

SYLLABUS FOR BACHELOR OF PHARMACY
SOLAPUR UNIVERSITY, SOLAPUR

Four Year B.Pharm.

4.1 PHARMACEUTICS-III (THEORY)

2Hrs. / Week

1. Sterile Delivery System classified into

- (A) Parenteral, ophthalmic & others and
- (B) Antibiotics and non-antibiotic products.

A) Parenteral preparations: -

[20-30 mks]

- a) General requirements
- b) Types and their formulation with reference to powders for reconstitution solutions, suspensions, emulsions and depot preparations, preparation of sterile water for injection. Pharmacopoeial evaluation of sterile water for injection.
- c) Containers and closures (glass, plastics and rubber) and their evaluation, Form, fill, seal technology, Evaluation of containers and closures including a mention of compatibility testing (to be covered more extensively under stability).
- d) Design of facilities and environmental control: Basic design concepts, cleanliness classes, air handling (HVAC systems), HEPA filters, Laminar flow and laminar flow rooms, change room design, materials of construction, sterilization, validation of environment and filters.
- e) Personnel factors: Selection, Training, Monitoring and motivation concepts to be considered for education of workers - personal hygiene, gowning and entry procedure, restrictions in work area and importance of the same.
- f) Processing of parenteral products by terminal sterilization, filtration sterilization followed by aseptic filling, and by aseptic compounding. Validation of sterilization and process validation.
- g) Quality control and Quality Assurance.

B) Ophthalmic products:

[4-8 mks]

General requirement / safety considerations, formulation, isotonicity adjustment, isotonicity calculation, manufacture, packaging and quality control. Introduction to inserts ocuserts.

2) Oral sustained and controlled Drug Delivery:

[30-40 mks]

Definitions - Historical development, components of a therapeutic system - Classification - Details of matrix and diffusion control systems.

- a) Biopharmaceutical aspects-steady state concept and calculation of maintenance dose, loading doses.
 - b) Diffusion and Dissolution-steady state diffusion, lag time, diffusion cells and study of permeability of polymer and biological membranes, Dissolution - the diffusion layer model, Drug Release, Drug in polymer matrices, effect of porosity and tortuosity, Membrane control, Reservoir type devices.
 - c) Design and evaluation of SR & CR preparations.
 - d) Brief introduction to polymers
 - e) Introduction to Novel Drug delivery: Mucosal, transdermal, parenteral implants & pumps, I. U. D. osmotic pumps, bioadhesive, targeted delivery, externally modulated devices and delivery: iontophoresis, sonophoresis, etc. (No details to be taught).
- 3) Medicated Aerosols - Components manufacture and Evaluation. **[9-14 mks]**
 - 4) Chemical Kinetics, Drug stability and stability prediction: - **[9-14 mks]**
 Mechanisms of drug instability: Hydrolysis, oxidation, Isomerisation photochemical decomposition, and polymerization. A revision of review of mechanisms of physical instability in dosage forms.
 Interactions with containers and closures and their evaluation - Compatibility testing. Chemical decomposition in the solid state-stability testing of drugs and tentative expiration date, OGMP guidelines in stability testing and expiration dating.
 - 6) Factory Layout: Different departments, Services and Utilities. **[4-10 mks]**
 - 7) Pilot Plant scale up technique – **[4-10 mks]**
 Groups responsibilities - Facilities - Example of scaling up.

BOOKS:

Text Book:

1. Industrial Pharmacy – Lachman et al. (Lea & Febiger)

Reference Books:

- 1) Pharmaceutical Dosage forms - Ansel - Popovich & Allen. (Text Book) and Drug Delivery System - (Williams & Wilkins)
- 2) American Pharmacy -Dittert (J. B. Lipincott)
- 3) Remington's Pharmaceutical Sciences - Alfonso R.Gennaro (Mack Publishing Co.)
- 4) Bentleys T. B. of Pharmaceutics - Rawlins (ELBS)
- 2) Pharmaceutical Microbiology- Hugo and Roussel – (McGraw Hill)
- 6) Modern Pharmaceutics - Banker and Rhodes -(Dekker)
- 7) Groves - Parenteral Products - (William Heinemann Medical Books Ltd.)
- 8) Hanlon - H.B. of package Engg. - (McGraw Hill)

- 9) Swarbrick & Boylan - Encyclopedia of Pharm. Technology. – (Dekker)
- 10) Osol, Remington's Pharmaceutical Sciences. (Mack)

4.1 PHARMACEUTICS-III (PRACTICALS)

3 Hrs. / Week

Note: 1) Products may be assayed to evaluate accuracy in regular practicals. Assays are not to be given to students in University Examinations.

2) Formulation of different dosage forms should give stress on raw material specifications, preformulation, process controls and documentation.

3) Formulation and evaluation of the following sterile dosage forms

- (i) SVPs
 - (a) Ascorbic acid Injection, I. P.
 - (b) Calcium gluconate Injection, I. P.
 - (c) An injection demonstrating co-solvent phenomenon.
 - (d) An injection containing Colloidal Calcium with Vitamin D.
- (ii) LVPs
 - (a) Sodium Chloride and Dextrose Infusion I. P.
 - (b) An injection containing fat emulsion
- (iii) OPHTHALMIC PREPARATION
 - (a) Sulphacetamide eye drops, B.P.C.
 - (b) Tetracycline eye ointment, I. P.
 - (c) Chloramphenicol eye ointment, I. P.
- (iv) Accelerated stability testing of an injection.
- (v) Multiparticulate oral Sustained Release Product in a capsule. Formulation and evaluation there of.

