

#### 3. Metabolism:

Introduction to drug metabolism

Factors affecting drug metabolism (Genetic factors, Physiological factors, Pharmaceutical factors)

Metabolic processes

Phase I (Oxidation, Reduction, Hydrolysis)

Phase II (Conjugation- Glucouronide, Acetylation, Methylation, Sulfate conjugation)

#### 4. The following classes of drugs should be studied in relation to:

Classification

Chemical nomenclature

Mechanism of action

Synthesis of compounds with asterisk\*

Structure-activity relationship (SAR)

Uses

#### a. Oral Hypoglycemic agents

First and second generation of Sulfonyl ureas, Tolbutamide\*, Chlorpropamide\*, Tolazamide, Acetohexamide, Glyburide, Glipizide, Glimepiride, Biguanides, Metformin, Phenformin.

#### b. Diuretics

Osmotic diuretics- Mannitol

Carbonic anhydrase inhibitors- Acetazolamide, Methazolamide, Dichlorophenamide.

Thiazide Diuretics- Chlorthiazide, Hydrochlorthiazide\*, Chlorothalidone.

Loop diuretics- Ethacrynic acid, Furosemide\*

Potassium sparing Diuretics- Spironolactone, Triamterene

#### c. Antiamoebic Agents

Ipecac Alkaloids- Emetine

Azole- Metronidazole\*, Tinidazole

Others- Diloxanide furoate

#### d. Anthelmintics

Trematode diseases (Schistosomiasis) - Lucanthone, Hycanthone, Niridazole, Oxamniquine, Praziquantel.

Cestode disease (Tapeworm) - Niclosamide\*

Nematode infections - Onchocerciasis ("river blindness") - Diethylcarbamazine

Gastrointestinal nematode infections - Benzimidazole like Mebendazoles\*, Parabendazole

Others- Pyrantel pamoate, Levamisole

**e. Antibiotics**

$\beta$ -lactam antibiotics- Penicillins - Penicillins-G and Penicillins-V, Amphotericin, Amoxicillin, Oxacillin, Cloxacillin, Dicloxacillin, Nafcillin. Methicillin, Becampicillin, Pivampicillin  
Cephalosporins- Cephalexin, Cephalethin, Cefaxitin, Cefuroxime, Cefotaxime, Cefepine, cefpirone.

Tetracyclines

Macrolides

Aminoglycoside

Polypeptides

Lincomycins

**References:**

1. Chemistry by Ashutosh Kar, 1<sup>st</sup> edition, New Age International Publications.
2. Vogel's Elementary M.E. Wolf: Burger's Medicinal Chemistry, John Wiley and Sons, New York.
3. R.F. Doerge, Wilson & Gisvold's: Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott.
4. W.O. Foye: Principles of Medicinal Chemistry, Lea & Febiger, Philadelphia.
5. D. Lednicer and L.A. Mitschier: All Organic Chemistry of Drug synthesis Vol. 1, II & III John Wiley and Sons, New York.
6. S.N. Pandeya: A Textbook of Medicinal chemistry, Vol-I, S.G.Publishers, Varanasi.
7. Ashutosh Kar: Medicinal Chemistry, Wiley Eastern, Ltd., New Delhi
8. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry by Wilson and Gisvold, J. Lippincot Co. Philadelphia.
9. Medicinal Chemistry-A Biochemical Approach by Nogrady T, Oxford University Press New York, Oxford.
10. Antibacterial Chemotherapeutic Agents by SL Dax, Blackie Academic and Professional Publications, Chapman and Hall, 1997.
11. Principles of Medicinal Chemistry by Kadam SS, Mahadik KR, Bothara KG, Vol. I & II, 10 th Edition, Nirali Prakashan.
12. Introduction to Medicinal Chemistry' – How Drugs Act and Why by Alex Gringauz,
13. Willey-VCH Publication 1997.
14. Practical Organic Chemistry by Mann FC & Saunders BC, The English Language
15. Book Society and Longman Group Limited, London.
16. Vogel's A Text book of Practical Organic Chemistry by Vogel, 3<sup>rd</sup> edition, The English language book society and Longman group limited, London.
17. Advanced practical Medicinal Practical Organic Chemistry Small Scale Preparation by Arthur I., 2<sup>nd</sup> Edition, Part-I, CBS Publication.

