

Detail Syllabus Outline of Bachelor of Pharmacy

First Semester			
S. No.	Course Code	Subjects	Credit
1.	PHAR 111 PHAR 111 Lab	Pharmaceutical Inorganic Chemistry Pharmaceutical Inorganic Chemistry Practical	3 1
2.	PHAR 112 PHAR 112 Lab	Pharmacognosy- I Pharmacognosy- I Practical	3 1
3.	PHAR 113 PHAR 113 Lab	Physical Chemistry Physical Chemistry Practical	3 1
4.	PHAR 114	Mathematics	4
5.	PHAR 115 PHAR 115 Lab	Basic Computer Applications Basic Computer Applications Practical	2 1
6.	PHAR 116	Communication Skill	2
		Total Credits	21
Second Semester			
S. No.	Course Code	Subjects	Credit
1.	PHAR 121 PHAR 121 Lab	Pharmaceutical Organic Chemistry –I Pharmaceutical Organic Chemistry –I Practical	3 1
2.	PHAR 122 PHAR 122 Lab	Pharmacognosy- II Pharmacognosy–II Practical	4 1
3.	PHAR 123 PHAR 123 Lab	Physical Pharmacy Physical Pharmacy Practical	3 1
4.	PHAR 124 PHAR 124 Lab	Pharmaceutical Analysis – I Pharmaceutical Analysis – I Practical	3 1
5.	PHAR 125 PHAR 125 Lab	Anatomy & Physiology I Anatomy & Physiology I Practical	3 1
		Total Credit	21
Third Semester			
S. No.	Course Code	Subjects	Credit
1.	PHAR 211 PHAR 211 Lab	Pharmaceutical Organic Chemistry –II Pharmaceutical Organic Chemistry -II Practical	4 1
2.	PHAR 212 PHAR 212 Lab	Pharmacognosy III Pharmacognosy III Practical	3 1
3.	PHAR 213 PHAR 213 Lab	Pharmaceutical Analysis –II Pharmaceutical Analysis –II Practical	4 1
4.	PHAR 214 PHAR 214 Lab	Pharmaceutical Engineering I Pharmaceutical Engineering I Practical	3 1
5.	PHAR 215 PHAR215 Lab	Anatomy & Physiology II Anatomy & Physiology II Practical	3 1
		Total Credits	22

Fourth Semester			
S. No.	Course Code	Subjects	Credit
1.	PHAR 221	Biochemistry	3
	PHAR 221 Lab	Biochemistry Practical	1
2.	PHAR 222	Chemistry of Natural Products	3
	PHAR 222 Lab	Chemistry of Natural Products Practical	1
3.	PHAR 223	Pharmaceutical Engineering II	3
	PHAR 223 Lab	Pharmaceutical Engineering II Practical	1
4.	PHAR 224	Pharmaceutical Microbiology	3
	PHAR 224 Lab	Pharmaceutical Microbiology Practical	1
5.	PHAR 225	Pharmacology I	4
	PHAR 225 Lab	Pharmacology I Lab	1
		Total Credits	21

Fifth Semester			
S. No.	Course Code	Subjects	Credit
1.	PHAR 311	Medicinal Chemistry I	4
	PHAR 311 Lab	Medicinal Chemistry I Practical	1
2.	PHAR 312	Pharmaceutical Technology I	3
	PHAR 312 Lab	Pharmaceutical Technology I Practical	1
3.	PHAR 313	Pharmaceutical Biotechnology	3
	PHAR 313 Lab	Pharmaceutical Biotechnology Practical	1
4.	PHAR 314	Pharmacology –II	3
5.	PHAR 315	Public Health Pharmacy	3
	PHAR 316	Public Health Pharmacy Field work	1
6.	PHAR 317	Pathophysiology	3
		Total Credits	23

Sixth Semester			
S. No.	Course Code	Subjects	Credit
1.	PHAR 321	Medicinal Chemistry II	4
	PHAR 321 Lab	Medicinal Chemistry II Practical	1
2.	PHAR 322	Pharmaceutical Technology II	3
	PHAR 322 Lab	Pharmaceutical Technology II Practical	1
3.	PHAR 323	Pharmacology –III	3
	PHAR 323 Lab	Pharmacology –III Practical	1
4.	PHAR 324	Biopharmaceutics & Pharmacokinetics	3
	PHAR 324 Lab	Biopharmaceutics & Pharmacokinetics Practical	1
5.	PHAR 325	Biostatics	3
6.	PHAR 326	Engineering Drawing	1
		Total Credits	21

Seventh Semester			
S.No.	Course Code	Subjects	Credit
1.	PHAR 411 PHAR 411 Lab	Dosage form Design Dosage form Design Practical	3 1
2.	PHAR 412	Pharmaceutical Management	3
3.	PHAR 413	Pharmacotherapeutics	3
4.	PHAR 414 PHAR 414 Lab	Research Methodology Literature Survey and Project Design Practical	3 1
5.	PHAR 415	Forensic Pharmacy	3
6.	PHAR 416 PHAR 416 Lab	Dispensing and Community Pharmacy Dispensing and Community Pharmacy	3 1
		Total Credits	21

Eighth Semester			
S.No.	Course Code	Subjects	Credit
1.	PHAR 421 PHAR 421 Lab	Hospital Pharmacy Hospital Pharmacy Practical	3 1
2.	PHAR 422 PHAR 422 Lab	Drug Delivery System Drug Delivery System Practical	2 1
3.	PHAR 423 PHAR 423 Lab	Quality Assurance & Instrumental Analysis Quality Assurance & Instrumental Analysis Practical	4 1
4.	PHAR 424	Clinical Pharmacy	2
5.	PHAR 425	Project Work	6
		Total Credits	20

FIRST SEMESTER

PHAR 111 Inorganic Pharmaceutical Chemistry [45 Hours]

Unit 1: Test of Purity, Importance of limit test and general principles of limit tests for chloride, sulphate and iron. (1hr)

Unit 2: Acid, Base, Buffers and Water (9 hrs)

Introduction/ Concept of acid and base, Importance of acids and bases in Pharmacy, storage condition. Official acids: Phosphoric acid (Conc/dil), HCl (Conc/dil), Boric acid. Official Bases: NaOH, KOH, Ca(OH)₂, dil. and strong NH₃, Na₂CO₃, Acidosis and Alkalosis. (3 hrs)

Buffer: Definition, types of buffer, properties, pH of buffer and calculation of pH (Handerson Hasselbalch equation), Mechanism of buffer action, buffer capacity, criteria for buffer selection, Role of buffers in pharmacy, some examples of buffer system, physiological acid-base balance, buffer system in body and their role (3 hrs)

Official buffer: Standard buffer system, pharmaceutical buffer system, composition of standard buffer: (Hydrochloric acid buffer, acid phthalate buffer, neutralized phthalate buffer, phosphate buffer, alkaline buffer) (1 hr)

Water: Importance, types of water (Potable water, Purified water, Water for injection/ Sterile), Types of Water Purification Method (Distillation, Ion Exchange Method & Reverse Osmosis Method) (2 hrs)

Unit 3: Gastrointestinal Agents (7 hours)

Antacids: Definition, criteria for selection, classification, non-systemic (Aluminum hydroxide, calcium carbonate, magnesium oxide, magnesium carbonate and magnesium trisilicate), systemic (sodium bicarbonate); combination preparations (types & significances) (3 hrs)

Protective & adsorbent: Definition, characteristics, Bismuth sub carbonate, Kaolin (1 hr)

Acidifying agents or Acidifiers: Definition, types of acidifiers, dilute hydrochloric acid. (1 hr)

Cathartics (Purgatives): Definition, classification of purgatives, mechanism of action of each purgatives, magnesium sulphate, sodium potassium tatarate, sodium phosphate (2 hrs)

Unit 4: Intracellular & Extracellular Electrolytes (3 hours)

Role of physiological ions (sodium, potassium, magnesium, sulphate, bicarbonate, phosphate) & acid base balance, electrolytes used in acid - base therapy (potassium citrate,

sodium acetate and Ammonium Chloride), Electrolyte used in replacement therapy (NaCl, KCl, composition of ORS, Ringer lactate solution)

Unit 5: Essential Trace elements (5 hours)

Definition of transition elements; Iron & haematenics; Functions of iron in the body, Causes of deficiency of iron. Focus on Compounds: Ferrous Fumarate; Ferrous Gluconate and Ferrous sulphate) Mineral Supplements (Cu, Zn, Cr, Mn, Sb, S, I).- Introduction, Role and deficiency.

Unit 6: Cations & Anion (1 hr)

Definition, Biological roles or importance of cations (Sodium, Potassium, Calcium) & anions (chloride, bicarbonate, phosphate)

Unit 7: Topical Agents (4 hrs)

Protective; - Definition, Classification, Focus on talcum, Zinc oxide, Calamine

Local anti-infective: Definition, Classification, Focus on H₂O₂, KMnO₄, Iodine, Povidone iodine; Advantage of Povidone iodine over iodine.

Astringents: Definition, Mechanism of action, Focus on Alum, ZnSO₄, AgNO₃,

Unit 8: Gases & Vapors (3 hrs)

Definition, role of gases in our body, focus on Oxygen, CO₂ **Inorganic anesthetics:** Definition, Nitrous oxide **Respiratory Stimulant:** Definition, Ammonia solution, spirit of ammonia

Unit 9: Dental Product (3 hrs)

Introduction and types of dental products with examples; Dentifrices: Calcium Carbonate and Dicalcium phosphate. Dental caries/dental plaque, Anti-caries agent: Role of fluoride as anticaries agent, consequences of fluoride overdosing, Sodium Fluoride and Stannous fluoride.

Unit 10: Complexing & Chelating agents used in therapy (3hrs)

Concept of complexation & chelation, properties of chelating agent, importance of chelation; Heavy metal poisoning and their antagonist (Activated Charcoal, Disodium edetate, desferroaxamine mesylate, D-penicillamine, dimercaprol). [3hr]

Unit 11: Miscellaneous Agents (3 hrs)

Definition, classification and uses with examples of inorganic Sclerosing agents, expectorants, emetics, sedatives, poisons and antidotes.

Definition with examples, Criteria of selection (If there) and Pharmaceutical uses of following agents: Antioxidants and preservatives, filter aids, adsorbents, diluents, excipients, suspending agents and colorants

Unit 12: Inorganic radio pharmaceuticals (3 hrs)

Definition, Isotopes, Radioactive decay particles, Units of radio activity & half life of radio elements , Precaution to be taken while handling & storage of radio isotopes, Application, Radio pharmaceutical preparation & clinical uses of Cobalt -57 & 60, Gold – 198, Iodine- 125 & 131, Radio opaque contrast media (BaSO_4); types, ideal properties of radio opaque contrast media.

PHAR 111 Lab Inorganic Pharmaceutical Chemistry I Practical

- Identification tests for pharmacopoeal inorganic pharmaceuticals and qualitative tests for cations & anions should be covered. At least four inorganic drugs should be prepared in the laboratory.
- Limit test for Chloride, sulphate and iron should be done according to current pharmacopoeia.

Books and other resources recommended

1. Practical pharmaceutical chemistry by A.H. Beckett and J.B. Stenlake
2. British pharmacopoeia, Indian pharmacopoeia
3. Text book of pharmaceutical chemistry by Bently and Driver
4. Inorganic pharmaceutical chemistry by G.R. Chatwal
5. Inorganic pharmaceutical and medicinal chemistry by Block, Roche, Soine and Wilson.

PHAR 112 Pharmacognosy- I

[45 Hours]

Unit – 1: Introduction (8 hours)

Definition, Historical back ground, present status and future scope of Pharmacognosy. Vegetation occurring in various climatic zones of Nepal, method of plant collection, preparation of herbarium and their storage including traditional and complementary system of medicine. (Ayurvedic, homeopathic, traditional Chinese, siddha system, unani system and Amachi system).

Unit – 2: Cultivation, collection, processing and storage of crude drugs (8 hours)

Methods of propagation, Factors influencing the cultivation of medicinal plants. Types of soil and fertilizers of common use. Pest management and natural pest control agents. Polyhouses and greenhouses. Plant hormones and their application, polyploidy and hybridization with the special references to medicinal plants. Introduction to plant tissue culture as a source of herbal ingredients.

Unit – 3: Plant Description (8 hours)

Key characters, family description of one member each from the following: Rutaceae, Umbelliferae, Labiatae, Solanaceae, Liliaceae, Myrtaceae and Rubiaceae.