4. Dissolution studies of Marketed Capsules & Tablets (two each)

BOOKS:

1. Ansel, Introduction to pharmaceutical dosage forms (Lea and Febiger)
2. Dittert, Sprowls American Pharmacy (J.B.Lipincott)
3. Martin, Remington's Pharmaceutical Sciences. (Mack)
4. Harkishin Singh, Pharmacopoeias and Formularies, Vallabh Prakashan, Delhi)
5. M.L. Shroff General Pharmacy Series
6. Mittal, Pharmaceutical Formulations
7. Lachman, Industrial Pharmacy (Lea & Febiger)
8. I.P., B.P. B.P.C., U.S.P.

4.2 BIOPHARMACEUTICS, PHARMACOKINETICS & CLINICAL PHARMACY (THEORY)

3 Hrs. / Week

1. Introduction: Definitions of absorption, distribution, metabolism, excretion, elimination, disposition, first pass effect, enterohepatic - cycling, bioavailability biopharmaceuticals, Pharmacokinetics and pharmacodynamics.

[6-10 mks]

2. Concepts of compartment models: pharmacokinetic of one compartment model drug, mathematical treatment to pharmacokinetic upon I.V. bolus dosing, I.V. infusion and first order extravascular input. Multicompartment model behavior (excluding derivation or mathematical treatment), Central and Peripheral Compartments, distribution phase and pseudo distribution equilibrium phase. Definition of pharmacokinetic parameters including volumes of distribution, clearance, biological half-life, renal clearance, non-renal clearances, additivity of clearance, absolute bioavailability, relative bioavailability, Bioequivalence and other miscellaneous parameters. Methods of estimation of pharmacokinetic parameters and parameters of bioavailability/ Bioequivalence, including method of residuals, rate method and sigma-minus method of estimation of renal clearance, area under the curve, area under moment curve, mean residence time.

[12-19 mks]

3. Plasma concentration and therapeutic response. An introduction to Pharmacodynamics.

[4-7 mks]

4. Non-linear pharmacokinetic: - Non-linearities in absorption and elimination. Examples of drug showing non-linear absorption or elimination's, Individualization of dosage regimens and non-linear Pharmacokinetics.

[4-6 mks]

5. Dosage regimens: - Factors affecting dosage regimens, utility curve and therapeutic window, multiple dose Pharmacokinetics, Fluctuation, accumulation index, steady state concept, time to reach steady state, loading dose, maintenance dose, drugs requiring individualization of dosage regimens - a discussion.

[6-10 mks]

6. Mechanisms of drug transport: - Different mechanisms of drug transport, passive transport and pH-partition theory, Facilitated diffusion, Active transport, Blood and its drug binding constituents as carriers of drugs in the body, Perfusion, limitation and permeability limitation in drug transport.

[8-13 mks]

7. Distribution: Rate of distribution, perfusion limitation and permeability limitation, Extent of distribution, plasma and tissue binding of drugs, drugs with small,

intermediate and high volume of distributions and their relative plasma and tissue binding. [4-7 mks]

8. Elimination: Organ Clearance Concepts, Hepatic clearance, Hepatic Extraction ratio, Blood flow limitation in hepatic clearance, first pass effect.
Clinical applications: Effect of enzyme induction, enzyme inhibition, blood flow and protein binding on hepatic clearance, bioavailability, steady state plasma concentration and dosage regimens Renal clearance and mechanisms of renal excretion, estimation of renal clearance, factors affecting renal elimination: Clinical applications. Biliary Clearance, enterohepatic cycling and other miscellaneous modes of drug elimination.

[6-9 mks]

9. Absorption: Modified pH-partition theory or effect of unstirred water layer. Physiochemical factors affecting the bioavailability of drugs. Dissolution rate and methods of enhancing dissolution rates. Official and unofficial methods of estimation of dissolution/in-vitro release of drugs from dosage forms. In-vitro in-vivo correlation and its significance. Physiology of the gastrointestinal tract and oral bioavailability. Formulation and dosage form related factors affecting oral bioavailability. Physiochemical and physiological factors affecting bioavailability of drugs from parenteral routes - examples of procaine penicillin G suspension and insulin - Zn suspension. Basic concepts of intranasal, oral, mucosal, rectal, transdermal, intravaginal, ophthalmic, and intrauterine delivery of drugs.

[10-15 mks]

10. Introduction : Concept of Clinical Pharmacy
mks]

[2-3

11. Community Pharmacy Practice :
mks]

[18-27

- a. Monitoring the patient in health and illness.
- b. Therapeutic performance of drugs
- c. Consultations: The drug information Drug Literature Utilization.
- d. Selection Evaluation and Communication.
- e. Investigational drugs
- f. Computers in Clinical practice.

BOOKS :

1. Wagner, J.G. Biopharmaceutics and Relevant Pharmacokinetics, Drug Intelligence Pub. Hamilton.
2. Swarbrick, J : Current Concepts in the Pharmaceutical Sciences: Biopharmaceutics. LEa and Febiger, Philadelphia.

3. Swarbrick, J: Current Concepts in the Pharmaceutical Sciences: Dosage Form Design and Bioavailability. Lea & Febiger, Philadelphia.
4. Wagner, J.G., Fundamentals of Clinical Pharmacokinetics. Drug Intelligence Publications, Hamilton.
5. Gibaldi, M: Biopharmaceutics and Clinical Pharmacokinetics. Lea & Febiger, Philadelphia.
6. Rowland, M, and Tozer, T.N. Clinical pharmacokinetic: Concepts and Applications. Lea & Febiger, Philadelphia.
7. Notari, R.E., Biopharmaceutics and Clinical Pharmacokinetics, Marcel Dekker.
8. Gibaldi, M and Perrier, D: Pharmacokinetics, Marcel Dekker.
9. Leon shargel and Andrew B.C. Yu., Applied Biopharmaceutics and Pharmacokinetics (Appleton Century - Crofts)
10. Sarfaraz Niazi - Text Book of Biopharmaceutics and Clinical Pharmacokinetics (Appleton Century Crofts, New York)
11. Clinical Pharmacy Practice - Blissit (Lea & Febiger)
12. Clinical Pharmacy Handbook - Kabat (Lea & Febiger)
13. Clinical Pharmacy Lawson & Richards Chapman Hall
14. Biopharmaceutics and Pharmacotherapeutics – Brahmankar
15. Textbook of therapeutics - Herfindal

4.3 PHARMACEUTICAL (MEDICINAL) CHEMISTRY-II (THEORY)

3 Hrs. / Week

Part-A:

- 1) Introduction to QSAR [6-9 mks]
Statistical prediction & pharmacological activity – partition coefficient, QSAR models, molecular modeling, steric factors, molecular modeling (CADD) Hansch equation.
- 2) Introduction to Receptor Concept [5-8 mks]
History, affinity, receptor & biological response, to protein receptor Drug receptor interaction, forces involved, conformational flexibility and multiple modes of action
- 3) Introduction to Prodrugs and orphan drugs [5-8 mks]

Part-B:

The following classes of drugs should be discussed in relation to:

- a) Introduction to the rational development (if any)
 - b) Mechanism of action
 - c) Synthesis of compounds with asterisk
 - d) Structure-activity relationship
 - e) Generic names
 - f) Chemical nomenclature
 - g) Detailed Classification of each class
1. Drugs acting on cholinergic nervous system : [5-8 mks]
Bethanechol, Carbachol, Methacholine, Neostigmine, Demecarium, Physostigmine, Ambenonium chloride, Echothiophate iodide, Isoflurophate, Parathion, Paraoxon, Malathion, Pralydoxine, Atropine, Scopolamine, Hyscyamine, Homatropine, Dicyclomine*, Cyclopentolate*, Papaverine, Mecamyramine, Piperodolate*, d-Tubocurarine chloride, Succinyl choline chloride, Erophonium bromide.
 2. a) Drugs acting on adrenergic nervous system: - [5-8 mks]
Methyldopa*, Guanethidine*, Reserpine, Ephedrine, Phenylpropanolamine, Amphetamine*, Methamphetamine, Phenteramine, Paraglyline, Norepinephrine, Epinephrine, Phenylphrine, Isoproterenol, Metarminol, Salbutamol*, Phenoxybenzamine, dibenamine, tolazoline*, Phentolamine, Sotalol, Propranolol, Practolol, Atenolol, Labetolol, Metoprolol.
 - b) General Anesthetics: [2-3 mks]

Ether, Nitrous Oxide, Halothane, ultra short acting Barbiturates

c) Hypotensive agents acting on vascular smooth muscle: **[2-3 mks]**

Nitrites, Amylnitrites, glyceryl, nitrite, sodium nitrite, tetranitrate, mannitol, tetranitrate, pentaerythritol tetranitrate, Isosorbide mononitrate, Isosorbide dinitrite.

3. Drugs acting on central nervous system :

a) Hypnotics and Sedatives : **[3-5 mks]**

Chloral hydrate, Ethinamate, Glutethimide*, Phenobarbital, Talbutal, Pentobarbital*, Secobarbital, Hexobarbital, Nitrazepam, Bromazepam, Ternazepam, Midazolam.

b) Drugs acting as anticonvulsants :- **[3-5 mks]**

Phenytoin*, Mephentoin, Trimethadione, Paramethadione, Clonazepam, Phensuximide*, Ethosuximide, Phenacimide, Phenobarbital, Mephobarbital (Classification of barbiturates) Metharbital, Primidone, Carbamazepine, Sodium Valproate

c) Psychotherapeutic Agents : Phenothiazines such as **[4-6 mks]**

Chlorpromazine*, Triflupromazine, Fluphenazine, Carphenazine, Chlorprothixene, Thioridazine, Fluplenthixol, Haloperidol, Chlorodiazepoxide, Flurazepam, Oxazepam, diazepam, Meprobamate*, Imipramine, Desipramine, Amitriptyline, Nortriptyline, Doxepin, Phenelzine, Nialamide, Tranylcypramine, Pargyline, Fluoxetine, Loxapine, Melindone, Pimozide,...

d) CNS Stimulants : **[2-3 mks]**

Phenmetrazine, Phendimetrazide, Fenfluramine, Methyl Phenidate, Nikethamide, Ipromiazide, PicROTOXIMES, Tetrazole and Hydrazine derivatives (5 only) Amphetamine, Methamphetamine.

4. Antihistaminics, Antiemetics and antiulcer drugs : **[3-5 mks]**

Metroclopramide, Diphenhydramine*, Doxylamine, Triprolidine, chlorpheniramine, Antazoline, Cyproheptadine, Terferadine, Cimetidine, Omeprazole, Lansoprazole, Ranitidine, Famotidine, Ondansetron, Tripelenamine*.