### 3.5.8 Medicinal Chemistry-I

Synthesis and characterization (Melting Point, TLC, Element/s detection and Functional group tests) of the following compounds

1. 8-Hydroxyquinoline
2. Benzylideneacetophenone (Chalcone)
3. 2,3-Diphenylquinoxaline
4. Fluorescein
5. Dibenzylacetone
6. Coumalic acid
7. 7-Hydroxy-4-methylcoumarin

### 3.5.4 Pharmaceutical Analysis-III

#### 1. Basic concepts in Spectroscopy:

Introduction: Electromagnetic radiation, EMR spectrum, wavelength, wave number, frequency, atomic spectra, molecular spectra.

#### 2. UV-Visible absorption spectroscopy:

Introduction, Origin and theory of UV spectra, Bathochromic and Hypsochromic shift, Choice of solvents, Beer-Lamberts Law, Instrumentation: Light sources UV & Visible, Monochromators: Filters, Gratings. Cells: Silica, glass, quartz, Detectors: Photo tubes, Photo diodes. Readout system, Spectrophotometer: Single beam spectrophotometer, Double beam spectrophotometer, Standard absorptivity value, Use of calibration graph, Single or Double standardization, Optimum conditions for spectrophotometric measurements, Quantitative spectrophotometric assay of medicinal substances, assay of substances in multi component sample, Application to structural analysis with special emphasis on Woodward Feiser rule.

#### 3. Fluorescence Spectroscopy:

Introduction, Fluorescence spectra, Excitation and emission spectra, Instrumentation, Factors affecting fluorescence intensity, Quantitative aspects, Applications of spectrofluorimeters and photofluorimeters.

#### 4. Atomic absorption spectrophotometry:

Principle, Differences between atomic absorption spectroscopy and flame emission Spectroscopy, Advantages of AAS over FES, Instrumentation-Single and double beam Spectrophotometers, Limitation, Applications.

#### 5. Flame Photometry:

Principle, Instrumentation, Interferences in Flame Photometry, Applications.

#### References:

1. Bassett J, Denny R C, Jeffery G H, Mendharn J, Vogel's Textbook of Quantitative Inorganic Analysis, ELBS, Longman, London.
2. Grant- Statistical Quality control (McGraw Hill).
3. Beckett A H and Stenlake J B, Practical Pharmaceutical Chemistry Vol. I and II, The Anthlone Press of University of London.
4. Gary Christian- Analytical Chemistry (John Wiley).
5. Instrumental methods of Analysis- Ewing.
6. Higuchi & Brochmann- Hanssen- Pharmaceutical Analysis- (Interscience).
7. Garrat- The quantitative analysis of Drug (Toppan & Co.)
8. Analytical Chemistry an introduction, Skoog, West, Holler, 6th Edition.
9. Florey- Analytical profiles of drug substances (Academic press).
10. Vogel Text Book of Practical Organic Chemistry – 5th edition
11. Pharmaceutical Analysis Vol. II, A. V. Kasture, S. G. Wadhodkar, K. R. Mahadik, H. N. More, Nirali Publication.
12. Instrumental methods of Analysis- Willard, Dean, Merrit and settle- (Wadsworth Pub. Co.)
13. Merck Index
14. Pharmaceutical Drug analysis by Ashutosh Kar.
15. Principles of Instrumental analysis, Skoog, Holler, Nieman, 5th Edition.
16. IP, BP, USP, EP and International Pharmacopoeia.
17. Meites-Hand book of Analytical Chemistry (McGraw Hill).
18. Hamilton, Simpson and Ellis- Calculation of Analytical Chemistry (McGraw Hill).
19. Instrumental methods of Chemical Analysis by B. K. Sharma, 13th Edition.
20. Spectrometric Identification of Organic Compounds by Silverstein, Webster, 6th Edition.
21. P.S. Kalsi. Spectroscopy of organic compounds (New age international Ltd.)
22. William Kemp. Organic spectroscopy. (ELBS)
23. Instrumental methods of chemical analysis, G.R.Chatwal and S.K.Anand, Himalaya publishing house.

### 3.5.9 Pharmaceutical Analysis-III

1. Study of UV-Visible spectrophotometer, colourimeter, fluorimeter, flame photometer.
2. Calibration of UV-Visible spectrophotometer as per I.P.
3. Assay of following formulations/ drugs using UV-Visible determination as per I.P.
  - Paracetamol Tablet
  - Rifampicin Capsule
  - Albendazole Tablet
4. Colourimetric estimations: Any two
5. Assay by fluorimetry - Quinine sulphate.
6. Determination of  $\text{Na}^+$  or  $\text{K}^+$  from NaCl or KCl by flame photometry after preparing calibration curve.