Unit – 4: Study of herbal resources (14 hours)

Classification of crude drugs (Alphabetical, morphological, taxonomical, chemical, pharmacological and chemotaxonomical with principle, merits and demerits and examples). Organized crude drugs- General morphological and anatomical study of subterranean organs, leaf, bark, wood, fruits and seeds. Unorganized crude drugs- general identifying characters.

Macroscopical and microscopical characters, varieties, cultivation, collection, principal, constituents, chemical nature, tests for identification, adulterants, substitutes and uses of the following drugs. Leaves: Eucalyptus. Flowers: Saffron. Fruit: Fennel. Powder: Lycopodium. Barks: Cinchona. Seeds: Ispaghula. Woods: Sandal

Unit – 5: Quality control of crude drugs. (7 hours)

Adulteration of crude drugs and their detection by organoleptic, microscopic, physical, chemical and biological methods of evaluation. WHO guide lines of the standardization of Herbal raw materials and finished products.

PHAR 112 Pharmacognosy- I Practical

Minimum 8 experiments covered in theory.

Proposed practical topics

1. Morphological characteristics of plant families in theory.
2. Microscopic measurements of cells contents: starch grains, calcium oxalate crystals and phloem fibers.

3. Determination of leaf constants such as stomatal index, stomatal number, vein islet number, vein termination number and palisade ratio.
4. Preparation of Herbarium sheet.
5. Identification of crude drugs mentioned in theory.
6. Study of fibers and pharmaceutical aids.

Books and other resources recommended

1. Atal, CK and Kappor, BM. Cultivation and Utilization of Medicinal Plants.
2. Trease, CE and Evans, WC. Textbook of Pharmacognosy. 11th to 14th Editions. Tindal L. U.K.
3. Tyler, VC Brady, LR and Robers JE. Pharmacognosy. 8th Edition, Lea & Febeger, Philadelphia.
4. Wallis, TE. Textbook of Pharmacognosy, 5th Edition, J & A, Churchill Limited, U.K.
5. Kokate, CK Purohit, AP. And Gokhale, SB. Pharmacognosy.

PHAR 113 Physical Chemistry

[45 Hours]

Unit – 1: Gaseous State (4 hrs)

Introduction, gas laws, kinetic theory of gaseous, derivation of kinetic gas equation, deduction of gas laws, deviation from ideal behaviors, Vander Waal equation of state for real gases, significances of Vander Waal constant a and b, critical phenomena and vander Waal constant value of a and b.

Unit – 2: Liquid State (6 hrs)

Introduction, vapor pressure and boiling point, surface tension, determination of surface tension by drop formation method, viscosity and its determination by ostwald's viscometer, effect of temperature on viscosity, additive and constitutive properties, parachor and reochor, refractive index, optical rotation, dipole moments.

Unit – 3: Solutions (10 hrs)

Mole concept, concentration terms, ideal and real solutions, Henry's law, colligative properties, ideal solution(non volatile solute), lowering of vapor pressure, Raoult's law, determination of molecular weight from vapor pressure lowering, ideal solution and deviation from Raoult's law, ideal solution of two volatile components, elevation of boiling point, determination of molecular weight from freezing point depression, osmotic pressure, distribution coefficient, application and limitations of distribution law, phase rule, statements, terms involved in phase rule, derivation of phase rule, single component system(water system). Conductance (specific conductance, equivalent conductance, molar conductance, cell constant), measurement of conductance, variation of conductance with dilution, Faraday's law of electrolysis, Debye -Huckel Theory.

Unit – 4: Adsorption (3 hrs)

Adsorption and absorption, Freundlich adsorption isotherm, Langmuir adsorption isotherms, application of adsorption.

Unit – 5: Thermodynamics (8 hrs)

Introduction, importance, limitation, terms/ terminology, state function , extensive and intensive properties, thermodynamic process and system, internal energy, work done(reversible and irreversible). First law of thermodynamics, enthalpy, enthalpy change, temperature dependence of enthalpy change, Hess's law of constant heat summation, application and calculations; heat of vaporization, heat of fusion, heat of formation, heat of combustion, heat of neutralization, heat capacities and relation between C_p and C_v ; criteria of spontaneous process, entropy, second law of thermodynamics, free energy, relation between free energy and equilibrium constant, relation between free energy and useful work. Third law of thermodynamics.

Unit – 6: Photochemistry (3 hrs)

Consequences of light absorption, Lambert-Beer's law, Laws of photochemistry, Quantum efficiency.

Unit – 7: Chemical Kinetics (8 hrs)

Introduction, rate of reaction, factor influences the rate of reaction, rate law equation, rate constant, order and molecularity of reaction, integrated rate equation for zero order, first order and second order (single and different types of reaction) and half life period, activation energy, temperature dependence of Arrhenius equation, opposing reaction (first order opposed by first order), parallel reaction, collision theory of bimolecular reaction (no derivation), unimolecular reaction, steady state approximation, catalysis, characteristics of catalysis, homogeneous catalysis, heterogeneous catalysis, acid base catalysis, enzyme catalysis, Michaelis Menten equation.

Unit – 8: Quantum Mechanics (3 hrs)

Postulates of Quantum Mechanics, Operator (Linear, Laplacian, Hamiltonian operator), and Schrodinger's wave equation.

Phar 113 Lab Physical Chemistry Practical

1. To determine molar mass by Rast method and cryoscopic method.
2. To determine refractive index of given liquids and find out the contribution of carbon, hydrogen and oxygen in molar refraction of a compound.
3. To determine molar mass of volatile liquids by Victor-Meyer method.
4. To determine the specific rotation of sucrose at various concentrations and determine the intrinsic rotation.
5. To determine the heat of solution, heat of hydration and heat of neutralization.
6. To determine the cell constant, verify Ostwald dilution law and perform conductometric titration,
7. To determine rate constant of simple reaction.

Books and other resources recommended

1. Essential of physical chemistry-B.S. Bahl
2. Meyer's University Chemistry
3. Physical pharmacy and pharmaceutical sciences by Alferd Martin

PHAR 114 Mathematics

[60 hours]

Unit-1: Differentiation (16 hrs)

Limits of functions, indeterminate forms, theorem on limits of algebraic, trigonometric, exponential & logarithmic functions; continuity of a function; graphs of discontinuity function; definition of differential coefficient, differentiation of standard functions, including function of a function (Chain rule). Differentiation of implicit functions, logarithmic differentiation, parametric differentiation, successive differentiation.

Unit-2: Integration (10 hrs)

Integration as inverse of differentiation, indefinite integrals of standard forms, integration by parts, substitution and partial fractions, formal evaluation of definite integrals.

Unit-3: Calculus (8 hrs)

Notation of limit and continuity of a function, derivatives of composite, implicit, parametric, inverse circular, hyperbolic functions, logarithmic differentiation, derivative of a function with reference to another function, application of differentiation, partial differentiation, computation of the first and second order partial derivatives.

Unit-4: Differential equations (16 hrs)

Revision of integral calculus, definition and formation of differential equations, equations of first order and first degree, variable separable, homogeneous and linear differential equations and equations reducible to such types, linear differential equations of order greater than one with constant coefficients, applications of differential equations, complementary function and particular integral, simultaneous linear differential equations, pharmaceutical applications.

Unit-5: Laplace transforms (10 hrs)

Definition, transforms of elementary functions, properties of linearity and shifting, inverse Laplace transforms, transforms of derivatives, solution of ordinary and simultaneous differential equations. (12 hrs)

Books Recommended

1. A Textbook of Mathematics for XI-XII Students, NCERT Publications, Vol. I-IV
2. Grewal B S, Higher Engineering Mathematics, Khanna Publishers, New Delhi.
3. Schaum, Differential Equations, McGraw-Hill Singapore
4. Prasad Gorakh Text book on differential calculus, Pothishala Pvt. Ltd., Allahabad.
5. Narayan Shanti, Differential calculus, Shyam Lal Charitable Trust, New Delhi.
6. Prasad Gorakh Text book on integral calculus, Pothishala Pvt. Ltd., Allahabad.

PHAR 115 - Basic Computer Applications

[30 Hours]

Unit- 1: Basic Concept

(10 hours)

History of computers, simple model of computer and working parts of the computer, CPU, memory, input/output devices, computer languages and their hierarchical machine language, assembly language, high level language, comparison of high level and low level languages especially C, C++, PASCAL

Unit-2: Operating Systems

(4 hours)

Introduction to types of operating systems, UNIX, MS-DOS, etc. RAM, ROM, Virtual Memory. Introduction to Computer Networks, Email and Internet.

Unit-3: Database Management

(6 hours)

Spread sheets (like MS-EXCEL, ACCESS), concepts and objectives of database and database management system, advantages and disadvantages of the database management system and examples of DBMS packages (like DBASE III), HINARI.

Unit- 4: Flow chart and algorithm development

(4 hours)

Definition and properties of the algorithm, Flow chart symbols and their uses, Examples of efficient algorithm and flow-chart, conversion of algorithm/flow-chart to high-level languages.

Unit-5: Software

(4 hours)

Introduction, SPSS, EPI Info, Chem Win, Chem 4D and Chem Draw

Unit-6: Computer Security System

(2 hours)

Antivirus and others

PHAR 115 Lab - Basic Computer Applications Practical

Day 1- Define Folder, Files, Icons, My computer, Introduction to Desktop, Creating, Renaming, moving, Deleting folders, Saving Text, Image, Bitmap to the folder and Changing Wallpaper

(Task: Create your own name folder in D:\student\ and make your own name written picture and set as desktop background).

Day 2- What is Name of Computer? Network File Sharing, Hard-disk Error Checking, Virus Scanning, Using internet for file attachment and Lock the Taskbar, Screensaver, Hide Desktop, Customize Desktop (Task: Create a text file which contains information about your computer's RAM, Processor and share with your friend in network).

Day 3 - PowerPoint Introduction, Creating 1st PowerPoint, Animation, Transition, Background, Layout, bullet & numbering and Inserting media, Show (Task:Create a presentation of your own favorite topic and at least 5 slides).

Day 4- Creating table and chart in PowerPoint, setting animation timing, inserting shapes to slide and editing picture shape (Task: Prepare a table and design a chart as per data provided).

Day5- Starting MS-Word,Introduction,creating new file, save, open, edit, copy, paste, find and replace, page setup-margin, inserting header and footer, Inserting page break and page number and alignment(Task: prepare application letter for applying to a given post).

Day 6- Indent Text, Setting tabs, margin using ruler, formatting text- B,I, U,bullet and numbered lists, font size and character spacing (Task: Prepare your own CV).

Day 7-Insert symbols, Header and Footer, Delete header and Footer, Formatting using show/hide button, text boxes- border / color and columns break (Task: prepare newspaper with image inserted)

Day 8 - Working with tables, Entering text in the table, creating chart, change text direction in table and inserting and deleting table, rows, resizing table and adding borders and shading (Task: make a table of SLC mark sheet and make a chart of data).

Day 9 - Working with shapes, word art drawing objects, drawing toolbar and working with picture and its alignment (Task: Design traffic signals and cover page of report. For advance: section break and page numbering)

Day 10 - Working with Excel, creating sheets, renaming sheets, understanding rows and column, inserting rows and column and simple formula (Task: Prepare personal information as well as monthly budget)

Day 11-15 Working with multiple worksheets, inserting and deleting worksheets, complex formula, merging cells, text and cell alignment, use of function, page setup and chart(Computer lab: Day Working with some common DOS Command) Demonstration and identification of hardware

Books and other resources recommended

1. Basic computer programming- V.K Jain, pusthak mahal, Delhi
2. Programming in basic by E.Balagurusami,tatamcgrawhill
3. Programming in basic-Gottfried,tata mcgrawhill
4. ABC of windows 98-BPB Publications , New Delhi
5. Working in microsoft office-Ronmansfield
6. Commercial application development using ORACLE developer 2000 by Iran bay ross,BPB Publications, New Delhi
7. Computer fundamentals with pharmacy applications by N.K.Tiwari published by pharma book syndicate.