5. Cardio Vascular drugs and antihypertensives including Antiarrhythmic agents, Calcium channel blockers lanotosides A,B,C, Strophanthin, Gitoxin, Digoxin, Quinidine, Procainamide*, Nifedipine*, Amlodipine, Verapamil, Antihypertensive agents which elicit their action through autonomous nervous system previously described under 1 and 2, Clonidine*, Diazoxide, Hydralazone, ACE Inhibitors, Enalapril and related drugs, Vasodilators such as Amyl nitrite,

Nitroglycerin, Isoxsuprine, Nylidrin, Sodium Nitroprusside.

[7-11 mks]

6. Steroids : [11-16 mks]
- a) Classification of steroids, configuration and conformation
 - b) Adrenocorticoids: Cortisol, Hydrocortisol acetate, Fludrocortisone acetate, Betamethasone, Flucinolone acetamide, Triamcindone, Methyl prednisolone
 - c) Androgens and Anabolic Steroids: Testosterone, Fluoxymesterone
 - d) Estrogens: Ethinyl estradiol, Estradiol, Mestramol, chlorotrainisene, Estrone, Dienesterol, Diethylstilbesterol and other non-steroidal estrogens
 - e) Progestational agents: Progesterone, Norethindrone, Norgestrel, Dimethisterone, Introduction to a steroid molecule, the following functional groups :-
 - 1. 9-Alpha-fluoro-11-Beta hydroxy
 - 2. 17-Alpha-Ethinyl and 17-Beta Methyl
 - 3. 16-Alpha, 17-Beta Acetonide
 - f) Oral contraceptives
7. Analgesics, Antipyretics and Anti-inflammatory agents:- [6-10 mks]
Aspirin*, Acetaminophen*, Phenylbutazone*, Oxyphenbutazone, Ibuprofen, Sulindac, Naproxin*, Probenecid, Allopurinol, Ketoprofen, Diclofenac, Oxycams like piroxicam, Nimesulide, Fenamates.
8. Narcotic Analgesic Agents : [5-8 mks]
Morphine, Oripavine, Codeine, ethylmorphine, dihydroxycodine*, Metopon, Levorphanol, Dextromethorphan, Meperidine*, anilaridine, Methadone*, meperidine, dextropropoxyphene and pentazocine.
9. Non-narcotic analgesic agents : [1-2 mks]
Dextropropoxyphene* and Ethoheptazine, Morphine antagonists, n-allyl-nor morphine levellorphone, naloxene.
10. Drugs used in Parkinsonism : [2-3 mks]
Benzotropine mesylate, procylidine, orphendine, hydrochloride, Ethopropazine, levodopa, Carbidopa, Benserazide, Amantadine*.
11. Drugs for Alzheimer's Diseases : [1-3 mks]
Tacrine, Velnacrine, Aniracetam, Sibopiridine

12.

[2-3 mks]

- a) Antilipemic Agents (Lipid lowering agents):
Lipoproteins- Classes & Metabolism – Hyperlipoproteinaemias, types and therapy
- b) Drugs to be studied –
- (i) Clofibrate, Gem fibrozil
 - (ii) HMG COA reductase inhibitors.
(Provastatin, Lovastatin, Simvastatin)
 - (iii) Resins- Cholestyramine.

TEXT BOOKS

1. Principles of Medicinal Chemistry, Foye, Lemke and Williams , Indian Ed. B.I.Waverly, Pvt. Ltd. New Delhi 1995.
2. Wilson and Gisvold, Textbook of Organic Medicinal and Pharmaceutical Chemistry, J.N. Delgado, W.A. Remers, Lipincott-Raven 10th Ed., 1998.

Reference Books:

1. J.B. Stenlake Vol. I & II : Foundations of Molecular Pharmacology - The Chemical basis of drug action (Athlone Press - The University of London).
2. Essentials of Medicinal Chemistry by Koralkovas, 2nd edition, Wiley- Inter science Pub. 1988.
3. The Organic Chemistry of Drug Synthesis : Daniel Ledmicer , John Wiley and Sons. Inc. Vols 1-6.
4. Profiles in Drug Synthesis : V.N. Gogte
5. Burger's Medicinal Chemistry and Drug Discovery (Vol. 1-5) Wiley Inter science Publication.
6. Textbook of Pharmaceutical Chemistry by Harkishansing & Kapoor.

4.3 PHARMACEUTICAL (MEDICINAL) CHEMISTRY-II (PRACTICALS)

3 Hrs./ week

Synthesis and Characterization of:

[TLC , M.P.& Chemical tests]

1. Sulfanilamide
2. Chloramine-T
3. Benzocaine
4. Hydantoin
5. Paracetamol
6. Reaction involving the following operation. Oxidation: Preparation of Iso-Nicotinic acid. Cyclization Preparation of Benzimidazole.
7. Benzalactone.
8. Benzophenone
9. Acetoacetanilide
10. 1,2,4 triazole

BOOKS:

- 1) Textbook of Practical Organic Chemistry - A.I. Vogel; ELBS
- 2) Practical Organic Chemistry - Mann and Saunders
- 3) The systematic identification of Organic Compounds - Shriver and Fuson
- 4) Systematic Qualitative organic Analysis by H. Middleton

4.4 PHARMACEUTICAL ANALYSIS-III (THEORY)

2 Hrs. / Week

1. **Introduction :** [2-3 mks]
Pharmacopoeial monograph, literature collection, data handling and expression of analytical results – Documentation and record keeping.
2. **Validation of Analytical Methods as defined in USP** [4-6 mks]
3. **Analysis of Drugs and Excipients in Solid State:** [4-6 mks]

Introduction to particle size analysis - Electrical sensing zone and light diffraction methods , scope of methods.
4. **Radiochemistry and radio pharmaceuticals -** [6-9 mks]
Introduction - fundamentals of radioactivity- properties of radiation, radiation protection, measurement of radioactivity, radiopharmaceuticals and radio nuclide generators, quality control of radio pharmaceuticals, radio chemical methods in analysis.
5. **Radioimmuno assay (RIA) and related immuno assay techniques , ELISA technique – Theory, Instrumentation and applications** [4-7 mks]
6. **Statistics and statistical quality control -** [6-9 mks]

Statistics in quality control - Definition of terms, normal distribution, T-test , F-test, Linear regression, Correlation Coefficient.
Methods of Statistical analysis as applied to sampling and interpretation of results, regression lines - sampling procedures.