### 3.5.5 Pharmacology-I

#### 1. General principles of pharmacology:

Introduction to Pharmacology- Definitions and scope of pharmacology.

Nature and sources of drugs, Essential drug (medicine) concept.

Routes of drug administration with special reference to their advantages and disadvantages.

#### 2. Pharmacokinetics:

Biological membranes- structure, types, properties and functions of biological membranes.

Physicochemical factors and processes in transfer of drugs across the biological membranes.

Drug absorption, Bioavailability, factors affecting Drug Absorption and Bioavailability.

Distribution, Protein Binding and Storage of Drugs in body.

Metabolism (Biotransformation) - General considerations, Phase-I & Phase-II, CYP-450 system, Enzyme Inhibition, Enzyme Induction.

Excretion (Elimination).

#### 3. Pharmacodynamics:

Site and Mechanisms of drug action.

Drug Receptors- Basic discussion about receptors, classification and families of receptors, Drug effects and regulation of receptors.

Drug-receptor interactions and their effects, affinity, intrinsic activity and efficacy, dose response relationships and therapeutic index, biological half life.

Drug Toxicity in man - Toxic effects of drugs on different systems, organs & tissues and its clinical significance.

#### 4. Pharmacology Autonomic Nervous System:

Autonomic Nervous system-General Considerations

Cholinergic drugs

Anti-cholinergic drugs

Neuromuscular blocking agents

Adrenergic drugs

Anti-adrenergic drugs

Ganglion stimulants and blockers

Skeletal Muscle relaxants

#### References:

1. Satoskar R.S. and Bhandarkar S.D.: Pharmacology & Pharmacotherapeutics, Popular Prakashan, Bombay.
2. Tripathi K.D.: Essentials of Medical Pharmacology, Jaypee Brothers, Medical Publishers, New Delhi.
3. Goodman and Gillman: Pharmacological Basis of Therapeutics, McGraw-Hill, Medical Publishing Division, New York.
4. Rang H.P. and Dale M.M.: Pharmacology, Churchill Livingstone, Edinburgh.
5. Katzung B.G.: Basic and Clinical Pharmacology, Lange Medical Publications, California.
6. Bowman W.C. and Rand M.J.: Textbook of Pharmacology, Blackwell Scientific Publications, Oxford.
7. Craig C.R. and Stitzel R.E.: Modern Pharmacology, Little Brown and Co., Boston.
8. Melman K.I. and Morelli H.F.: Clinical Pharmacology: Basic Principles in Therapeutics, Macmillan Press, New York.
9. Laurence D.R. and Bennett P.N.: Clinical Pharmacology, Churchill Livingstone, Edinburgh.
10. P.N Bennett & M J Brown.: Clinical Pharmacology, Churchill Livingstone, Edinburgh.
11. Bevan J.A. and Thompson J.H.: Essentials of Pharmacology, Harper and Row Publishers, Philadelphia.

12. Drill V.A.: Pharmacology in Medicine, McGraw Hill Co., New York.
13. Grollman A.: Pharmacology & Therapeutics, Lea & Fabiger, Philadelphia.
14. Avery G.S.: Drug Treatment, Adiss Press, Sydney.
15. Das M.M. and Dutta S.K.: Ghosh's Modern Concepts on Pharmacology & Therapeutics, Hilton & Co., Calcutta.
16. Krantz and Carr: Pharmacology Principles of Medical Practice, Williams & Wilkins Co, Baltimore.
17. Pharmacopoeia of India (1985), Controller of publication, Delhi.
18. Pradhan S.N., Maickel R.P. and Dutta S.N.: Pharmacology in Medicine-Principles and Practice, S.P. Press International Inc., Maryland.
19. P Jagadish Prasad.: Conceptual Pharmacology, Universities Press(India), Pvt Ltd. Hyderabad.

### 3.5.6 Biotechnology

#### 1. Introduction:

Definition, scope related to pharmaceutical industry and achievements.

#### 2. Fermentation technology:

Construction and working of conventional fermenter, downstream processing, fermentation monitoring, in-situ recovery of fermentation products. Bioconversion and biotransformation, General applications of fermentation in manufacturing of antibiotics (Penicillin, streptomycin) dextran, Vitamin B12, Production of single cell proteins, Definition of BOD and COD

#### 3. Tissue culture:

Plant tissue culture - Introduction to plant cell, media & laboratory requirements for tissue culture Types of tissue and cell cultures: Callus, suspension, Protoplast culture & protoplast fusion, Germplasm storage & cryopreservation

Animal tissue culture– Requirements, media, culture techniques for anchor dependant and anchor independent animal cells, passaging, trypsinization, preservation of cell cultures, cell growth.

#### 4. Enzyme technology:

Enzyme production, Methods for enzyme immobilization (adsorption. Covalent binding. Entrapment. Matrices with example) Applications.

#### 5. Genetic Engineering:

Central dogma (DNA replication, transcription and translation) Details of restriction endonuclease, Ligases, vectors (plasmid, cosmid), rDNA Technology, gene transfer, gene expression Polymerase chain reaction (PCR), DNA sequencing, Blotting techniques and electrophoresis, Gene machine, Production of Insulin, Human growth hormone, Interferon. DNA hybridization, Human gene therapy.

#### 6. Immunology and health:

Immunological products- vaccines & sera – definitions and classification outline of general method of preparation of bacterial & viral vaccines. Hybridoma technology and MAbs production, Applications of MAbs.

#### References:

1. U. Satyanarayana., Biotechnology, 1st Edition, 2005, Books and Allied (P) Ltd. Kolkata.
2. Trevan Keshav, Biotechnology, 4th Edition, 1990, New Age International Ltd. Pub., New Delhi
3. Casida L. E., Industrial Microbiology, 2000, New Age International, Delhi.
4. Freifelder David, Molecular Biology, 2nd Edition, 1998, Narosa Publishing House.
5. Kumar H. D., Textbook of Biotechnology, II Ed., 1991, East West Press Pvt. Ltd., New Delhi
6. Hugo W. B., Russell A. D., Pharmaceutical Microbiology, 6th Edition, 1998
7. J. I. Disouza, Killedar S. G., Biotechnology and Fermentation Process, Nirali Prakashan.
8. Stanbury P. F., Whitekar A. and Hall S. J., Principles of Fermentation Technology, 2nd Edition, 1997, Aditya Books (P) Ltd., New Delhi.
9. Vyas, S. P., Dixit V. K., Pharmaceutical Biotechnology, 1st Edition, 1999, CBS Publishers and Distributors, Delhi
10. Singh B. D., Biotechnology, 2001, Kalyani Publisher.
11. Tortora, An introduction to microbiology, 9th edition, Pearson publication

### 3.5.10 Biotechnology

#### 1. Industrial Microbiology

Soil sampling for micro-organisms and screening them for antibiotic/ enzyme (cellulose etc.) producing organism.

Fermentation of antibiotics / vitamins / wine.

#### 2. Plant Biotechnology

Preparation of plant cell culture media

Development of callus or tissue culture

#### 3. Molecular Biology

Replica plating for selection and isolation of bacteria.

Isolation of DNA / RNA / plasmid DNA from blood cells / plant cells or bacterial cells.

Quantitation of extracted DNA ( $OD_{260}$  /  $OD_{280}$ )

SDS PAGE or Gel electrophoresis

Colorimetric estimation of DNA or RNA

#### 4. Enzyme technology

Immobilization of enzymes and cells by calcium alginate/ Gelatin/ agar

Enzyme activity

Restrictional digestion activity of restrictional enzyme on DNA or RNA

#### 5. Immunology

Antigen-Antibody reaction.

## *Semester-VI*

### **3.6.1 Semisolid Dosage Forms**

#### **1. Introduction:**

Classification, structure of skin, penetration, absorption and bioavailability of drugs, factors affecting drug permeability.

#### **2. Ointments:**

Ointment bases and their selection, properties of the drug and the base governing drug release from ointments, manufacturing processes and equipments, packaging and evaluation.

#### **3. Creams:**

Definition, advantages and disadvantages, types, ingredients, formulation and stability of creams and evaluation.

#### **4. Gels and Jellies:**

Definition, natural and synthetic gelling materials, types of gels, formulation and components, stability and evaluation.

#### **5. Paste:**

Definition, advantages and disadvantages, types, ingredients, formulation and evaluation.

#### **6. Cosmetics:**

Definition, Classification, Formulation and Evaluation of following preparations;

Skin: Vanishing cream and cold cream.

Eyes: eye shadow, Mascara.

Lips: Lipstick.

#### **References:**

1. Banker and Rhodes. Modern Pharmaceutics, 4th ed 2002 Marcel Dekker Inc.
2. E.A.Rawlins: Bentley's Textbook of Pharmaceutics, University Printing House, Oxford, 1988.
3. James Swarbrick and James C. Boylan: Encyclopedia of pharmaceutical Technology, Marcel Dekker Inc. New York.
4. L. Lachman, H. A. Lieberman and J. L. Kaing: The Theory and practice of Industrial Pharmacy, Vargheese Publishing House, Mumbai, 1987.
5. M. E. Aulton: Pharmaceutics, Science of Dosage Form Design.
6. Martin: Physical Pharmacy, Varghese Publishing House, Mumbai, 1991.
7. Pharmaceutical Dosage Forms and Drug delivery systems. and 7th Ed. Ansel, Lippincott Williams and Wilkins, PA, 1999.
8. Remington's "The Science and Practice of Pharmacy", 20th Ed; 2000, Lippincott. Williams and Wilkins.
9. Sanju nanda, Arun Nanda, Roop K.khar, Cosmetic Technology, Birla publication, 2007.
10. E.G.Thomssen, Modern Cosmetics, Universal Publishing Corporation, 2006.

### 3.6.7 Semisolid Dosage Forms

Formulation, Preparation and Evaluation of the following dosage forms.

1. **Ointments:**

Pain balm

Antifungal ointment

Medicated Gel

Anti-acne preparation

Non staining Iodine ointment with Methyl Salicylate

Evaluation Parameters: pH, Spreadability & Organoleptic properties.

2. **Creams:** any two

3. **Gels:** any two

4. **Paste:** any two

5. Study of Batch Manufacturing Record

### 3.6.2 Medicinal Chemistry-II

**The following classes of drugs should be studied in relation to:**

Classification  
 Chemical nomenclature  
 Mechanism of action  
 Synthesis of compounds with asterisk\*  
 Structure-activity relationship (SAR)  
 Uses

**1. Sulphonamides:**

Sulphamethoxazole, Trimethoprim, Sulphacetamide, Sulphapyridine, Sulphasalazine, Sulphamoxol, Sulphafurazole, Sulphaguanidine, Sulphadoxine, Sulphadimidine

**2. Quinoline Antibacterial agents:**

Nalidixic acid\*, Norfloxacin, Ciprofloxacin, Sparfloxacin

**3. Anti-Tubercular And Antileprotic Agents:**

Isoniazide\*, Ethambutol, Pyrazinamide, Ethionamide\*, Paraminosalicylic acid\*, DOT (Direct Observation Therapy)

**4. Anti-Neoplastic Agents:**

Alkylating agents like Mechlorethamine, Chlorambucil, Mitomycin C, Busulfan, Carmustine, Lomustine, Dacarbazine and Procarbazine.

Antimetabolites like Azaserine, Methotrexate\*, 5-Fluorouracil, Ara-C, 6-MP and 6-TG

Antibiotics like Dactinomycin, Doxorubicin, Bleomycin

Natural products like Vincristine, Vinblastine, Paclitaxel (only highlights of structure)

Miscellaneous compounds like Cisplatin and some newer derivatives

Note on Combination Therapy.

**5. Antivirals:**

Viral replication

Nucleoside derivative- Amantadine\*, Idoxuridine, Vidarabine, Acyclovir\*

Reverse transcriptase inhibitor

Nucleoside derivative - Zidovudine, Lamivudine, Stavudine

Nucleotide derivative – Tenofovir, Adefovir

Non nucleoside - Nevirapine

**6. Antifungals:**

Azole- Ketoconazole, Clotrimazole\*, Fluconazole, Itraconazole, Griseofulvin, Tolnaftate, Flucytosine.