PHAR 116- Communication Skills

[30 Hours]

Unit- 1; Communication

[4hours]

Definition of communication; Importance of communication

Major forms of communication

Internal operational communication

External operational communication

Personal communication

Dimension of communication

Downward communication

Upward communication

Horizontal communication

Types of communication

Verbal communication

Oral communication

Written communication

Nonverbal communication

Body language

Sign language

Para language

Haptics/Touch language

Time language

Barriers to effective communication

Tips to improve communication

Unit-2: Note Taking Practice from Authentic Textual Materials including the use of Audio Visuals (2 hours)

Aims of note taking; Taking notes from texts, Taking notes from lectures

(Branching notes, Listing and numbering)

Practical work: taking notes

Unit-3: Writing Article and Summaries(4 hours)

Definition of articles; Format of writing articles; Definition of summary

The five “**R**” techniques of writing summary (Read, Reduce, Record, Review and Rewrite)

Practical work: writing articles and summaries

Unit 4: Minutes (5 hours)

Definition of minute; Parts of a minute (Beginning or introduction, Attendance

Special attendance, Agenda, Decisions, Closing signature)

Practical work: preparing minutes

Unit -5: Writing Proposals (3 hours)

Definition of proposal

Parts of a proposal; Difference between proposal and report

Practical work: preparing proposals.

Unit -6: Report writing (4 hours)

Definition of research report; Qualities of a good report

Parts of a research report

Preliminary

Title page

Letter of authorization

Acknowledgement

Abstract

List of contents

List of tables

List of figures

List of abbreviations

Body part

Introduction

Objectives

Significance

Limitations

Methodology

Source of data

Data collection tools

Data analysis

Findings

Conclusions

Recommendations

End part

References/Bibliography

Appendix

Practical work: preparing reports

Unit- 7: Seminar (3 hours)

Definition of seminar

Types of discussion groups

Conducting seminars

Practical work: conducting a seminar

Unit-8: Business correspondence (5 hours)

Definition of letter

Parts of business letters

Formats of business letters

Full block format

Modified format

Semi blocks or indented form

Types of business letters

Enquiry letters
Quotation letters
Order letters
Complaint letters
Replies to complaints
 Acceptance for adjustments
 Refusal for adjustments

Job application and resume

Memorandum

 Definition of memorandum
 Parts of a memo

 Subject line
 Introduction
 Discussion
 Conclusion

Practical work: writing business letters, job application letters, memos and preparing resume.

Books and Other Resources Recommended

1. Business communication skill, Asha Kaul
2. Technical Writing, Gearson and Gearson

SECOND SEMESTER

PHAR 121 Organic Chemistry –I [45 hours]

Unit-1: Structure and Properties (12 hrs)

Atomic structure, Atomic orbital, Molecular orbital theory, wave equation, Molecular orbital, Bonding and Antibonding orbital, Covalent bond, Hybrid orbital, Intermolecular forces, Bond dissociation energy, Polarity of bonds, Polarity of molecules, structure and physical properties, Intermolecular forces, Acids and bases.

Unit-2: Stereochemistry (8 hours)

Isomerism and nomenclature and associated physicochemical properties, optical activity, stereoisomerism, specification of configuration, Reactions involving stereoisomers, chirality, and chiral reagents conformations.

Unit- 3: Structure, Nomenclature, Preparations and Reactions of: (25 hrs)

Alkanes, Alkenes, Alkynes; Cycloalkane's, Dienes, Benzene, Polynuclear aromatic compounds, Arenes, Alkyl halides, Alcohols, Ethers, Epoxides, Amines, Phenols, Aldehydes and ketones, Carboxylic acids, Functional derivatives of carboxylic acids, Reactive intermediates - carbocations, carbanions, carbenes, nitrene and nitrenium ions.

PHAR 121 Lab Organic Chemistry –I Practical

I. Introduction to Equipment & Glassware, Recrystallization method, details of M.P, B.P and distillation

II. Preparation of organic compounds (each involving a specific organic reaction covered in theory)

1. N-Acetylation: Preparation of Acetanilide from Aniline
2. O-Acetylation: Preparation of Aspirin from Salicylic acid
3. Nuclear Bromination : Preparation of p-Bromoacetanilide from Acetanilide
4. Hydrolysis: Preparation of p-Bromoaniline from p-Bromoacetanilide
5. Nuclear Nitration : Preparation of m-Dinitrobenzene from nitrobenzene
6. Oxidation: Preparation of Benzoic acid from : Benzyl chloride
7. Esterification: Preparation of n-Butylacetate from n-Butylalcohol
8. -Naphthyl methyl ether β Etherification : Preparation of -Naphthol.
9. Halogenation : Preparation of Iodoform from Oxidation of Acetone α
10. Extensive Nuclear Substitution: Preparation of Tribromophenol or Bromination, Tribromoaniline from Phenol or Aniline

References and other resources:

1. Vogel's Textbook of Practical Organic Chemistry (5th Edition)
2. Modern Organic Synthesis: An introduction. George S. Zweifel and Michael H. Nantz
3. Problems in Organic Synthesis by Hasan Palandoken
4. Workbook for Organic Synthesis: Strategy and Control
5. Organic Synthesis, 3rd Edition by Professor Michael B. Smith
6. Organic chemistry by Morrison and Boyd
7. Organic chemistry by B.S. Bahl

PHAR 122 Pharmacognosy- II

[60 hours]

Unit-1: Natural source of drugs

4 hrs

Plant, Animal and Microorganism as a source of drugs. Traditional healer's practices in Nepal. Role of Medicinal & aromatic plants in National Economy.

Unit-2: Tissue culture

4 hrs

General procedure involved in plant tissue culture as a source of herbal ingredients. Plant tissue culture in production of phytopharmaceuticals, biochemical conversion, clonal propagation and production of immobilized plant cells.

Unit-3: Systematic Pharmacognostic Study of the Following Drugs (30 hours)

Definition, general occurrence and distribution, classification, properties, screening tests of following phytochemicals:

Resins: Cannabis, Capsicum, Benzoin, Turmeric, Ginger.

Tannins: Gambir, Black catechu.

Volatile oil: Mentha, Coriander, Cinnamon, Lemon peel, Lemon grass, Citronella, Spearmint, Clove, Fennel, Eucalyptus, Chenopodium, Cardamom, Valerian, Palmarosa, Sandalwood.

Alkaloid containing drugs: Tobacco, Belladonna, Hyoscyamus, Datura, Opium, Catharanthus, Kurchi, Ephedra, Colchicum, Solanum, Coffee & Tea, Passiflora.

Glycoside containing drugs: Digitalis, Squill, Thevetia, Liquorice, Aloe, Senna, Asparagus, Almond, Mustard, Visnaga, Ammi, Vanilla.

Unit-4: Phytochemistry

5 hours

General methods associated with the phytochemical investigation of herbal drugs- Authentication of plant materials, various methods of extraction, general ideas of isolation (in example of Atropine and Nicotine) and, purification of the chemical constituents and characterization of isolated compounds.

Unit-4: Carbohydrates and Derived Products

6 hrs

Definition, classification, properties, general test and isolation of carbohydrates. Systematic pharmacognostic study of Agar, Guar gum, Honey, Tragacanth and Isabgol.

Unit-5: Lipids

6 hrs

Definition, classification, properties, general chemical test and analytical parameters of lipids. Systematic pharmacognostic study of castor oil, cod liver oil, linseed oil, sesame oil, arachis oil and yellow bees wax.

Unit-6: Pharmaceutical aids

3 hrs

Study of pharmaceutical aids like talc, diatomite, kaolin, bentonite and gelatin.

Unit-7: Plant Allergens

2 hrs

Introduction, classification of allergens; Fungi and mould causing allergy.

PHAR 122 Lab Pharmacognosy –II Practical

1. Identification of crude drugs mentioned in theory.
2. Study of Talc and gelatin pharmaceutical aids.
3. Microscopic studies of seven-selected crude drugs and their powders mentioned under the category of carbohydrate, Lipid and Resin in theory and their chemical tests,
5. Identification of crude drugs listed in theory.
6. Standardization of some traditional drug formulations.

Books and other resources recommended

1. Atal,CK and Kappor,BM.Cultivation and Utilization of Medicinal Plants.
2. Trease,CE and Evans,WC. Textbook of Pharmacognosy.11th to 14th Editions. Tindal L. U.K.
3. Tyler,VC Brady, LR and Robers JE.Pharmacognosy.8th Edition, Lea & Febeger, Philadelphia.
4. Wallis,TE. Textbook of Pharmacognosy,5th Edition,J & A,Churchill Limited,U.K.
5. Kokate,CK Purohit,AP. And Gokhale, SB.Pharmacognosy.

PHAR 123 Physical Pharmacy

[45 hours]

Unit – 1: Matter, Properties of Matter [4 hours]

State of matter, change in the state of matter, latent heats and vapor pressure, sublimation-critical point, Eutectic mixtures, gases, aerosols-inhalers, relative humidity, liquid. Complexes, liquid crystals, glassy state, solids-crystalline, amorphous and polymorphism.

Unit – 2: Micromeritics and Powder Rheology [7 Hours]

Particle size and distribution, average particle size, number and weight distribution, particle number, methods for determining particle volume, optical microscopy, sieving, sedimentation, measurement, particle shape, specific surface, methods for determining surface area, -permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.

Unit – 3: Surface and Interfacial Phenomenon [7 hours]

Liquid interface, surface and interfacial tensions, surface free energy, measurement of surface and interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB classification, solubilization, detergency, adsorption at solid interfaces, solid-gas and solid-liquid interfaces, complex films, electrical properties of interface.

Unit – 4: Viscosity and Rheology [5 hours]

Newtonian systems, Law of flow, kinematics viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling ball, rotational viscometers.

Unit – 5: Dispersion Systems [10 hours]

Colloidal Dispersions: Definition, types, properties of colloids, protective colloids, applications of colloids in pharmacy; Suspensions and Emulsions: Interfacial properties of suspended particles, settling in suspensions, theory of sedimentation, effect of Brownian movement,, sedimentation of flocculated particles, sedimentation parameters, wetting of particles, controlled flocculation, flocculation in structured vehicles, rheological considerations; Emulsions-types, theories, physical stability.

Unit – 6: Complexation [3 hours]

Classification of complexes, methods of preparation and analysis, applications.

Unit – 7: Kinetics and Drug Stability [6 hours]

General considerations& concepts, half-life determination, Influence of temperature, light, solvent, catalytic species and other factors, Accelerated stability study, expiration dating.

Unit 8. Buffers (3 hours)

Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.

PHAR 123 Lab Physical Pharmacy Practical

1. Determination of latent heat, vapor pressure, critical point.
2. Studies on polymorphs, their identification and properties.
3. Determination of particle size, particle size distribution and surface area using various methods of particle size analysis.
4. Determination of derived properties of powders like density, porosity, compressibility, angle of repose etc.
5. Determination of surface/interfacial tension, HLB value and critical micellar concentration of surfactants.
6. Study of rheological properties of various types of systems using different Viscometers.
7. Studies of different types of colloids and their properties.
8. Preparation of various types of suspensions and determination of their sedimentation parameters.
9. Preparation and stability studies of emulsions.
10. Studies on different types of complexes and determination of their stability constants.
11. Determination of half-life, rate constant and order of reaction.
12. To study the influence of various factors on the rate of reaction.
13. Accelerated stability testing, shelf-life determination and expiration dating of pharmaceuticals.
14. Preparation of pharmaceutical buffers and determination of buffer capacity.
15. Experiments involving tonicity adjustments.

References and other Resources:

1. Martin: Physical Pharmacy, K.M.B. Varghese Co. Bombay.
2. A.T. Florence and D. Attwood W: Physiochemical principles of Pharmacy.
3. Shotton and Ridgeway: Physical Pharmaceutics.
4. Remingtons Pharmaceutical Sciences, Mark Publishing Co.
5. H.S. Beans, A.H. Beckett and J.E. Carless: Advances in Pharmaceutical Sciences, Vol. 1 to 4.

6. S.P.Agarwal, Rajesh Khanna: Physical Pharmacy, CBS Publishers, New Delhi.
7. Tutorial pharmacy by Cooper and Gunns
8. Physical Pharmaceutics by CVS Subhramanyan

PHAR 124 Pharmaceutical Analysis – I

[45 hours]

Unit-1: Fundamental of Analysis

(8 hrs)

Significance of quantitative analysis in quality control, different techniques of analysis, preliminaries and definitions, significant figures, selection of sample, precision and accuracy, repeatability and reproducibility, fundamentals of volumetric analysis, methods of expressing concentration, primary and secondary standards.