Statistical Quality Control Charts.
7. **Medicaments in Formulations:** [6-10 mks]

Introduction, Quality control of formulated products, Sterility testing and microbial contamination- aerosol, inhalations, capsules , creams, emulsions , eye drops, injections, lozenges, mixtures, ointments, suppositories, tablets.
8. **NMR** [6-10 mks]
Introduction to NMR- Basic principles involved, Chemical shift, Spin-Spin coupling, Applications, Quantitative analysis.
9. **Mass Spectrometry** [8-13mks]
Preliminary discussion on theory and applications of mass spectrometry. Different mass spectrometers available.

10. Chromatography

[26-40 mks]

Terminology, Retention time, Retention volume, Adjusted retention volume, specific retention volume, relative retention volume, height equivalent to theoretical plate, temperature programming, resolution, Partition coefficient, qualitative analysis, column performance, internal standard, normalization, derivatives, detection.

Classification of Chromatography - Adsorption, partition, gas-liquid chromatography, size exclusion (gel) chromatography and ion exchange chromatography and to be discussed in brief.

Column Chromatography, paper chromatography, Thin layer chromatography (TLC), High performance thin layer chromatography (HPTLC), Gas chromatography (GC), High performance liquid chromatography and their pharmaceutical applications.

DEVELOPMENT OF CHROMATOGRAM

- I. PAPER CHROMATOGRAPHY – Introduction, Ascending chromatography, Descending chromatography, 2-dimensional chromatography.
 - Applications
 - to separate mixtures of Oxalic, succinic and glutaric acid
 - pharmacopoeial applications (Any two)
(no specific application should be asked in the examination)

- II. THIN LAYER CHROMATOGRAPHY- Introduction, selection of adsorbent, preparation of the plate, spotting, Development of chromatogram, Detection of compound, Recovery of components, Quantitative measurements, photo- documentation.
 - Applications
 - Identification of compounds, Impurities
Applications to HPTLC analysis

- III. GAS CHROMATOGRAPHY – Introduction, Carrier gas, Columns, Injection system, Detectors, Thermal conductivity detector (TCD), Electron Capture detector (ECD), Thermionic detector (TID), Flame ionization detector (FID), Nitrogen Phosphorous detector (NPD), Photoionisation detector (PID), Head space analysis
 - Pharmacopoeial application
Assay of Ampicillin sodium

- IV. HPLC –

Instrumentation-

Pumps (Reciprocating pumps, Displacement pumps, Pneumatic pumps)
Mobile phase reservoirs, solvent treatment systems, Isocratic Elution, Gradient Elution, Injection system,

Detectors- Photometric detectors (Single wavelength, Multi wavelength, variable wavelength, programmable, Diode array, Fluorescence detectors), Refractive index detectors, Electrochemical detectors

Columns, Analytical columns, Guard columns, column thermostats, Types of column packing

V. ION EXCHANGE CHROMATOGRAPHY -__ Ion exchange resins, Applications

VI. GEL PERMEATION CHROMATOGRAPHY- Introduction, Apparatus and technique

11. **Raw material analysis (RMA)** [4-6 mks]

11. **Packaging Material Testing (PMT)-** [5-7 mks]
Testing of primary packaging materials, bottles, tubes, testing of foils. Permeability of plastics, burst and tensile strength. Testing of secondary packaging materials, cartons drop test, folding endurance test.

Text Book

1. Practical Pharmaceutical chemistry, Part I and Part II , by Beckett and Stenlke.

Books

1. Grant - Statistical quality control (McGraw Hill)
2. Lamprecht - Implementing ISO -9000 series (Dekker)
3. Instrumental Methods of Analysis - Willard, Dean, Merrit and Settle- (Wadsworth Pub. Co.)
4. Instrumental Methods of Analysis - Ewing
5. Higuchi & Brochmann - Hanssen - Pharmaceutical Analysis - (Interscience)
6. Garratt - The quantitative analysis of Drugs (Tropan &Co.)
7. Meites- H.B. of Analytical Chemistry (McGraw Hill)
8. IP, USP, BP, European- Pharmacopoeia, International Pharmacopoeia.
9. Florey- Analytical profiles of Drugs substances (Academic Press)
10. Gary Christian - Analytical Chemistry (John Wiley)
11. Skoog - Principles of instrumental analysis (Saunders)
12. Haftmann - Chromatography (McGraw Hill)
13. Browning - Chromatography (McGraw Hill)
14. Hamilton , Simpson and Ellis - Calculation of Analytical Chemistry (McGraw Hill)
15. OPPI - Quality Assurance Guide.
16. Juran- Quality Control Handbook - McGraw Hill.
17. Kasture, Mahadik, Wadodkar, More- Pharmaceutical Analysis Vol-1&2 (Nirali prak.)