**7. Antimalarials:**

Life cycle of parasite and drugs acting on the various stages

Cinchona alkaloids - Artemisine and derivatives, Synthetic Antimalarials

4-Aminoquinoline - Chloroquine\* and others

8-Aminoquinoline - Primaquine\* and others

9-Aminoacridine - Quinacrine

2,4-Diamino pyrimidines - Pyrimethamine\*, Trimethoprim

Quinoline methanol derivative - Mefloquine

Folic acid inhibitors

**References:**

1. Chemistry by Ashutosh Kar, 1<sup>st</sup> edition, New Age International Publications.
2. Vogel's Elementary M.E. Wolf: Burger's Medicinal Chemistry, John Wiley and Sons, New York.
3. R.F. Doerge, Wilson & Gisvold's: Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott.
4. W.O.Foye: Principles of Medicinal Chemistry, Lea & Febiger, Philadelphia.
5. D.Lednicer and L.A. Mitschier: Ale Organic Chemistry of Drug synthesis Vol. 1, II & III John Wiley and Sons, New York.
6. S.N.Pandeya: A Textbook of Medicinal chemistry, Vol-I, S.G.Publishers, Varanasi.
7. Ashutosh Kar: Medicinal Chemistry, Wiley Eastern, Ltd., New Delhi
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9. Medicinal Chemistry-A Biochemical Approach by Nogrady T, Oxford University Press New York, Oxford.
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11. Principles of Medicinal Chemistry by Kadam SS, Mahadik KR, Bothara KG, Vol. I & II, 10 th Edition, Nirali Prakashan.
12. Introduction to Medicinal Chemistry' – How Drugs Act and Why by Alex Gringauz,
13. Willey-VCH Publication 1997.
14. Practical Organic Chemistry by Mann FC & Saunders BC, The English Language
15. Book Society and Longman Group Limited, London.
16. Vogel's A Text book of Practical Organic Chemistry by Vogel, 3<sup>rd</sup> edition, The English language book society and Longman group limited, London.
17. Advanced practical Medicinal Practical Organic Chemistry Small Scale Preparation by Arthur I., 2<sup>nd</sup> Edition, Part-I, CBS Publication.

### 3.6.8 Medicinal Chemistry-II

Synthesis and characterization (Melting Point, TLC, Element/s detection and Functional group tests) of the following compounds:

1. *p*-Aminobenzoic acid
2. Sulpanilamide
3. Benzotriazole
4. Benzimidazole
5. 1,2,3,4-Tetrahydrocarbnole
6. Nicotinic acid / Isonicotinic acid
7. Phenyl toluene -*p*-sulfonate

### 3.6.3 Pharmaceutical Analysis-IV

#### 1. Infrared spectroscopy:

I.R. regions, requirements for I.R. absorption, vibrational and rotational transitions, dipole changes, types of molecular vibrations, potential energy diagrams (harmonic oscillator and non-harmonic oscillator), Vibrational frequency, factors influencing vibrational frequencies, vibrational modes (normal mode, combination bands and overtone bands), Instrumentation: light source, frequency selector, sample preparation, detectors, double beam I.R. Spectrophotometer (schematic diagram), Qualitative applications (identification of functional groups, identity by fingerprinting).

#### 2. Polarimetry:

Introduction to electromagnetic properties of lightwaves. monochromatic radiation, production of linearly polarized light, definitions – circular birefringence, left and right circularly polarized light, optical rotatory dispersion, molecular ellipticity, circular dichroism, Instrumentation: Light source, polarizer, sample cell, analyzer, Anisotropic crystals, Nicol's Prism, Determination of optical activity (Half shade effect), Applications.

#### 3. Refractometry:

Specific and molar refraction, Refractive index, Measurement of angle of refraction, Instrumentation and applications.

#### 4. Electrochemical Analysis:

Definitions of all types of electrochemical analysis.

##### Conductometry:

Introduction, measurement of conductivity, conductivity apparatus, conductometric titrations, applications of conductometric titrations & high frequency titrations

##### Potentiometry:

Introduction, Different types of electrodes, measurement of electrode potential and pH, Applications including potentiometric titrations.

**Polarography:** Introduction, Principle, Dropping Mercury Electrode and Other Mercury Electrodes, Polarogram, half wave potential, Linear Scan & Differential Pulse Polarography, applications covering non-aqueous polarography

**Amperometry:** Introduction, Instrumentation and Applications including amperometric titrations.

#### 5. Thermal analysis:

Differential Scanning Calorimetry (DSC): Definition, Types, Instrumentation, Principle, applications. Thermogravimetric Analysis (TGA): Introduction, Definition, Types, Instrumentation, Principle, applications. Differential Thermal Analysis (DTA): Introduction, Definition, Principle Instrumentation, applications.

#### References:

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2. Grant- Statistical Quality control (McGraw Hill).
3. Beckett A H and Stenlake J B, Practical Pharmaceutical Chemistry Vol. I and II., The Anthlone Press of University of London.
4. Connors K A, A Textbook of Pharmaceutical Analysis, Wiley Interscience, New York.
5. Gary Christian- Analytical Chemistry (John Wiley).
6. Instrumental methods of Analysis- Ewing.
7. Higuchi & Brochmann- Hanssen- Pharmaceutical Analysis- (Interscience).
8. Garrat- The quantitative analysis of Drug (Toppan & Co.)
9. Vogel Text Book of Practical Organic Chemistry – 5th edition.

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11. Analytical Chemistry an introduction, Skoog, West, Holler, 6th Edition.
12. Florey- Analytical profiles of drug substances (Academic press).
13. Instrumental methods of Analysis- Willard, Dean, Merrit and settle- (Wadsworth Pub. Co.)
14. Merck Index.
15. Pharmaceutical Drug analysis by Ashutosh Kar.
16. Principles of Instrumental analysis, Skoog, Holler, Nieman, 5th Edition.
17. Latest editions of IP, BP, USP, EP and International Pharmacopoeia.
18. Meites-Handbook of Analytical Chemistry (McGraw Hill).
19. Hamilton, Simpson and Ellis- Calculation of Analytical Chemistry (McGraw Hill).
20. Instrumental methods of chemical analysis, G.R. Chatwal and S.K. Anand, Himalaya.
21. Spectrometric Identification of Organic Compounds by Silverstein-Webster, 6th Edition.
22. P.S. Kalsi. Spectroscopy of organic compounds (New age international Ltd.)

### 3.6.9 Pharmaceutical Analysis-IV

1. Study of polarimeter, conductometer, potentiometer.
2. Assay of dextrose injection by polarimetry.
3. To determine the specific rotation of sucrose of different concentrations and determine the intrinsic rotation.
4. Calibration of Refractometer and measurement of RI of some organic solvent.
5. Calibration of conductometer.
6. Conductometric titration (Strong acid Vs Strong base and Weak acid Vs Strong base).
7. Calibration of pH meter.
8. Potentiometric analysis: - pKa determination of phosphoric acid / boric acid.
9. Potentiometric titration of (Strong acid Vs Strong base and Weak acid Vs Strong base).
10. Demonstration experiments on identification of functional groups from IR spectra.

### 3.6.4 Pharmacology-II

Basic pharmacology (classification, mechanism of action, pharmacokinetics, pharmacological actions, adverse effects, contraindications, therapeutic uses, drug interaction, dosage, symptoms and treatment of poisoning) and Clinical Management of diseases and drugs acting on following categories:

#### 1. Drugs acting on Cardiovascular System:

Diuretics

Congestive Heart Failure- Cardiac glycosides.

Antihypertensive drugs.

Antianginal and Vasodilator drugs, including calcium channel blockers and beta adrenergic antagonists.

Antiarrhythmic drugs

Antihyperlipidemic drugs

Drugs used in the therapy of shock.

#### 3. Pharmacology of drugs acting on blood and blood forming organs:

Haemopoietics.

Coagulants and Anticoagulants.

Thrombolytics and Antiplatelet agents.

#### 4. Pharmacology of autacoids and their antagonists:

Histamine and histamine antagonists.

5-HT and 5-HT antagonists.

Kinins, and angiotensin.

Lipid derived autocoids: Prostaglandins, Leukotrienes & Platelet Activating Factor.

#### 5. Drugs acting on Respiratory tract:

Drugs for the treatment of cough, bronchial asthma and COPD

#### 6. Drugs acting on Gastrointestinal tract:

Drugs for the treatment of peptic ulcers

Drug therapy of Ulcerative colitis and Crohn's disease

Emetics and antiemetics

Drugs for the treatment of constipation and diarrhoea

#### 7. Principles of Toxicology:

Definition of poison, general principles of treatment of poisoning with particular reference organophosphorous and atropine poisoning.

Heavy metals and heavy metal antagonists

#### References:

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3. Goodman and Gillman: Pharmacological Basis of Therapeutics, McGraw-Hill, Medical Publishing Division, New York.
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5. Katzung B.G.: Basic and Clinical Pharmacology, Lange Medical Publications, California.

6. Bowman W.C. and Rand M.J.: Textbook of Pharmacology, Blackwell Scientific Publications, Oxford.
7. Craig C.R. and Stitzel R.E: Modern Pharmacology, Little Brown and Co., Boston.
8. Melman K.I. and Morelli H.F.: Clinical Pharmacology: Basic Principles in Therapeutics, Macmillan Press, New York.
9. Laurence D.R. and Bennett P.N.: Clinical Pharmacology, Churchill Livingstone, Edinburgh.
10. P.N Bennett & M J Brown: Clinical Pharmacology, Churchill Livingstone, Edinburgh.
11. Bevan J.A. and Thompson J.H.: Essentials of Pharmacology, Harper and Row Publishers, Philadelphia.
12. Drill V.A.: Pharmacology in Medicine, McGraw Hill Co., New York.
13. Grollman A.: Pharmacology & Therapeutics, Lea & Fabiger, Philadelphia.
14. Avery G.S.: Drug Treatment, Adiss Press, Sydney.
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16. Krantz and Carr: Pharmacology Principles of Medical Practice, Williams & Wilkins Co, Baltimore.
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19. P Jagadish Prasad.: Conceptual Pharmacology, Universities Press (India), Pvt. Ltd. Hyderabad.

### 3.6.5 Clinical Pharmacology

#### 1. Introduction to Clinical pharmacology

#### 2. Clinical Pharmacokinetics:

- Definition and Scope
- Dosage adjustments in patients with hepatic and renal failure
- Chronic Pharmacology- Consequences of prolonged drug administration
- Withdrawal symptoms due to discontinuation
- Individualization of drug therapy

#### 3. Evaluation of drugs in humans:

- Experimental Therapeutics
- Ethics of research
- Rational introduction of a new drug
- Need for statistics
- Types of Trials, Designs and Size
- Meta-analysis
- Pharmacoepidemiology

#### 4. Unwanted effects and adverse drug reactions:

- Definition
- Attribution and degrees of certainty
- Sources of ADR, Allergy etc. in response to drug

#### 5. Drug Interactions:

- General considerations
- Types of drug interactions
- Factors contributing to the occurrence of drug interactions
- Mechanisms of drug interactions
- Using of drug interaction information

#### 6. Clinical Case Studies:

- COPD, Bronchial Asthma
- CHF, Acute MI

#### 7. Drug therapy in Pregnancy, Neonates, Paediatric and Geriatric Patients

#### References:

1. P.N Bennett & M J Brown.: Clinical Pharmacology, Churchill Livingstone, Edinburgh.
2. Melman K.I. and Morelli H.F.: Clinical Pharmacology: Basic Principles in Therapeutics, Macmillan Press, New York.
3. Herfindal E.P. "Textbook of Therapeutics: Drug and Disease Management"
4. Richard H. "Drug Interactions Guide"
5. Speight T.M. "Avery's Pharmacology", 4th edition, Adis Press, Auckland, 1997
6. Wang H. and Chow S. C. "Encyclopedia of Clinical Trials", Wiley, 2007
7. Katzung B.G.: Basic and Clinical Pharmacology, Lange Medical Publications, California
8. Seth S. D.: Textbook of Pharmacology, Elsevier Publications.
9. Schwinghammer T. L.: Pharmacotherapy Casebook-A patient approach Mc.Graw Hill Publications.
10. Davidson's Principles and practice of Medicine, Churchill Livingstone, Elsevier publication.
11. Bhattacharya S.K, Parantapa S, Arunabha Ray: Pharmacology, Elsevier publication.
12. Harrison's Principles of Internal Medicine.
13. Dipiro, Pharmacotherapy- A Pathophysiologic Approach.

### 3.6.6 Pharmacognosy-II

1. Introduction to Quantitative Microscopy with reference to leaf constants
2. General biosynthetic pathway of phytoconstituents along with various metabolites
3. Systematic Pharmacognostic study:  
Carbohydrates and derived products: Agar, Acacia, Isabgol, Starch  
Resins and their combinations: Benzoin, Cannabis, Ginger, Podophyllum, Turmeric  
Tannins: Black Catechu, Pale Catechu, Myrobalan, Bahera  
Lipids: Castor oil, Cod liver oil, Shark liver oil, Bees wax  
Volatile Oils: Fennel, Cassia, Clove, Cardamom, Mentha piperata, Musk.  
Natural pesticides: Neem, Pyrethrum, Tobacco  
Natural fibers: Cotton, Silk, Jute.

#### References:

1. Indian Pharmacopoeia, Government of India Publication.
2. Indian Herbal Pharmacopoeia, IDMA Publication
3. Pharmacognosy, Brady, Tyler & Roberts
4. Text Book of Pharmacognosy: T E Wallis
5. Text Book of Pharmacognosy: Trease & Evans
6. Text Book of Pharmacognosy: Kokate & Purohit.
7. Practical Pharmacognosy: C K Kokate
8. Practical Pharmacognosy: M.A Iyengar
9. Practical Evaluation of Phytopharmaceuticals: Brain & Turner
10. Harborne J.B Phytochemical Methods: A guide to Modern techniques.

### 3.6.10 Pharmacognosy-II

1. Quantitative microscopy
  - Determination of stomatal index
  - Determination of stomatal Number
  - Determination of Vein islet Number
  - Determination of Vein termination Number
  
2. Morphology, Microscopy (only T.S) and chemical tests of the following drugs:
  - Ginger
  - Fennel
  - Cassia
  - Clove
  
3. Systematic chemical analysis of following drugs
  - Agar
  - Acacia
  - Benzoin
  - Black catechu
  - Pale catechu
  
4. Group Experiment
  - Isolation and estimation of volatile oil contents