Unit-2: Acid Base Titration

(10hrs)

Acid base concepts, role of solvent, relative strengths of acids and bases, ionization, law of mass action, common ion effects, ionic product of water, pH, Hydrolysis of salts, Henderson-Hassel Balch equation, Buffer solutions, Neutralization curves, Acid Base indicators, theory of indicators, choice of indicators, mixed indicator, polyprotic system, polyamine and amino acid systems, amino acid titration, applications in assay of H_3PO_4 , NaOH etc.

Unit-3: Oxidation Reduction Titration

(10 hrs)

Concepts of oxidation, reduction and oxidation number, Redox reactions, Strength and equivalent weight of oxidizing and reducing agents, balancing of redox reaction (ion electron method or oxidation number method), theory of redox titrations, redox indicators, cell representations, measurement of electrode potential, Oxidation-reduction curves, Iodimetry and Iodometry, titrations involving ceric sulphate, potassium iodate, potassium bromate, potassium permanganate

Unit-4: Precipitation Titration

(8 hrs)

Precipitation reactions, solubility products, effect of acids, temperature and solvent upon the solubility of precipitate, argentometric titrations and titrations involving ammonium or potassium thiocyanate & mercuric nitrate, precipitation indicators, Mohr's method, Volhard's method and Fajan's method.

Unit-5: Gravimetric Analysis

(9 hrs)

Precipitation techniques: supersaturation, co-precipitation, post precipitation. Colloidal state, digestion and washing of the precipitate, filtration and ignition. Filter paper and crucibles used for precipitate separation, thermogravimetric curves (pyrolysis curves), specific examples like barium sulphate, aluminium as aluminium oxide, calcium as calcium oxalate and magnesium as magnesium pyrophosphate, organic precipitants.

(12 hrs)

PHAR 124 Lab Pharmaceutical Analysis – I practical

Minimum 8 experiments in the topics covered in theory.

Books and other resources recommended

1. Text Books of qualitative chemical analysis - (Vogel's)
2. Quantitative analysis - (R.A. Day, Jr.A.L. Underwood)
3. Pharmaceutical drug analysis (Ashutoshkar)

PHAR 125 Anatomy and Physiology I

[45 hours]

Unit-1: Introduction (2 hours)

Scope of anatomy and physiology and basic terminology used these subjects. Anatomical planes, anatomical positions

Unit-2: Cell membrane and their function (4 hours)

Structure of cell, its components and their functions, body fluids, membrane physiology through cell membrane, cell metabolism, membrane potential and neurotransmission and muscle contraction mechanism.

Unit-3: Human Tissues and their function (4 hours)

Elementary Tissues of the Human Body: Epithelial, connective, muscular and nervous tissues, their sub-types and their characteristics.

Unit-4: Osseous System: (6 hours)

Structure, composition and functions of skeleton, classification of joints, terminologies of movements of joints. Types of bone and its feature, parts of long bone.

Unit-5: Skeletal Muscle: (5 hours)

Skeletal Muscles: Gross anatomy; physiology of muscle contraction, physiological properties of skeletal muscles.

Unit-6: Haemopoietic System (6 hours)

Composition and functions of blood and its elements, their disorders, blood groups and their significance, mechanism of coagulation, disorders of platelets and coagulation. Erythropoiesis, coagulative factors.

Unit – 7: Lymph and Lymphatic System (4 hours)

Composition, formulation and circulation of lymph; basic physiology and functions of spleen. Important group of lymph nodes (auxiliary, inguinal and others)

Unit – 8: Cardiovascular System (7 hours)

Basic anatomy of the heart, Physiology of heart, blood vessels and circulation. Basic understanding of Cardiac cycle, heart sounds and understanding of cardiac cycle, heart sounds and electrocardiogram. Blood pressure and its regulation.

Unit-9: Digestive System (7 hours)

Gross anatomy of the gastro-intestinal tract, functions of its different parts including those of liver, pancreas and gall bladder, various gastrointestinal secretions and their role in the absorption and digestion of food. Gastro intestinal movement. Basic concept of peritoneum.

PHAR 125 Lab Anatomy and Physiology I Practical

1. Study of human skeleton.
2. Study of different systems with the help of charts and models.

3. Microscopic study of different tissues.
4. Estimation of hemoglobin in blood, blood grouping, Determination of bleeding time, clotting time; R.B.C. Count, Total leucocytes count, D.L.C. and E.S.R.
- 5 Recording of body temperature, pulse rate and blood pressure, basic understanding of Electrocardiogram-PQRST waves and their significance.

Books and Other resources Recommended

1. Sujit K. Chaudhuri: Concise Medical Physiology.
2. C.C. Chatterjee: Human Physiology.
3. Kathleen J.W. Wilson Ross and Wilson: Anatomy and Physiology in Health and Illness
4. T.W.A. Glenister and Jean R.W. Ross: Anatomy and Physiology for Nurses
5. Arthur C. Guyton: Textbook of Medical Physiology.
6. Cyril A. Keele, Erie Neil, Norman Joels and Samson Wrights: Applied Physiology

THIRD SEMESTER

PHAR 211 Organic Chemistry-II [60 hours]

Unit -1: Nucleophilic Aromatic Substitution (7 hours)

Introduction to Nucleophilic Substitution in aromatic compound. Comparison of Nucleophilic aromatic substitution in aromatic & aliphatic substrate. Mechanism of nucleophilic aromatic substitution:-

Bimolecular aromatic Nucleophilic substitution (SN Ar mechanism) Reactivity & orientation in SN Ar rxⁿ in aromatic substrate and Benzyne mechanism & its evidences.

Unit -2: Unsaturated Carbonyl Compounds (4 hours)

Introduction to unsaturated carbonyl compounds. Preparation of unsaturated carbonyl compounds by Aldol condensation, Perkin reaction, from α - halo acids. (related to pharmaceutically active product) Reactions:-Electrophilic addition, Nucleophilic addition, Michael reaction and Diel's Alder reaction

Unit -3: Conservation of Orbital Symmetry:- (10 hours)

Concepts of molecular orbital with respect to same organic molecule. Concept to conservation of orbital symmetry. Introduction to pericyclic reaction and its types (Electro cyclic reaction. Cycloaddition reaction and Sigmatropic reaction).

Unit -4: Neighboring Group Effect:- (3 hours)

Effect of neighboring group in nucleophilic substitution. Stereochemistry of product. Explain anchimeric assistance with examples.

Unit -5: Catalysis by Transition Metal Complexes:- (2 hours)

Role of transition metal complex in organic reaction. Role of Wilkinson Catalyst in homogenous hydrogenation of alkenes & its stereochemistry. Role of octacarbonyldicobalt in oxo process.

Unit -6: Stereo Selective & Stereo Specific Reaction:-(2 hours)

Introduction to stereo selective & stereo specific reaction. Difference between stereo selective & stereo specific showing suitable examples.

Unit -7: Heterocyclic Compounds (12 hours)

Introduction to heterocyclic compounds. Preparation and properties of following heterocyclic compounds- Five membered ring: pyrrole, furan & thiophane. Six membered ring : pyridine (Basicity , Substitution rxⁿ) Higher membered ring : Indole (2,3 - Benzopyrrole), Quinoline 2,3 – Benzopyridine and Isoquinoline.

Unit -8: Carbohydrate (8 hours)

Classification of Carbohydrate. Glucose: Mutarotation, various structure. Classification, Sources & Structure of (Fructose, Sucrose, Maltose and starch). Amylose, Amylopectin, Cellulose. Chain lengthening reaction of aldoses : Killiani – fisher synthesis. Shortening of carbon chain of aldoses : Ruf degradation and Formation of osazone.

Unit -9: Lipids: (4 hours)

Occurrence & composition of fats. Saponification of fats. Detergents. Hydrogenation of oils. Phosphoglycerite and Phospholipids.

Unit -10: Proteins & Nucleic acids (5 hours)

Structure of Amino acids. Amino acid as dipolar ions. Isoelectric point of amino acid. Preparation & peptide linkage. Protein and its classification. Structure of protein. Denaturation of protein. Nucleic acid structure of DNA & RNA Watson & Crick model.

Unit -11: Uses and preparation of some new organic reagents used in drug synthesis: (3 hrs)

Salicylic acid, cinnamic acid, quinoline, ethylacetoacetate, acetic anhydride, pyridine, benzaldehyde, acetophenone, dimethylaniline, tosyl chloride, diphenyl, succinic anhydride.

PHAR 211 Lab Pharmaceutical Organic Chemistry-II Practical

Synthesis and test of the following compounds (Minimum 8 experiments)

m-dinitrobenzene from nitrobenzene, p-nitroacetanilide from Acetanilide , p-bromoacetanilide from Acetanilide , Oxazolone from Benzoylglycine , Acetanilide from Aniline , p- Benzanilide from benzophenone oxime (Beckmann's rearrangement), benzil from benzoin, fluorescein from phthalic anhydride, Eosin from fluorescein, O-chlorobenzoic acid from anthranilic acid (Sand mayer reaction), m-Dinitrobenzene from nitrobenzene, 2, 5-Dioxopiperazine from Glycine. Diazonium Coupling Reaction of p-Nitrobenzenediazonium sulfate and N,N -Dimethylaniline: Synthesis of p-(4-nitrobenzeneazo)-N,N-dimethylaniline.

Systematic analysis of organic binary mixtures (Determination of Acid value of fixed oils, Determination of Acid value of fixed oils, Determination of Saponification value of a fixed oil, Determination of Acetyl value of a fixed oil. Stereochemical Study of Organic Compounds via Models and R and S configuration of optical isomers.

Reference:

1. Vogel's Textbook of Practical Organic Chemistry (5th Edition)
2. Modern Organic Synthesis: An introduction. George S. Zweifel and Michael H. Nantz

3. Problems in Organic Synthesis by Hasan Palandoken
4. Workbook for Organic Synthesis: Strategy and Control
5. Organic Synthesis, 3rd Edition by Professor Michael B. Smith

PHAR 212 Pharmacognosy III

[45 hours]

Unit – 1: Evaluation of Herbal Drugs and Formulation (20 hours)

- 1.1. Development of analytical techniques for the estimation of markers present in the Herbal and classical formulations.
- 1.2. Evaluation of Herbal drugs and formulations by Biological methods. General animal models for screening of Herbal drugs and formulations.
- 1.3. Toxicological evaluations of herbal drugs and formulations. Methods and materials for Acute, sub acute and chronic toxicity studies. Teratogenicity, mutagenicity and carcinogenicity studies. WHO and other regulatory requirements for toxicological evaluations.
- 1.4. WHO, Nepalese and Indian regulatory requirements of Clinical trials for herbal formulations.
- 1.5. Techniques in estimation of enzymes and endogenous substances in body fluids in physiological and pathological conditions.
- 1.6. Department of Drug Administration, (DDA) Nepal and Indian requirements (Schedule T) and other regulatory requirements for the manufacturing of Herbal and Ayurvedic products.
- 1.7. Comparative study of British herbal pharmacopeia Ayurvedic pharmacopeia of India, Chinese, Japanese herbal pharmacopoeias, European pharmacopoeia, US Formulary, W.H.O guidelines for herbal medicinal products.

Unit – 2: Global Trading of Herbs and herbal constituents. (10 hours)

Utilization and production of phytoconstituents such as Taxus resin, quinine, morphine, Reserpine, Sennosides, Digitalis glycosides, Diosgenin and Atropine. Herb collection centers around Nepal.

Worldwide trade in medicinal plants and derived products with special reference to diosgenin, taxol, digitalis, tropane alkaloids containing plants, papain, cinchona, ipecac, liquorice, ginseng, aloe, valerian, Rauwolfia and plants containing laxatives.

Unit – 2: Study of traditional drugs (10 hours)

Common Vernacular name, Biological sources, morphology, chemical nature of chief constituents, pharmacology, categories and common uses and toxicological activity of marketed formulations of following indigenous drugs: Amla, Kantkari, Satavari, Tylophora, Bhilwa, Kalijiri, Vach, Rasna Punarnava, Chitrak, Apamarg, Gokhru, Shankhpushpi, Brahmi, Methi, Lehsoun, Palash, Guggul, Gymnema, Shilajit, Tulsi, Nagarmotha, Majith, Malkanguni and Neem.

Unit- 3: Alternative system of therapy. (5 hours)

Introduction and principals of Ayurvedic, Unani, Sidha and Homeopathic system of medicine. Introduction to Ayurvedic dosages form: preparations and standardization of Ayurvedic preparations such as Aristas, Asvas, Gutika, Tailas, Churnas, Lehyas and Bhasmas.

PHAR 212 Lab Pharmacognosy III Practical

Extraction and Isolation of some important phyto constituent mentioned in the theory.

2. Extractions of volatile oil and their chromatographic profile.
3. Chromatographic studies of some important phytoconstituent.

Books and other resources recommended

1. Indian pharmacopoea, Indian Herbal Pharmacopoea.
2. Ayurvedic Formulary of India.
3. Screening methods of Pharmacology By Robert turner
4. WHO guide lines for the quality control of Herbal plant materials
5. The Practical evaluation of Phytopharmaceuticals by Brain and Turner.
6. Thin layer chromatography by Egon stahl.
7. Drug Discovery & Evaluation by H.Gerhard Vogel
8. British Herbal Pharmacopeia
9. Quality Standards of Indian Medicinal Plants Vol-I, ICMR, New Delhi
10. Scheuer, P.J., Marine Natural Products. Academic Press, London.
11. Swain, T. Chemical Plant Taxonomy Academic Press, London.
12. Reinert, J & Bajaj, Y.P.S. Applied and Fundamental aspects of plants cell, tissue and organ culture Berlin.
13. Atal C.K. and Kapoor, B.M. cultivation and utilization of medicinal plants. R.R.L. Jammu.
14. Barz, W., Reinhard, E. and Zerk, M.H. plant tissue culture and its Biotechnological application. Springer, Berlin.
15. Chadha, K.L. and Gupta, R. advance in horticulture vol. II medicinal and aromatic plants. Malhotra publishing house, New Delhi.
16. Export potential of selected medicinal plants; prepared by basic chemicals, pharmaceuticals and cosmetic export promotion council, Mumbai and other reports.
17. Trease, G.E. and Evasn W.C. Pharmacognosy. Baillier, Tindall, Eastbourne, U.K.
18. Kokate, C.K., Purohit, A.P. and Gokhale, Pharmacognosy, Nirali Prakashan, Pune.
19. Tyler, V.C., Brady, L.R., and Robers, Pharmacognosy, Lea and Febiger, Philadelphia.
20. Kalia, A.N. Textbook of Industrial Pharmacognosy, CBS Publishers and Distributors, New Delhi.
21. Vyas and Dixit, Biotechnology, CBS Publishers New Delhi
22. Dewick, P.M, (2002) Medicinal Natural Products (II edition), John Wiley and Sons, Chichester.

PHAR 213 Pharmaceutical Analysis – II

[60 hours]

Unit-1: Non-aqueous Titration (5 hrs)

Principle of non-aqueous titration; aprotic, protogenic, protophillic and amphiprotic solvents; effect of temperature in non-aqueous titration; indicators in non-aqueous titration; end point detection by potentiometry, titration of alkali metal salts of organic acid, amines and amine salts of organic acid, halogen acid salts of bases and acidic substances, preparation & standardization of standard perchloric acid & methoxide solution, applications in assay of metronidazole, chloroquine phosphate, chlorpromazine HCl

Unit-2: Complexometric Titration (7 hrs)

Theory of complexometric titration; chelating and sequestering agents; effect of pH on complex formation; stability of complexes- stability constant, factors affecting stability constant, absolute & effective stability constant; types of complexometric titrations; end point detection using physical methods (spectrophotometric detection, potentiometric titration, amperometric titration, high frequency titration) and pM indicators; pM indicators, methods of increasing titrant selectivity-pH adjustment, use of selective indicators, use of selective precipitants & use of masking and demasking agents; disodium edetate titrations; application in determination of hardness of water, applications in assay of calcium gluconate.

Unit-3: Miscellaneous Methods of Analysis (6 hrs)

Diazotisation titrations, Kjeldahl method of nitrogen estimation, Karl-Fischer titration, Oxygen flask combustion, Gasometric analysis.

Unit-4: Extraction procedures including separation of drugs from excipients (4 hrs)

Nernst law, extraction efficiency & selectivity, factors influencing solvent extractions- effect of temperature, inert solutes, pH, ion pair formation & synergistic extraction, separation of drugs from excipients in pharmaceutical preparations- chloroquine phosphate tablets, codeine tablets.

Unit-5: Chromatography (20 hrs)

Introduction, classification of chromatographic techniques, modes of separation, distribution coefficient, retention volume, dead volume, retention time, dead time, selectivity factor, capacity factor, resolution, chromatographic theories- plate theory & rate theory, Sources of band broadening- eddy diffusion, longitudinal diffusion & non equilibrium mass transfer, van Deemter equation.

Paper Chromatography

Principle, Migration parameters- R_f & hR_f , R_m , R_x , types of paper chromatography- ascending, descending, ascending-descending, radial & two dimensional chromatography,

choice of filter paper, developing solvent, detection method, applications of paper chromatography.

TLC: Principle, Advantages of TLC over paper chromatography; steps in TLC- selection of coating material, preparation of TLC plate, activation of plate, purification of plate, sample application, selection of mobile phase, development of plate, detection of components; Problems in TLC: Over-large Spots, Uneven Advance of Solvent Front and Streaking, applications of TLC.

HPTLC: Comparison of HPTLC & TLC; HPLC & HPTLC; Principle, Instrumentation- Sample applicator, Development Chamber, Scanner; Applications.

HPLC : Principle, Instrumentation: Solvent reservoir & degassing system, Solvent programming, Pumps- reciprocating pump, syringe pump, constant pressure pumps, Sample injection system, Columns, Bonded phase, Column switching, Detectors- bulk & solute property detectors, Photometric detectors, fluorescence detectors, refractive index detectors, electrochemical detectors; Elution methods: Gradient, Isocratic & Stepwise elution; Internal Standard; Peak asymmetry, peak tailing & peak fronting; Ghost peaks, System suitability test, Pharmaceutical applications of HPLC.

GC: Principle, Instrumentation-carrier gas supply & flow regulators, sample injection system, detectors (ECD, FID, DTC, thermionic emission detector); Temperature programming, Headspace analysis, pharmaceutical applications of GC; limitations of GC.

Column Chromatography: Principle, Applications, Ion Exchange Chromatography, Principle, Cation exchanger, Anion exchanger, Ion exchange capacity; Suppressor column, Pharmaceutical applications of IEC, Size Exclusion Chromatography, Principle; Gel Permeation & Gel Filtration chromatography; Packing Material for column and Solvent; Detector, Applications of SEC.

Unit-6: Potentiometry (5 hrs)

Reference electrodes (SHE, SCE, Silver- silver chloride electrode) and indicator electrodes (metal electrodes-first, second, third & inert electrodes; membrane indicator electrodes-glass electrode including its advantages & disadvantages); potentiometric titrations-advantages, apparatus & methods of end point detection -graphical, differential and Gran's plot; applications.

Unit-7: Conductometry (3 hrs)

Ohm's law, specific, molar & equivalent conductance, measurement of conductivity, cell constant, conductometric titrations: acid-base titrations (SA vs.SB, SA vs. WB, WA vs.SB, WA vs.WB, mixture of acids with strong base), applications of conductometry in precipitation titrations, redox titration, complexometric titration; advantages of conductometric titrations.

Unit-8: Coulometry (2 hrs)

Current efficiency, principle of coulometry, types of coulometric titration, coulometric titrations, advantages & application of coulometric titration including application in Karl Fischer titration.

Unit-9: Polarography (5 hrs)

Principle, instrumentation, residual current, migration current, diffusion current, limiting current, equation of polarographic waves, Ilkovic equation, DME- advantages & limitations; polarographic maxima, polarographic methods of analysis-direct comparison method, use of calibration curves, internal standard or pilot ion method, quasi-absolute method & standard addition method; pharmaceutical applications of polarography-metronidazole & diazepam.

Unit-10: Amperometry (3 hrs)

Principle, Amperometric titration curves, Rotating platinum electrodes & its advantages, Dead stop end point technique, Advantages of amperometry & Pharmaceutical applications of amperometry.

PHAR 213 Lab Pharmaceutical Analysis– II Practical

Minimum 8 experiments in topics covered in theory.

Books and other resources recommended

1. Principles of Instrumental Analysis by Skoog, Holler, Nieman, 5th Ed..Saunders College Publishing
2. A Text book of Pharmaceutical Analysis by Kenneth A. Connors, 3rd Ed. John Wiley & Sons
3. Instrumental Methods of Chemical Analysis by Galin W. Ewing, 5th Edition, N.C. Graw-hill International Edition
4. Instrumental Methods of Analysis by Willard, Merritt, Dean, Settle, CBS Publishers, 7th Edition
5. Spectrometric Identification of Organic Compounds by Silverstein, Dassler, Morrill, 5th Ed. John Willey & Sons inc.
6. Pharmaceutical Analysis: Modern Methods by James Monson, Marcel Dekker inc.
7. Practical Pharmaceutical Chemistry-I & II by A. H. Backett & Jacket Stanlake, 4th Ed.. CBS Publishers
8. Indian, British & United State Pharmacopoeia.
9. P D Sethi Quantitative Analysis of Drugs in Pharmaceutical formulations.
10. Bochmman & Hassan, Pharmaceutical Analysis, edited by: Higuchi.

PHAR 214 Pharmaceutical Engineering I [45 hours]

Unit- 1: Introduction to Unit operation, (2 hours)

Law of conservation of matter, Law of conservation of energy, introduction to Gas Laws, Dalton's law of partial pressure.

Unit- 2: Fluid Flow(10 hours)

Fluid Flow: Properties of fluid, Viscosity, Compressibility and Surface tension, static and dynamic flow, fluid in motion, Bernoulli's theorem, Flow measurement and flow meters, Laminar and Turbulent flow, Liquids in flow pipe, Significance of Reynolds' flow, Reynolds's experiment and Reynolds number, flow of fluid through packed bed, pumps, positive displacement pumps, centrifugal impeller pump, . Measurement of rate of flow of liquids- measuring devices (Manometer, Orifice meter, venturimeter, Rota meter). Liquid handling (transportation of fluids)- valves, pumps and pump impeller..Flow of purified water in pharmaceutical manufacturing unit.

Unit- 3: Handling of solids (2 hours)

Sliding and flow of powder, Method for free flowing powder and granules, methods for cohesive powders Bins, Vacuum and conveyor.

Unit- 4: Handling of steam and gas – Cylinder, steam traps, valves and pipes and pipe handling system. (2 hours)

Unit- 5: Filtration and clarification (6 hours)

Mechanism (straining, impingement, entanglement, attractive force) , types of filtration , difference between surface and depth filtration and Theory of filtration (Poiseuille's equation, Darcy's equation, Kozeny's-Carman Equation), factors influencing filtration, filter media including materials (rigid media, flexible media) and filter aids, handling of filter aids, and filtration equipments (Gravity filters, Vacuum filters, Pressure filters and the centrifuge filters)

Unit- 6: Centrifugation (3 hours)

Theory and application, classification of centrifuge (sedimentation, filtration) and equipment (perforated basket centrifuge, non-perforated basket centrifuge, short cycle batch centrifuge, continuous horizontal centrifuge, Super centrifuge, conical disc centrifuge).

Unit- 7: Crystallization (5 hours)

Theory and application, characteristics of crystals (geometry, habit, crystal lattice, crystal systems), pharmaceutical solids (crystalline, amorphous,), polymorphs and isomorphs, crystal hydrate and caking of crystals. Crystal hydrates and crystal solvates, Production of very fine crystals, Production of large crystals. Crystallizers (Agitated batch crystallizers, Swenson Walker Crystallizer, Krystal Crystallizer, vacuum crystallizer).

Unit- 8: Heating, Ventilation and Air conditioning (HVAC) (8 hours)

Definition of Humidity, Absolute humidity, Relative humidity, specific humidity, humidity chart and its utility, dry bulb and wet bulb thermometers. Dew point, methods of dehumidification, Types of dehumidifiers, Approaches to dehumidification, heat exchangers. HVAC terms, Application of HVAC in pharmaceutical unit – Air handling

units (AHU), Factors that contribute to quality of pharmaceutical products. The manufacturing environment is critical for product quality, Role of AHU for the reduction of cross contamination, laminar and turbulent air flow. Refrigeration: Principle, Refrigeration cycle and condensers.

Unit- 9: Material of construction (4 hours)

Factors affecting selection of material of construction(physical, chemical and economical); Ferrous metal (including stainless steel – 202,304,316 and 316L), Alloys, nonferrous metal (aluminum, aluminum alloy, copper lead, Tin), Non-metals (inorganic-glass – Types: soda lime, borosilicate glass, Pyrex, quartz, neutral, fiber glass with special reference to glass for pharmaceutical use.) organic (rubber natural and synthetic(silicon rubber) special reference to pharmaceutical use) and plastic (polymers)- Type of plastic: Cellulose based plastic, Polystyrene and PVC, Nylon, Rubber, and their uses in Pharmacy. Common plastic and special purpose plastic.

Unit- 10: Industrial Hazards and safety precautions (3 hours)

Hazards (mechanical, chemical, electrical, environmental, fire, noise abatement), dust explosion personal protective equipments (masks, gloves, respirators, spectacles, suits). Biological Hazard Protection, manmade hazards and Technological hazards; Fire and types of fire extinguisher.

PHAR 214 Lab Pharmaceutical Engineering I Practical

1. Determination of water flow by a water pump.
2. Study of factors affecting filtration using filter media and/or aids.
3. Demonstration of centrifugation.
4. Study of crystallization behavior of Ibuprofen, Salicylic acid and sodium carbonate.
5. Observation of HVAC.
6. Determination of humidity using dry and wet bulb thermometer. Learning the skill of using thermometers and psychometric charts.
7. Observation of different construction materials focus to utensils, equipments and machines.
8. Demonstration of different personal safety equipments.

Books and other resources Suggested

1. Pharmaceutical Engineering –principles and practices by CVS Subrahmanyam, J T Setty, S Suresh and V K Devi. Vallabh Prakashan Delhi.
2. Pharmaceutical Engineering by K Sambamurthy – New age international publisher.
3. Theory and Practice of industrial Pharmacy by Lacman and Lieberman.
4. Unit Operation by Anthony J Hiki
5. Pharmaceutical Process scale-up: by Michel Levin- Marcel Dekker.
6. Pharmaceutical production facilities; design and application by Cole G- 2nd edition Taylor Francis, 1998.
7. Pharmaceutical Process Engineering - Anthony J Hickey, Marcel Dekker 2001.

PHAR 215 Anatomy & Physiology II

[45 hours]

Unit-1: Respiratory System (8 hours)

Anatomy of respiratory organs & its functions, respiration, mechanism and regulation of respiration, respiratory volumes and vital capacity. Acid base balance and brief description of respiratory system. Bronchopulmonary segments, nervous control of respiration, Basic concept about hypoxia, anoxia, hyperventilation.

Unit-2: Central Nervous System (8 hours)

Functions of different parts of brain and spinal cord. Neurohumoral transmission in the central nervous system, reflex action, specialized functions of the brain, Cranial nerves and their functions. C.S.F and its route of transmission; Pyramidal tracts.

Unit-3: Autonomic Nervous System (6 hours)

Physiology and functions of the autonomic nervous system. Mechanism of neurohumoral transmission in the A.N.S.

Unit-4: Urinary System (5 hours)

Various parts, structures and functions of the kidney and urinary tract. Physiology of urine formation and acid-base balance.

Unit-5: Reproductive System (4 hours)

Male and female reproductive systems and their hormones, physiology of menstruation, spermatogenesis & oogenesis. Pregnancy its maintenance and parturition.

Unit-6: Endocrine System (5 hours)

Basic anatomy and physiology of Pituitary, Thyroid, Parathyroid. Adrenals, Pancreas, Testes and ovary, their hormones and functions.

Unit-7: Sense Organs (5 hours)

Basic anatomy and physiology of the eye (vision), ear (hearing), taste buds, nose (smell) and skin (superficial receptors).

Unit-8: Body Temperature Regulation (4 hours)

Structure and function of skin, heat production and dissipation, nervous factors involved in body temperature regulation.

PHAR 215 Lab Anatomy & Physiology II Practical

1. Study of different systems with the help of charts and models.
2. Microscopic studies of different tissues.
3. Simple experiments involved in the analysis of normal and abnormal urine: Collection of specimen, appearance, and determination of pH, Sugars, proteins, urea and creatinine.
4. Physiological experiments on nerve-muscle preparations.
5. Determination of vital capacity, experiments on spirometry.

Books and Other resources Recommended

1. Sujit K. Chaudhuri: Concise Medical Physiology.
2. C.C. Chatterjee: Human Physiology.
3. Kathleen J.W. Wilson Ross and Wilson: Anatomy and Physiology in Health and Illness
4. T.W.A. Glenister and Jean R.W. Ross: Anatomy and Physiology for Nurses
5. Arthur C. Guyton: Textbook of Medical Physiology.
6. Cyril A. Keele, Erie Neil, Norman Joels and Samson Wrights: Applied Physiology

FORTH SEMESTER

PHAR 221

Biochemistry

[45 hours]

Unit -1: Biochemical organization of the cell and transport process across cell membrane. (1 hr)

Unit -2: The concept of free energy, bioenergetics, production of ATP and its biological significance. (2 hrs)

Unit -3: Enzymes: Nomenclature, enzyme kinetics and its mechanism of action, mechanism of inhibition, enzymes and iso-enzymes in clinical diagnosis. (4 hrs)

Unit -4: Carbohydrate Metabolism: Conversion of polysaccharide to glucose-1-phosphate, Glycolysis and fermentation and their regulation, gluconeogenesis and glycogenolysis, Metabolism of galactose and galactosemia, role of sugar nucleotides in biosynthesis, and Pentosephosphate pathway. (6 hrs)

Unit -5: The Citric Acid Cycle: Significance, reactions and energetic of the cycle, Amphibolic role of the cycle. (4 hrs)

Unit -6: Lipids Metabolism: Oxidation of fatty acids, β -oxidation & energetic, α -oxidation, ω -oxidation, Biosynthesis of ketone bodies and their utilization, Biosynthesis of saturated and unsaturated fatty acids, Control of lipid (6 hrs)

Unit -7: Biological Oxidation: Enzymes and co-enzymes involved in oxidation, reduction & its control, respiratory chain, its role in energy capture and its control, Inhibitors of respiratory chain and oxidative phosphorylation, Mechanism of oxidative phosphorylation. (6 hrs)

Unit -8: Metabolism of Ammonia and Nitrogen Containing Monomers: Nitrogen balance, Biosynthesis of amino acids, Catabolism of amino acids, Conversion of amino acids. Formation of bile pigments, hyperbilirubinemia, Purine biosynthesis, Purine nucleotide interconversion. (6 hrs)

Unit -9: Biosynthesis of Nucleic Acids: Brief introduction of genetic organization of the mammalian genome, alteration and rearrangements of genetic material, Biosynthesis of DNA and RNA. (4 hrs)

Unit -10: Genetic Code and Protein Synthesis: Genetic code, Components of protein synthesis, and Inhibition of protein, synthesis. Brief account of genetic engineering and polymerase chain reactions. Regulation of gene expression. (6 hrs)

PHAR 221 Lab Biochemistry Practical

Proposed topics for practical

1. Preparation of standard buffers (citrate, phosphate and carbonate) and measurement of pH.
2. Titration curve for amino acids.
3. Separation of amino acids by two dimensional paper chromatography and gel electrophoresis.
4. Separation of lipids by TLC.
5. Separation of serum proteins by electrophoresis on cellulose acetate.
6. Quantitative estimation of amino acids.
7. Quantitative estimation of proteins.
8. Determination of glucose by means of the enzyme glucose oxidase.

9. Enzymatic hydrolysis of glycogen by alpha- and beta- amylases.
10. Isolation and determination of RNA and DNA.
11. Effect of temperature on the activity of alpha-amylase.
12. Estimation of SGOT, SGPT, Alkaline phosphotase and Bilirubin in the serum.

Books and other resources recommended

1. Conn, E.E. and Stump, P.K. Outlines of Biochemistry. John Wiley & Sons, New York.
2. Jayaraman, J. Laboratory Manual in Biochemistry. Wiley Eastern Ltd., New Delhi
3. Lehninger, A.L. Biochemistry, Worth Publisher, Inc.
4. Plumer, D.T. An Introduction to Practical Biochemistry. Tata McGraw Hill, New Delhi.
5. Harper's Biochemistry, Lange Publishing Group.
6. Harrow, B and Mazur, A. Textbook of Biochemistry. W.B. Saunders Co., Philadelphia.
7. Lehninger, A.L. Principles of Biochemistry. CBS Publishers.
8. Martin, D.W., Mayos, P.A. and Redwell, V.M. Harper's Biochemistry. Lange Medical Publications.
9. Mussay, R.K., Granner, D.K., Mayos, P.A. and Redwell, V.M. Harper's Biochemistry. Prentice-Hall International.
10. Ramarao Textbook of Biochemistry UBSPD.
11. Stryer, L. Biochemistry. W.H. Freeman & Co., San Fransisco.

PHAR 222 Chemistry of Natural Products [45 hours]

Unit-1: Introduction (6 hrs)

Introduction to natural product chemistry, primary & secondary metabolites & fundamental metabolic pathways—the acetate, shikimate, mevalonate, and deoxyxylulose phosphate pathways.

Unit-2: Application of chromatographic & spectroscopic techniques. (4 hrs)

Unit-3: Terpenoids(8 hrs)

Chemistry and pharmacological activity of medicinally important monoterpenes (limonene, menthol), sesquiterpenes (zingiberene), diterpenes (taxol, forskolin, phorbol, steviol) and triterpenoids (fusidic acid), biogenetic relationship among monoterpenes.

Unit-4: Carotenoids (4 hrs)

Chemistry & pharmacological activity of alpha-carotene, beta-carotene, Vitamin A & medicinally important xanthophylls-capsorubin & capsanthin.

Unit-5: Glycoside (6 hrs)

Chemistry, biosynthesis (those marked with * only) & pharmacological activity of digitoxin^{*}, digoxin^{*}, hecogenin, sennosides, diosgenin^{*} and sarsapogenin.

Unit-6: Alkaloids (10 hrs)

Chemistry, biogenesis (those marked with * only) and pharmacological activity of atropine^{*} and hyoscine^{*}, quinine^{*}, reserpine^{*}, morphine^{*}, papaverine^{*}, ephedrine^{*}, ergot, and vinca alkaloids.

Unit-7: Lignans (7 hrs)

Chemistry and pharmacological activity of medicinally important lignans (lignans of *Podophyllum* spps, *Piper cubeba* & *Linum usitatissimum*); flavanoids (flavanoids of *Ginkgo biloba*-Kaempferol, Quercetin, Myricetin ; *Liquorice*-Liquirtin, Liquirtigenin) and quassanoids (Quassia wood).

PHAR 222 Lab Chemistry of Natural Products Practical

1. Laboratory experiments on isolation, separation, and purification of various groups of chemical constituents of pharmaceutical significance.
2. Exercises on paper and thin layer chromatographic evaluations of herbal drug constituents.

Books recommended

1. Paul M Dewick Medicinal Natural Products-A Biosynthetic Approach 3rd Edition.
2. Trieber, Quantitative TLC & industrial Application.
3. Vepoorte Swendson – Chromatography of alkaloids.
4. V K Srivastava – Introduction to Chromatography – Theory and Practice.
5. Harbone – Phytochemical Methods of Chemical Analysis.
6. Ara Dermarderosia – The Review of Natural Products.
7. H F Liskens and J F Jacksons- Modern Method of Plant Analysis- HPLC in Plant Science.

PHAR 223 Pharmaceutical Engineering II

[45 hours]

Unit 1: Heat Transfer: Sources of heat (steam and electricity, Mechanism of heat transfer (conduction, convection and radiation), Conduction: Fourier's law, Conduction through Single Metal Wall, Compound resistances in series, heat flow through a cylinder; Convection: Temperature gradient in forced circulation; Radiation: Black body, Grey Body Fourier Law (heat flow through a metal wall and through a cylinder); equipments (heat exchangers and interchangers); Heat exchangers: tubular heater, multi pass heater; Heat interchangers: Baffles, liquid to liquid interchanger, double pipe heat interchanger, Numerical on heat transfer [6 hours]

Unit 2: Evaporation: Introduction, factors affecting evaporation, evaporators:- tube evaporators (horizontal and vertical), film evaporators (Rising film and falling film), Forced Circulation Evaporator, multiple effect evaporators. [4 hr]

Unit 3: Drying: Definition, pharmaceutical application of drying, theory of drying (drying equation), terms used in drying process (bound water, unbound water, equilibrium moisture content, measurement of EMC, free moisture content, loss on drying, percentage moisture content, drying rate), behaviours of solids during drying (drying rate curves) , Classification and types of dryers, dryers used in pharmaceutical industries:- Tray Dryer, Spray Dryer, Fluidised Bed Dryer, Vacuum Dryer, Freeze Dryer and drum dryer, Numerical on drying [6 hrs]

Unit 4: Distillation: Definition, application, theory of distillation (Raoult's law, Dalton's law, phase diagrams, volatility), general equipments for distillation (still, condenser, receiver), Distillation methods(simple distillation, flash distillation, fractional distillation, principle of working of fractionating column, packed column & plate column (bubble cap plates), azeotropic and Extractive distillation, steam distillation, distillation under reduced pressure, rectification), molecular distillation, destructive distillation, compression distillation, calculation of theoretical plates (Mc. Cabe-thiele method), Equipments, production of WFI in pharmaceutical industries. [6 hours]

Unit 5: Size Reduction and size separation: Definition, pharmaceutical application of size reduction, factors affecting size reduction/selection of size reduction equipments, laws of size reduction (Rittinger's Law, Kick's Law and Bond theory), mechanism of size reduction (cutting, compression, impact and attrition), Size reduction equipments (cutter mill, roller mill, hammer mill, edge and end runner mill, ball mill, fluid energy mill and colloid mill) [5 hours]

Size Separation: Introduction, Official standards for powders (powder grades according to IP/BP), sieve analysis using sieve shaker (Sieve size BSS standards), equipments for size separation (Sieving and Screening equipments:- shaking screens, cyclone separator, air separator and bag filter) [3 hours]

Unit 6: Mixing: Theory of mixing, applications, mechanism of **mixing in solids**, degree of mixing (Perfect mixing, Alternative to mixing (Random & ordered Mixing)) and statistical evaluation, factors influencing mixing, equipments for solid mixing (double cone blender, Ribbon blender, sigma blade blender, planetary mixer, barrel type continuous mixer, zigzag continuous blender); **Mixing of liquids:-** mechanism, mixing

vessels(baffles) and devices (propeller, turbines, paddles), flow pattern during mixing, vortex formation and its prevention, equipments for continuous mixing (air jet mixers and jet mixer) ; **Mixing of immiscible liquids**- emulsification (equipments: -Silverson Mixer, colloid mill and ultrasonic emulsifier). Mixing of semi-solids (equipments:- Triple roller mill). [6 hours]

Unit 7: Automated Process Control Systems - definition, history, advantage and disadvantage, Automation tools, automated manufacturing, introduction to PID controller, control panel and PLC. CAM- introduction, origin, advantage and disadvantage, Introduction and list of Computer added techniques and devices, five basic Technologies that adopted for CAM, introduce Computer Integrated Manufacturing Open System Architecture and Manufacturing process management [5 hours]

Unit 8: Reactors and fundamentals of reactors design for chemical reactions: Chemical reactors- introduction and type, important process variables of chemical reactors, aspects of the CSTR, Plug Flow Reactor, Semi-batch reactor, Catalytic reactor, microreactor and Upflow Anaerobic Sludge Blanket (UASB) Reactors. [4 hours]

PHAR 223 Lab Pharmaceutical Engineering II Practical.

1. Determination of overall heat transfer coefficient
2. Determination of rate of evaporation.
3. Two experiments on distillation.
4. Determination of drying rate and verification of drying curve.
5. Experiments on milling of solid
6. Experiments on sieve analysis.
7. Demonstration of mixing of solids
8. Demonstration of mixing of miscible liquids and study of vortex formation during liquid mixing.
9. Demonstration of mixing of immiscible liquids
10. Demonstration of APCS.

Books and Other Resouces Suggested

1. Pharmaceutical Engineering –principles and practices by CVS Subrahmanyam, J T Setty, S Suresh and V K Devi. Vallabh Prakashan Delhi.
 2. Pharmaceutical Engineering by K Sambamurthy – new age international publisher.
- Reference Books
1. Theory and Practice of industrial Pharmacy by Lachman and Lieberman.
 2. Unit Operation by Anthony J Hiki
 3. Pharmaceutical Process scale-up: by Michel Levin- Marcel Dekker.
 4. Pharmaceutical production facilities; design and application by Cole G- 2nd edition Taylor Francis, 1998.

PHAR 224 Pharmaceutical Microbiology

[45 hours]

Unit -1: Introduction (2 hours)

History, branches of microbiology and importance of pharmaceutical microbiology. Contribution of Antony Van Leeuwenhoek, Robert Koch, Louis Pasteur and Alexander Fleming.

Unit -2: Structure of bacterial cell. (8 hours)

Microscopy– Principle and description of light microscopes and electron microscope. Structure of procaryotic and eucaryotic cells and their comparison. Theory of staining, simple, Gram's, acid fast, negative, flagella and spore staining methods. Classification of microbes and their taxonomy. Actinomycetes, bacteria, rickettsiae, spirochetes and viruses. Nutrition, culture media, cultivation, isolation of bacteria, actinomycetes, fungi, viruses. Microbial genetics and mutation.

Unit -3: Control of Microbial Growth (2 hours)

Disinfection, factors influencing disinfectants, dynamics of disinfection, disinfectants and antiseptics and their evaluation. Sterilization, different methods of sterilization, validation of sterilization methods & equipments. Introduction to microbiology of water. Bacteriological examination for assessment of the quality of water. Microbial limit tests for E. coli and Pseudomonas.

Unit -4: Sterility testing of all pharmaceutical products (8 hours)

General methodology, Method of membrane filtration, Method of direct transfer, Negative product control test, Media for use in sterility testing, diluents, solvents and wash solution for use in sterility testing. Sterility testing environment. Limulus amoebocyte lysate (LAL) Test, introduction to aseptic technique.

Unit -5: Immunity (8 hours)

Immunity: Definition of antigen and antibody, types of antigens and antibodies, classification of immunoglobulin, types of immunity. Antigen-antibody reactions (agglutination, precipitation, neutralization and complement fixation). Types of Hyper sensitivity reactions. Definition of infection, non-specific defense mechanisms, bacterial toxins, virulence and virulence factors and attenuation.

Unit -6: Microbial assays of antibiotics, vitamins & amino acids. (10 hours)

Principles and Methods involved in Assay of Antibiotics, Vitamins, Amino acids & Bio-Sensors in Analysis.

PHAR 224 Lab Pharmaceutical Microbiology Practical

Experiments devised to prepare various types of culture media, sub culturing of common aerobic and anaerobic bacteria, fungus and yeast, various staining methods, various methods of isolation and identification of microbes, sterilization techniques and their validation, evaluation of antiseptics and disinfectants, testing the sterility of pharmaceutical products as per pharmacopoeial requirements, microbial assay of antibiotics and vitamins.

Proposed List of experiments:

1. Preparation of nutrient broth; 2. Preparation of nutrient agar; 3. Inoculation of bacteria;
4. Isolation of pure cultures; 5. Simple staining; 6. Gram's staining; 7. Motility of bacteria;
8. Spore staining; 9. Oligodynamic action of copper; 10. Liquefaction of gelatin; 11. Starch hydrolysis; 12. Nitrate reduction; 13. H₂S production 14. Phenol coefficient; 15. Chick Martin coefficient; 16. Viable count; 17. Fermentation of carbohydrates; 18. Microbiology of water;
19. Microbiology of milk; 20. Antibiotic sensitivity test; 21. Morphology of yeast, fungi and actinomycetes. 21. Sterility testing

Books and other resources Recommended

1. Microbiology by Pelczar, M.J. Reid, R.D. and Chan, E.S. Tata McGraw Hill Publishing Co. Ltd.;
2. Medical microbiology edited by Robert Cruick Shank. ELBS edition;
3. Pharmaceutical microbiology by Harrish M. Baillere, Tindal and Co., London;
4. Pharmaceutical microbiology edited by Hugo and Russel, P.g. publishing company Ltd., New Delhi.
5. 1 Heritage, J Introductory Microbiology.
6. Nester, Anderson, Roberts, Pearsall, Microbiology, McGraw-Hill.
7. Hugo, W B Pharmaceutical Microbiology.
8. Tortora, Gerard Text Book of Microbiology.
9. E.A Rawlins, Betley's Text Book of Pharmaceutics, Latest edition.
10. Garg, F C Experimental Microbiology
11. Gaud, R.S Practical Microbiology
12. Recommendations for Sterility Testing- <http://www.picscheme.org>
13. USP Sterility Testing USP <71>
14. TGA guidelines for sterility testing of therapeutic goods.
15. Denyer SP et al. : Filtration Sterilization : In Principles and Practice of Disinfection, Preservation and Sterilization (ed. Russell AD et al.) Blackwell Scientific Publications, Oxford (UK), Latest edition.
16. Hugo WB and Russell AD : Pharmaceutical Microbiology, PG Publishing Pvt. Ltd., Singapore, 3rd edn, Latest edition.
17. Indian Pharmacopoeia: Published by the Controller of Publications, Delhi, Vol. II, 1996 and 2007.
18. Remington: The Science and Practice of Pharmacy, Lippincott Williams & Wilkins, New York, Vol.-1, 21st. edn, 2006.
19. 20. Interference with the LAL Test and How to Address It, LAL Update, October 2005.

PHAR 225 - Pharmacology I

[60 Hours]

Part -1: General Pharmacology

Unit-1: Introduction to Pharmacology:

Terms used in Pharmacology, Drug nomenclature **(0.5 Hr.)**

Unit-2: Sources of drugs:

Plant, Animal, Microorganism, Mineral, Inorganic, Synthetic and laboratory (genetic) source with examples from each source.

Dosage forms: Classification of different dosage forms with examples. **(1 Hr.)**

Unit-3: Route of drug administration:

Factors governing choice of route of drug administration, Classification (Local and systemic), Advantages and disadvantages of various routes of drug administration, Characteristics of Topical and Systemic routes (Oral and Parenteral) **(1.5 Hr.)**

Unit-4: Pharmacokinetics: **(8 Hrs.)**

Absorption:

Introduction to biological membranes, Drug transport processes, (including Passive diffusion, Filtration, Specialized transport, Facilitated diffusion and Pinocytosis).

Factors affecting absorption, Bioavailability (Chemical equivalent and Biological equivalent),

Distribution:

Apparent volume of distribution (Vd), Significance of high and low Vd, Conditions altering Vd, Redistribution, penetration into brain and cerebrospinal fluid, Passage across placenta, Plasma protein binding and its significance, examples of few clinically important displacement interactions.

Metabolism (Biotransformation):

Definition of first pass metabolism, sites and consequences of drug metabolism, Types with examples (Phase I and Phase II reaction), enzyme inhibition and its consequence (in brief) and use, First pass metabolism and its attributes.

Excretion:

Routes (renal and non-renal) of excretion of drugs with few examples. Plasma half-life and its importance, Clearance Loading dose and Maintenance dose, Therapeutic Drug Monitoring and its indications, Fixed dose Combination (Advantage and Disadvantage)

Unit-5: Pharmacodynamics: **(9 hrs)**

Introduction, Principles of drug action, Mechanism of drug action, Action through enzymes (Enzyme inhibition and its type using suitable examples).

Action through receptors, Terms used in describing drug-receptor interaction, Receptor occupation theory, Two-state receptor model, nature of receptors, Receptor sub-types, Action-effect sequence.

Transducer mechanisms (G-protein coupled receptors, Receptors with intrinsic ion channels, Enzyme linked receptors, receptors regulating gene expression), regulation of receptors, Functions of receptors,

Dose-response relationship (dose response curve), therapeutic index, Drug potency and efficacy, Selectivity, Risk-benefit ratio, combined effects of drugs.

Tolerance and dependence:

Definition of tolerance and its types (Natural and Acquired), Mechanism of development of tolerance (Pharmaokinetic Tolerance, Pharmacodynamic Tolerance, Cross tolerance, Tachyphylaxis), Drug dependence and its types, Drug abuse, addiction and habituation, Drug withdrawal reactions. (2 hrs)

Pharmacogenetics:

Definition and introduction. Explanation using suitable examples (0.5 hr)

Basic and clinical pharmacokinetics:

Order of reaction (equation only, **NO** derivation required), Concept and graph for one and two compartment model.

Evaluation of Pharmacokinetic parameters (V_d , Cl and $T_{1/2}$). (1 hr)

Adverse drug reaction and treatment of poisoning:

Definition and types of ADR, Predisposing factors, Mechanism of ADR types (in brief), Hypersensitivity and its types, Route of exposure and general method of treatment of poisoning.

(2 hrs)

Unit-6: Bioassay of drug and Biological standardization:

Concept and purpose of bioassay, type and techniques of bioassay assessment. (2 hrs)

Unit-7: Discovery and development of new drugs:

Various phases of clinical trials (1 hr)

Part -2: Pharmacology of Peripheral Nervous System (15 hours)

Unit-8: Neurohumoral transmission

Classification, Mechanism of action, Side-effects, Contraindications, Precautions and doses of commonly used drugs:

Differences between Sympathetic, Parasympathetic Nervous system. Steps Involved in Neurotransmission. Cholinergic Transmission. Muscarinic and Nicotinic Receptors.

Adrenergic Transmission. Adrenergic Receptors. Prejunctional Regulation of Norepinephrine Release.

Unit-9: Parasympathomimetics and Parasympatholytics:

Classification, Mechanism of action, Side-effects, Contraindications, Precautions and doses of:

Acetylcholine, Carbachol, Pilocarpine, Physostigmine, Neostigmine, Organophosphate, Pralidoxime. Atropine, Scopolamine, Hyoscine.

Unit-10: Sympathomimetics and Sympatholytics:

Adrenaline, Epinephrine, Norepinephrine, Isoprenaline, Dopamine, Dobutamine, Clonidine, Salbutamol (Albuterol), Salmeterol, Formoterol, Terbutaline and Amphetamine, Prazosin, Terazosin, Tamsulosin, Propranolol, Methyldopa, Timolol, Atenolol and Metoprolol.

Ganglionic stimulant: Pilocarpine

Ganglionic blocker: Hexamethonium, Mecamylamine, Trimethaphan, Nicotine

Unit-11: Neuromuscular blocker and Local anaesthetic:

Tubocurarine, Pancuronium, Succinylcholine (depolarizing), Tizanidine. Procaine, lidocaine, Bupivacaine, Topical anesthesia (surface), Infiltration, Plexus block, Epidural (extradural) block and Spinal anesthesia (subarachnoid block).

Part 3: Pharmacology of the Central Nervous System (16 hours)

Neurohumoral transmission in the CNS:

Classification, Mechanism of action, Side-effects, Contraindications, Precautions and doses of commonly used drugs. Steps in neurohumoral transmission.

Unit-12: General anesthetics:

Stages of General Anesthesia, Types and ideal characteristics

Mechanism of action, indication, ADRs, C/I, Doses of commonly used GAs (Halothane, Isoflurane, Nitrous oxide, Ketamine, Thiopental)

CNS Stimulants: Methylxantines, Doxapram, Amphetamine.

Unit-13: Alcohol and Disulfiram

Effect of alcohol in CNS, kidney and Liver. Use of Disulfiram for alcohol withdrawal, Recommended dose, Precautions, Side-effects, Potential interaction.

Unit-14: Anxiolytics, Sedative and hypnotics:

BZDs: Alprazolam, Diazepam, lorazepam, chlordiazepoxide. Phenobarbital: Phenobarbitons.

Unit-15: Drugs used as:

Anti-psychotics: Haloperidol, Clozapine.

Anti-depressants: Fluoxetine, Duloxetine, Bupropion, Amitriptylline, Imipramine, Nortriptyline,

Mood Stabilizers: Valproate semi-sodium, Lithium salts.

Anti-epileptic drugs: Phenytoin, Carbamazepine, Oxcarbazepine, and Topiramide. .

Anti-Parkinsonian drugs: Levodopa, Carbidopa, Selegiline.

. PHAR 225 Lab Pharmacology –I Practical

1. Introduction to experimental pharmacology.
2. Preparation of different solutions for experiments.
3. Drug dilution, use of molar and W/V solutions in experimental pharmacology.
4. Common laboratory animals and anesthetics used in animal studies.
5. Commonly used instruments in experimental pharmacology.
6. Some common and standard techniques. Bleeding and intravenous injection, intragastric administration procedure for rendering animal's unconscious, stunning or redents, pithing of frogs, chemical anesthesia.
7. Experiments on intact preparation :
8. Study of different route of administration of drugs in mice/rats.
9. To study the effect of hepatic microsomal enzyme inhibitors and introduction of the Pentobarbitone sleeping time in mice.
10. Evaluation of local anesthetics.
11. To study the effect of autonomic drugs on rabbit eye.
12. To study the effect of various agonists and antagonists and their characterization using isolated preparation like frogs rectus abdominus muscle and isolated ileum preparation of rat, guinea pig

Books Recommended:

1. C.R.Craig and R.E.Stitzel: Modem Pharmacology
2. Theodore W.Rall, Alan S.Nies and Palmer Taylor: Goodman Gilman's : The Pharmacological Basis of Therapeutics by Alfred Goodman Gilman.
3. D.R.Laurence and P.N.Bennett: Clinical Pharmacology.
4. K.D.Tripathi: Essentials of Medical Pharmacology.
5. R.S.Satoskar and S.D.Bhandarkar: Pharmacology and Pharmacotherapeutics.
6. F.S.K. Barar: Essentials of Pharmacotherapeutics.
7. H.P.Rang and M.M.Dale: Pharmacology.
8. James Crossland: Lewis's Pharmacology, revised.
9. Pharmacological experiments on isolated preparations by Edinburgh University Pharmacology Staff, 1968.
10. Robert A.Turner and Peter Hebbom: Screening methods in Pharmacology, Vol.1 edited
11. S.K.Kulkarni: Handbook of experimental Pharmacology
12. M.N.Ghosh: Fundamentals of experimental pharmacology
13. Ian Kitchen: Text book of invitro Pharmacology
14. U.K.Sheth, N.K.Dadkar, Usha G.Kamat: Selected topics in Experimental Pharmacology
7. K. K. Pillai: Experimental Pharmacology, CBS, Delhi.

FIFTH SEMESTER

PHAR 311 Medicinal Chemistry I

(60 hours)

Unit- 1: Physicochemical parameters, transducer mechanism, biotransformation & prodrug – (8hrs)

- 1.1 Solubility, Partition coefficient, pKa & degree of ionization, Isomerism (Geometrical, Optical) & bioactivity, Bioisosterism (classical/non classical)
- 1.2 Types of Drug-receptor interaction, transduction mechanism (G-protein coupled receptor, ligand gated ion receptor, tyrosine kinase receptor, intracellular receptor)
- 1.3 Biotransformation (phase I and Phase II - conjugation)
- 1.4 Prodrug

Unit- 2: Principles of Drug Design (Theoretical Aspects): (7 hours)

2.1. Quantitative Structure Activity Relationship: Introduction, QSAR Parameters, QSAR Methods, Linear & nonlinear relationship between Log P and Biological activity, Electronic parameters, Steric substituent constant, effect of electronic and steric parameters on lipophilicity, Experimental determination of partition coefficients, Methods used in QSAR studies, achievements & limitation of QSAR and introduction to molecular modeling. Introduction to Computer aided drug designing (CADD).

2.2. Introduction to Hansch equation, Craig plot, Topliss scheme & Free-Wilson approach

Study of the following classes of compounds including their chemical classification, structure and nomenclature, physicochemical properties, mechanism of action, structure activity relationship (SAR), uses and outline of synthesis (of compounds with star).

Unit- 3: Cholinergic receptors and Drug Affecting Cholinergic Neurotransmission (8 hours).

- 3.1 Cholinomimetics: Cholinergic receptors, Acetylcholine – biosynthesis and release, SAR, Classification of Cholinomimetics, Structure, Synthesis, property and use of Methacholine*, Neostigmine, Physostigmine, Pyridostigmine*, Donepezil, Organophosphate Poisoning and reactivation of phosphorylated Cholinesterase.
- 3.2 Anticholinergics: Natural Belladonna alkaloids (Atropine sulphate), Semi synthetic alkaloids (Ipratropium bromide), Synthetic substitutes –Tropicamide*, Dicyclomine*, Trihexyphenidyl HCl* and Pirenzepine. Drotaverine as antispasmodic.

Unit- 4: Adrenergic receptors and Drug Affecting Adrenergic Neurotransmission (8 hours).

4.1 Adrenomimetics- Adrenoreceptors, Dopamine, Epinephrine*, Phenylephrine, Terbutaline, Salmeterol, Isoproterenol, Resorcinol, Metaproterenol, Albuterol*(Salbutamol), Phenylephrine, indirect acting (Amphetamine, L-(+)-Pseudoephedrine,), adrenergics with mixed mechanism of action (Ephedrine, phenylpropanolamine). Nasal Decongestant – Phenylpropanolamine, Phenylephrine, Oxymetazoline, Xylometazoline.

4.2 Antiadrenergics: α - Adrenergic blockers (ergometrine, Prazosin, Terazosin and Tamsulosin). β - Adrenergic blockers: Propranolol*, Atenolol.

Unit- 5: Antihistaminic and Antiulcer (4 hours)

5.1 H1 receptors antagonist –Diphenhydramine*, Tripelennamine, Methapyrilene, Chlorcyclizine, Promethazine, Terfenadine; Astemizole; Loratadine, Triprolidine, Cetirizine, Chlorpheniramine Maleate*; Cyproheptadine Hydrochloride.

5.2 H2 receptors antagonist- structure, Cimetidine, Ranitidine and Famotidine.

5.3 Proton Pump Inhibitors; structure, Omeprazole, Pantoprazole and Esmoprazole. Sucralfate and Bismuth salts.

Unit- 6: Non-steroidal anti-inflammatory Agents and Neuromuscular blockers: (4 hours)

6.1. Salicylate, Arylacetic acids, Propionic acids, Fenamic Acid, Pyrazoles and Enolic acid, Aspirin, Mefenamic acid, Indomethacin, Ibuprofen*, Ketoprofen, Diclofenac, Naproxen, Piroxicam, Ketorolac, Acetaminophen*, Mefenamic acid, Phenylbutazone.

6.2. Skeletal Muscle relaxants: Tubocurarine chloride, Succinylcholine*, Pancuronium, Baclofen, Danthrolin, Tizanidine and Chlorzoxazone.

Unit- 7: Oxytocics and Prostaglandin (2 hours)

Structure, property and uses of - Oxytocin, Ritodrine, Isoxsuprine. Prostaglandins F₂, Prostaglandin E₂, Prostaglandin E₁, Carboprost, Misoprostol, Bimatoprost.

Unit – 8: Steroids (4 hours)

Cortisone, Hydrocortisone, Beclomethasone, Budesonide, Prednisolone*, Methylprednisolone, Triamcinolone, Dexamethasone, Fluticasone and Mometasone. Estrogens (Estradiol, Diethylstilbistrol), Progesterone, Testosterone,

Unit-9: CVS Drugs (11 hours).

9.1 Cardiac glycosides (Digoxin), Glyceryl nitrate, Propranolol.

9.2 Antihypertensive agents: Reserpine, Prazosin, Terazosin, Clonidine, Hydralazine*, Sodium Nitroprusside*, Minoxidil, Captopril, Enalapril, Losartan, Nifedipine.

9.3 Diuretics: Acetazolamide*, Hydrochlorothiazide*, Frusemide, Spironolactone and Mannitol.

9.4 Anticoagulants: Heparin and Warfarin.

9.5 Antiplatelet drugs: Aspirin, Dipyridamol, Streptokinase.

Unit – 10: Local anti-infective agents (2 Hours)

Ethyl Alcohol, isopropyl alcohol, formaldehyde, phenols, cresol, hydrogen peroxide, povidine iodine, halozone, Chlorhexidine gluconate, Gentian violet, Nitrofurazone, Merbromin. Salicylic acid and benzoic acid.

Unit-11: Sulphonamides (2 Hours)

General structure of sulphonamides, and MOA, Classification and SAR, Sulphamethoxazole and trimethoprim combination (MOA and uses), Sulphadimethoxin, Sulfacetamide and silver sulphadiazine.

PHAR 311 Lab Medicinal Chemistry II Practical (Minimum 8 experiments)

Synthesis & pharmacopoeial analysis of some medicinal compounds:

- Hexamine
- Dibenzalacetone
- Barbituric acid from Diethyl Malonate
- Benzoic acid from Benzyl chloride
- Benzimidazole from o-phenylenediamine (Phillip's Reaction)
- Acetanilide from acetophenone
- P-amino benzoic acid (P-ABA) from P-nitrobenzoic acid
- Benzocaine from para- nitro benzoic acid
- Benzyl alcohol by Cannizzaro's reaction
- Benzoylglycine from Benzaldehyde
- Benzoyl Alanine from Benzoyl Chloride.

Books and other resources recommended:

1. Block JH, Beale JM, editor. