

SOLAPUR UNIVERSITY, SOLAPUR FACULTY OF ENGINEERING & TECHNOLOGY

Bachelor of Pharmacy

Third Year B. Pharmacy (2016-17)

CGPA Syllabus



SOLAPUR UNIVERSITY, SOLAPUR

Faculty of Engineering & Technology

Bachelor of Pharmacy

Credit System Structure of Teaching & Examination w.e.f. 2016-17
Third Year B. Pharmacy (Semester-V)

Code	Course	Hrs./Week			Credits	Examination Scheme			
		L	Т	Р		ISE	ESE	ICA	Total
3.5.1	Pharmaceutics-III	3	-	-	3	30	70	-	100
3.5.2	Biopharmaceutics	3	-	-	3	30	70	-	100
3.5.3	Medicinal Chemistry-I	3	-	-	3	30	70	-	100
3.5.4	Pharmaceutical Analysis-III	3	-	-	3	30	70	-	100
3.5.5	Pharmacology-I	3	-	-	3	30	70	-	100
3.5.6	Biotechnology	3	-	-	3	30	70	-	100
	Total	18	-	-	18	180	420	-	600
	Practical								
3.5.7	Pharmaceutics-III	-	-	3	1.5	-	70	30	100
3.5.8	Medicinal Chemistry-I	-	-	3	1.5	-	70	30	100
3.5.9	Pharmaceutical Analysis-III	-	-	3	1.5	-	70	30	100
3.5.10	Biotechnology	-	-	3	1.5	-	70	30	100
3.5.11	Project	-	-	3	-	1	-	-	-
	Total	-	-	15	06	ı	280	120	400
	Grand Total	18		15	24	180	700	120	1000

Abbreviations: L- Lectures, T- Tutorials, P-Practicals,

ISE - In Semester Exam., **ESE** - End Semester exam, **ICA**- Internal Continuous Assessment **Note**: **ISE** -Three Tests , **ESE** - University Theory paper shall be of 70 marks of 3 hrs. duration



SOLAPUR UNIVERSITY, SOLAPUR

Faculty of Engineering & Technology

Bachelor of Pharmacy

Credit System Structure of Teaching & Examination w.e.f. 2016-17

Third Year B. Pharmacy (Semester-VI)

Code	Course	Hrs	Hrs./We		Credits	Examination Scheme			
		L	Т	Р		ISE	ESE	ICA	Total
3.6.1	Pharmaceutics-IV	3	-	-	3	30	70	-	100
3.6.2	Pharmacognosy-II	3	-	-	3	30	70	-	100
3.6.3	Medicinal Chemistry-II	3	-	-	3	30	70	-	100
3.6.4	Pharmaceutical Analysis-IV	3	-	-	3	30	70	-	100
3.6.5	Pharmacology-II	3	-	-	3	30	70	-	100
3.6.6	Clinical Pharmacology	3	-	-	3	30	70	-	100
	Total	18	-	-	18	180	420	-	600
	Practical								
3.6.7	Pharmaceutics-IV	-	-	3	1.5	-	70	30	100
3.6.8	Pharmacognosy-II	-	-	3	1.5	-	70	30	100
3.6.9	Medicinal Chemistry-II	-	-	3	1.5	-	70	30	100
3.6.10	Pharmaceutical Analysis-IV	-	-	3	1.5	-	70	30	100
3.6.11	Project	-	-	4	2.0	-	-	100	100
	Total	ı	-	16	8.0	-	350	220	500
	Grand Total	18		16	26	180	700	220	1100

Abbreviations: L- Lectures, T- Tutorials, P-Practicals,

ISE - In Semester Exam., **ESE** - End Semester exam, **ICA**- Internal Continuous Assessment

Note: ISE -Three Tests, ESE - University Theory paper shall be of 70 marks of 3 hrs. duration

3.5.1 PHARMACEUTICS-III (Theory)

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

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.