4.4 PHARMACEUTICAL ANALYSIS-III (PRACTICALS)

3 Hrs./ week

I. Demonstration experiments

- i) Analytical method development: Demonstration of use of statistical treatment for validation of analytical method by titrimetric method.
- ii) Determination of Percentage purity of given drug sample using HPLC
- iii) Polarographic assays.
- iv) Identification of given drug by TLC and determination of impurities.

Experiments to be performed by Students

- i) Estimation of chlorine in Dioxanide Furoate using oxygen combustion flask technique.
- ii) Tests for evaluation of packaging materials which should include, Tensile strength
(using universal or other suitable tester) moisture vapour transmission (using permeability cups) this test can be performed on polyethylene or other plastics as well as craft papers used for packaging.
- iii) Finished product evaluation should include the general test, including the recording of
 - 1) Description 2) pH 3)Viscosity 4)Optical rotation 5) Clarity 6)Acidity 7)Alkalinity 8) Limit test 9) Assay

Following examples to be consider

- 1) Bromohexene and Salbutamol
- 2) Eye / Ear drops (any allopathic preparation)
- 3) Hydrochlorothiazide and propanolol
- 4) Atenolol and Nifedipine
- 5) Nephazoline and Antazoline sulphate

II. Excipients

Evaluation of following Excipients may be considered

- 1) Hydroxy propyl methyl cellulose
- 2) Polymethyl Acrylates

III. Determination of the uniformity of dose from Isoprenaline Aerosol Inhalation

IV. Assay of Sodium thiosulphate injection IP

V. Assay of Aspirin powder/tablets and its purity determination.

VI. Assay of Salbutamol sulphate

VII. Assay of Salbutamol sulphate injection

VIII. Assay of Salbutamol sulphate syrup

IX. Assay of Salbutamol sulphate tablets

X. Moisture content by Karl Fischer titrator.

BOOKS

1. Practical Pharmaceutical chemistry, Part I and Part II , by Beckett and Stenlke.
2. Semimicro quantitative organic analysis, by Cheronis and Entrikin, Interscience Pub.
3. Indian Pharmacopoeia, US Pharmacopoeia British Pharmacopoeia and European Pharmacopoeia.
4. Thin layer Chromatography- Egon Stahl.
5. Higuchi & Brochmann - Hanssen - Pharmaceutical Analysis - (Interscience).
6. Garratt - The quantitative analysis of Drugs (Tropan &Co.).
7. Identifications of Drugs in Pharmaceutical Formulations by thin layer Chromatography by P.D.Sethi (CBS Publications)
8. Quantitative analysis of Drugs in Pharmaceutical formulation 3rd edition by P.d. Sethi (CBS Publications)

4.5 PHARMACOLOGY AND BIOASSAY (THEORY)

3 Hrs./ week

1. Central Nervous System: [12-18 mks]

General Considerations

Alcohol

General Anesthetics

Local Anesthetics

Sedative & Hypnotics

Drugs effective in mental disorders

Analgesic

Antipyretic & Anti-inflammatory agents

Central Nervous system Stimulants

2. Chemotherapy: [24-38 mks]

General considerations: - General principles of chemotherapy of infections

Mechanism of action, Pharmacokinetics, Uses & Adverse effect only to be discussed

- a) Sulfonamides, Cotrimoxazole, Quinolones
- b) Antibiotics effective against Gram-positive organisms- Penicillins & Macrolide antibiotics
- c) Antibiotics effective against Gram negative organisms- Amino glycosides
- d) Antibiotics effective against both Gram positive & Gram negative organisms- Cephalosporins, Tetracycline & chloramphenicol

Chemotherapy of: -

- a) Tuberculosis & leprosy
- b) Protozoal infections (Antimalarials, antiamoebics, Trichomoniasis, leishmaniasis & Kala azar infections)
- c) Helminthiasis
- d) Fungal infections
- e) Viral infections
- f) Urinary tract infections & STDS

g) Antineoplastic agents

3. **Immuno pharmacology:** - Immunosuppressants & Immunostimulants [8-12 mks]

4. **Hypoglycemic agents:** - Insulin & oral. Anti diabetics [12-19 mks]

5. **Bioassays:** [12-19 mks]

- Applications, Principles & Types of bioassays
- Bioassay of d-Tubocurarin, Heparin, digoxin, insulin & Adrenalin

6. Drug interactions*: - [6-10 mks]

General Considerations, Types of drug interaction factors contributing to the occurrence of drug interactions, Using of drug interaction information & mechanisms of drug interactions

7. **Miscellaneous** [6-10 mks]

- ◆ Drug induced diseases
- ◆ Modification of drug dosage regimen in kidney & liver dysfunction
- ◆ Drug therapy in pregnancy & lactation

Reference:

1. Satoskar, Bhandarkar & Ainapure: Pharmacology & Pharmacotherapeutics: Publ. Popular prakashan, Mumbai.
2. Remington: The Science & Practice of Pharmacy, 19th edition 1995, Publ: Mack Publishing company, Easton, Pennsylvania. 18042)
3. Alfred Goodman Gilman: The Pharmacological basis of therapeutics, 9th Edn. 1996, Publ. The Macmillan Company, NY
4. Lawrence & Bennet, Clinical Pharmacology, ELBS Edn.
5. James Crossland: Lewis Pharmacology
6. K. D. Tripathi: Essentials of Medical Pharmacology, 4th Edn. . Jaypee Publ.
7. Charles R Craig & Robert E Stitzel: Modern Pharmacology; 4th Edn. Little Brown & Co.
8. M. M. Das, S. K. Datta: R. Ghosh's Modern concepts on pharmacology & therapeutics 24th Edn. Calcuttai Hilton & Co.
9. H.P. Rang & M.M. Dale : Pharmacology ; 3rd Edn. 1996, Churchil Livingstona, Edin burgh

4.5 PHARMACOLOGY AND BIOASSAY (PRACTICAL)

3 Hrs./ week

Studies on isolated heart of frog:

1. Effect of adrenaline / Isoprenaline on heart rate and its force of contraction.
2. Effect of acetylcholine on rate and force of contraction.
3. Influence of propranolol on adrenaline/Isoprenaline induced effects on frog's heart.
4. Effect of muscarinic receptor blocking drugs on the responses evoked by acetylcholine on frog's heart.

Bioassays:

1. Bioassay of acetylcholine using frog rectus abdomens muscle.
2. Bioassay of gallamine / d-tubocurarine using frog rectus abdomens muscle.

DEMONSTRATION

1. Bioassay of histamine using guinea-pig ileum.
2. Bioassay of oxytocin using rat uterus.
3. To demonstrate the effect of increased venous return on the cardiac output and the effect of digitalis on the cardiac output and force of contraction in a failing heart.
4. To demonstrate effect of changes in ionic composition i.e.
 - a. excess of calcium/potassium ions on perused frog heart.
 - b. lack of sodium, potassium, and calcium ions on perused frog heart.
5. To demonstrate effect of different routes of drug administration on the effects produced.
6. To demonstrate the role of liver in biotransformation of drugs and the intensity of effects produced by them in rats pretreated with carbon tetrachloride.

Reference:

1. Sheth & Others - Selected topics in experimental Pharmacology (Kothari Book Dept).
2. Perry - Pharmacological experiments on Isolated preparations (E & S Livingston)
3. Mc. Leod LJ - Pharmacological experiments on intact preparation (E & S Livingston)
4. Gaitonde BB & Nanivadekar - Tutorials in Pharmacology (New Literature Pub.)
5. M M Ghosh : Fundamentals of Experimental Pharmacology
6. S. K. Kulkarni : Hand book of Experimental Pharmacology

4.6 PHARMACOGNOSY AND PHYTOCHEMISTRY - II (THEORY)

2 Hr. / Week

1. Phytochemical investigation of Crude Drugs and preliminary phytochemical screening.
[7-10 mks]
2. Introduction of standardisation of Herbal and Ayurvedic formulations. [7-10 mks]
3. Plant growth regulators. [4-7 mks]
4. Detailed study of each category of drug under Pharmacognostical and phytochemical scheme including Biosynthesis.
A] Tannins :- [7-10 mks]
Definition, description, classification - study of drugs containing tannins including - Bahera, Myrobalan, pale catechu, Black catechu.
B] Volatile oils and terpenoids – [13-20 mks]
Definition composition, chemistry, extraction of volatile oil, Biosynthesis, terpeneless volatile oil, study of drugs containing vol-oils including - Umbelliferous fruits (fennel, Dill, Coriander), cardamom, mentha piperata, cinnamon, Eucalyptus, clove, lemon grass, nutmeg, jatamansi, Rasna, tulsi and artemesia. Oils used in perfumery :- Musk, Jasmine, lavender, sandalwood, and Vaj.
C] Alkaloids :- [13-20 mks]
Definition, Distribution, Classification, isolation and biogenesis : study of Ashwagandha, Lobelia, Belladonna, Cocoa leaves, Cinchona, Ipecac, Ergot, Rauwolfia, Vinca, Nux-Vomica, Ephedra, Colchicum, Vasaka, Poppy, Tea and Coffee.
D] Lipids and Waxes : [7-10 mks]
Castor oil, Olive oil, Cod liver oil, Shark liver oil and Beeswax.
5. Plant Allergens :- [6-10 mks]
Classification (inhalants, injectants, contactants, infectants, enfestants), plants causing hay fever, molds causing allergy.
6. Natural Pesticides :- Pyrethrum, Nicotine, Neem. [4-6 mks]
6. Marine drugs – [6-9 mks]
cardiovascular drugs, cytotoxic compounds, antimicrobial compounds, antibiotic compounds, anti-inflammatory and antispasmodic agents and other therapeutically valuable compounds.
7. Study of Ayurvedic drugs, herbs and Herbal food :- [6-10 mks]

Introduction status, safety and efficacy considerations. Brief study of cucumber, garlic, onion, Shatavari, Gokhru, Shankhpushpi, Brahmi, Gugul, Gaduchi, Shilajit, Amla, Ginseng & honey.

Books:

1. Indian Pharmacopoeia
2. Pharmacognosy : Tyler, Brady and Roberts (Lea Febiger)
3. Text Book of Pharmacognosy T.E. Wallis (CBS Pub. Delhi)
4. Text Book of Pharmacognosy, Trease & Evans (ELBS).
5. Text Book of Pharmacognosy - Kokate & Purohit - Pharmacognosy, (Nirali Publ).
6. Herbal pharmacopoeia – IDMA publication.
7. Ayurvedic formulary of India – Govt. of India publication.
8. Practical Pharmacognosy – C.K. Kokate.
9. Powdered Crude Drugs. – M. A. Iyengar.
10. Practical evaluation of Phytopharmaceuticals – Brain and Turner.
11. Anatomy of crude drugs.- M. A. Iyengar.

4.6 PHARMACOGNOSY AND PHYTOCHEMISTRY - II (PRACTICALS)

3 Hr. / Week

1. Pharmacognostical study (including morphology histology and powder characteristics) of the following
Cinchona, Ipecac, Rauwolfia, Vinca, Nux Vomica, Ephedra, Fennel, Cardamom, Cinnamon, Clove.
2. Pharmacognostical study (excluding histology) of the following plants
Catechu, Bahera, Myrobalan, Nutmeg, Jatamansi, Sandalwood, Tulsi, Pyrethrum, Ergot, Colchicum.
1. Group Experiments :
 - A] Extraction of active constituents and identification by suitable method.
 - i. Curcuminoids from *Curcuma longa*
 - ii. Extraction of alkaloids from *Nux Vomica* alkaloids.
 - iii. Extraction of Caffeine from tea
 - iv. Extraction of Hesperidin (flavonoid) from orange peel.
 - v. Extraction of Citric acid from Lemon.
 - B] Ayurvedic formulations and standardisation of important Official preparations such as
Asava, Arista, Churna, Lepa, Etc.
 - C] Preparation of Herbal cosmetics like Shampoos, Creams, Lotions and Herbal foods.

Books :

2. Indian Pharmacopoeia
3. Pharmacognosy : Tyler, Brady and Roberts (Lea Febiger)
4. Text Book of Pharmacognosy T.E. Wallis (CBS Pub. Delhi)
5. Text Book of Pharmacognosy, Trease & Evans (ELBS).
6. Text Book of Pharmacognosy - Kokate & Purohit - Pharmacognosy, (Nirali Publ).
7. Text Book of Pharmacognosy (Practical) - By Kokate
8. Herbal pharmacopoeia – IDMA publication.
9. Ayurvedic formulary of India – Govt. of India publication.
10. Powdered Crude Drugs. – M. A. Iyengar.
11. Practical evaluation of Phytopharmaceuticals – Brain and Turner.
12. Anatomy of crude drugs. – M. A. Iyengar.

4.7 PHARMACEUTICAL MARKETING AND JURISPRUDENCE (THEORY)

3 Hr. / Week

1. Management: **[10-14 mks]**
Business Management Thought, Functions, types of Organizations, Techniques of Communication, direction Participation, delegation, decision making, control Tools like PERT, CPM, systems.

2. Sales & Marketing Management : **[12-19 mks]**
Marketing Management Concepts, Behavior of Doctors, Retailers and Customers, Marketing Research, Advertising and Sales promotion, Pricing, Distribution, Selling, Product Management, New Product Selection, New Product Management, Sales Forecasting, Budgeting, various types of pricing.

3. Operations Management (passing references of following terms : **[12-19 mks]**
Production planning & Control systems, Materials Management systems, Quality Management systems, Financial planning & Control systems, Inventory Management systems, Project Management

STATUS OF PROFESSION OF PHARMACY IN PRE - AND POST - INDEPENDENT ERA - REPORTS OF CHOPRA ENQUIRY COMMITTEE, HATHI AND BERKER COMMITTEES AND ACTIONS THEREON - HISTORICAL PERSPECTIVE.

An objective study of the following with amendments :

1. Drugs & Cosmetics Act 1940/Rules 1945 : **[12-19 mks]**
Extent, commencement - Important definitions - Drugs Technical Advisory Board & Central Drugs laboratory - their composition and functions - Ayurvedic/Allopathic drugs, prohibitions - Ayurvedic, Homeopathic & Allopathic medicines in respect of Import & Export, Indigenous manufacture, sale or distribution - Drugs Consultative Committee, its composition and functions - Inspectors - their powers & duties - sampling procedure - Inspection enquiry, Investigation/Cosmetics/Ayurvedic drugs) - Imported drugs, Cosmetics and Indigenously manufactures drugs and cosmetics - offences and penalties, confiscation's - Govt. Analyst, Licensing Authorities & Controlling Authority, qualifications, functions & powers - Licenses for different systems for Medicine.

2. Drugs & Magic Remedies Act 1954 **[6-10 mks]**
Definitions, Official's duties, Prohibitions, Penalties

3. Narcotic Drugs & Psychotropic Substances Act 1985 – **[6-10 mks]**
Historical background of Opium Act and Dangerous Drugs Act. Prohibitions and penalties.

4. Prevention of Food adulterations Act 1954 & Rules 1955 : **[6-10 mks]**

Important definitions, Central Board of Food Standard, Central Food Laboratory, Composition & Functions.

Public Analyst : Qualifications, duties, Food Inspectors : Qualification powers, duties sampling procedures.

5. Drugs Price Control Order 1987 **[4-7 mks]**
Historical background - Essential commodities Act - Relevant provisions, Drugs Prices Display Rule 1961 & other relevant orders - Applicability to Imported drugs & Indigenously manufactured drugs - definitions - prices to wholesaler and retailer - MAP - penal provisions.
6. Pharmacy Act 1948. **[8-12 mks]**
7. Prevention of cruelty to animals act-CPSEA rules. **[4-6 mks]**

REFERENCE BOOKS :

1. Pharmaceutical Jurisprudence – N. K. Jain.
2. D & C act 1940 and rules 1945
3. Pharmaceutical marketing management – Mukhopadhyaya
4. Textbook of Forensic Pharmacy. – B. M. Mithal
5. Textbook of Forensic Pharmacy. – B. Suresh
6. Bare Acts.
7. PERT and CPM : Principles and Application.
8. Salesmanship, Sales management and advertisement – M. Satyanarayana.
9. Business organisation and management – M. C. Shukla
10. Principles of Pharmaceutical marketing. – Smith.
11. Modern marketing – Hapnar
12. Economics – A general introduction – Fredrick Benham
13. Personal management
14. Handbook of Drug Laws – M. L. Mehta.