4. Factory Layouts

Objectives, Locational analysis, types of layouts, Factors influencing layouts

References:

- 1. Remington "The science and practice of pharmacy" 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.Poporich; L.V.Allen "Pharmaceutical dosage forms and Drug Delivery systems" 9th edition, Wolters kluwer- Lippincott Williams and wilkins, 2009.
- 4. L.Lachman; H.A.Liberman; J.L.Kanig "The Theory and Practice of Industrial Pharmacy" 3rd edition; Verghese publishing House, Mumbai 1991.
- 5. M.E.Aulton "Pharmaceutics: The design and manufacture of medicines" 3rd edition; Churchil livingstone, 2007.
- 6. Bentley's "Test book of Pharmaceutics" Bailliere Tindall; 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.Schwart "Pharmaceutical dosage forms: Tablets" Marcel Dekker, Vol. I, II, III 1998.

3.5.7 PHARMACEUTICS-III (Practical)

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 (Theory)

1. Introduction to Biopharmaceutics, Pharmacokinetics

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 extravascular 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, Cmax, tmax, 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.

- 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 (Theory)

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

β-lactam antibiotics- Penicillins - Penicillins-G and Penicillins-V, Amphicillin, Amoxicillin, Oxacillin, Cloxacillin, Dicloxacillin, Nafcillin, Methicillin, Becampicillin, Pivampicillin

Cephalosporins- Cephalexin, Cephalethin, Cefaxitin, Cefuroxime, Cefotaxime, Cefepine, cefpirone.

Tetracyclines

Macrolides

Aminoglycoside

Polypeptides

Lincomycins

- 1. Chemistry by Ashutosh Kar, 1st 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
- 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, 10th Edition, Nirali Prakashan.
- 12. Introduction to Medicinal Chemistry' How Drugs Act and Why by Alex Gringauz, Willey-VCH Publication 1997.
- 13. Practical Organic Chemistry by Mann FC & Saunders BC, The English Language Book Society and Longman Group Limited, London.
- 14. Vogel's A Text book of Practical Organic Chemistry by Vogel, 3rd edition, The English language book society and Longman group limited, London.
- 15. Advanced practical Medicinal Practical Organic Chemistry Small Scale Preparation by Arthur I., 2nd Edition, Part-I, CBS Publication.

3.5.8 MEDICINAL CHEMISTRY-I (Practical)

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. DibenzylacetoneCoumalic acid
- 6. 7-Hydroxy-4-methylcoumarin

3.5.4 PHARMACEUTICAL ANALYSIS-III (Theory)

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 Feisher 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.

- 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 & 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..
- 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 (Practical)

- 1. Study of UV-Visible spectrophotometer, colourimeter, fluorimeter, flamephotometer.
- 2. Calibration of UV-Visible spectrophotometer as per I.P.
- **3.** Assay of one tablet, one capsule and one injection by using UV-Visible spectrophotometer
- **4.** Colourimetric estimations: Any two substances
- **5.** Assay by fluorimetry Quinine sulphate.
- **1.** Determination of Na⁺ or K⁺ from NaCl or KCl by flame photometry by calibration curve method.

3.5.5 PHARMACOLOGY-I (Theory)

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. 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

3. 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

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.

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, NewYork.
- 4. Rang H.P. and Dale M.M.: Pharmacology, Churchill Livingstone, Edinbergh.
- 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 (Theory)

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. Genetic Engineering

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

5. Immunology and Health

Method of preparation of bacterial & viral vaccines. Hybridoma technology and MAbs production, Applications of MAbs.

- 1. U. Satyanarayana., Biotechnoligy, 1st Edition, 2005, Books and Allied (P) Ltd. Kolkata.
- 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 (Practical)

1. Plant Biotechnology

Preparation of plant cell culture media

Development of callus or tissue culture

2. Molecular Biology

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

Quantitation of extracted DNA (OD260 / OD280)

SDS PAGE or Gel electrophoresis

Colorimetric estimation of DNA or RNA

3. Enzyme technology

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

4. Immunology

Antigen-Antibody reaction.

3.6.1 PHARMACEUTICS-IV (Theory)

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.

7. Suspension and Emulsion

Components of formulation, Methods of preparation and Evaluation

8. Pharmaceutical Aerosols

Definition, general information, pharmaceutical applications, components, principle of working, important physicochemical parameters of aerosol system, classification, uses, safety and regulatory considerations of propellants, containers and closures, metered dose aerosols, formulations like solutions, suspensions, emulsions and dry powder inhalers, manufacturing techniques, official and unofficial methods of evaluation of aerosols

- 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.
- 11. J. Hickey; Pharmaceutical Inhalation Aerosol Technology; 1st ed, Marcel Decker, 2004.

3.6.7 PHARMACEUTICS-IV (Practical)

Formulation, Preparation and Evaluation of the following dosage forms.

- 1. Ointments: any two
- **2. Creams:** any two
- 3. Gels: any two
- **4. Paste:** any two
- **5. Suspension:** any two
- **6. Emulsion:** any two

3.6.2 MEDICINAL CHEMISTRY-II (Theory)

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 & 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*, Iodoxuridine, 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

Quninoline methanol derivative - Mefloquine

Folic acid inhibitors

- 1. Chemistry by Ashutosh Kar, 1st 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
- 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, 10th Edition, Nirali Prakashan.
- 12. Introduction to Medicinal Chemistry' How Drugs Act and Why by Alex Gringauz, Willey-VCH Publication 1997.

- 13. Practical Organic Chemistry by Mann FC & Saunders BC, The English Language
- 14. Book Society and Longman Group Limited, London.
- 15. Vogel's A Text book of Practical Organic Chemistry by Vogel, 3rd edition, The English language book society and Longman group limited, London.
- 16. Advanced practical Medicinal Practical Organic Chemistry Small Scale Preparation by Arthur I., 2nd Edition, Part-I, CBS Publication.

3.6.8 MEDICINAL CHEMISTRY-II (Practical)

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-Tetrahydrocarbazole
- 6. Nicotinic acid / Isonicotinic acid
- 7. Phenyl toluene -p-sulfonate

3.6.3 PHARMACEUTICAL ANALYSIS-IV (Theory)

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 nonharmonic 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

Linearly polarized light.

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

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.

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.

6. X-Ray Diffraction:

Theory, Instrumentation, Applications.

- 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. Connors KA, 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.
- 10. Pharmaceutical Analysis Vol. I & II, A.V.Kasture, S.G.Wadhodkar, K.R.Mahadik, H.N.More- Nirali Publication.
- 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 (Practical)

- 1. Study of polarimeter, conductometer, potentiometer, refractometer.
- 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 (Theory)

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

Antihyperlipedemic drugs

Drugs used in the therapy of shock.

2. Pharmacology of drugs acting on blood and blood forming organs

Haemopoietics.

Coagulants and Anticoagulants.

Thrombolytics and Antiplatelet agents.

3. Drugs acting on Respiratory tract

Drugs for the treatment of cough, bronchial asthma and COPD

4. 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 diarroehea

5. 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

- 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, NewYork.
- 4. Rang H.P. and Dale M.M.: Pharmacology, Churchill Livingstone, Edinbergh.
- 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.

3.6.5 CLINICAL PHARMACOLOGY (Theory)

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

Therapeutic Drug Monitoring

3. Evaluation of drugs in humans

Experimental Therapeutics

Historical Background: Belmont report, Nuremberg Code, Declaration of Helsinki,

Thalidomide Tragedy

Ethics of research

Rational introduction of a new drug

Need for statistics

Phases of Clinical Trial

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

Pharmacovigilance

Safety reporting

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

- 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.: Pharmaccotherapy 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 (Theory)

- 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.

- 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 (Practical)

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:

Fennel, Cassia, Clove

3. Systematic chemical analysis of following drugs

Agar

Acacia

Black catechu

Pale catechu

4. Group Experiment

Isolation and estimation of volatile oil contents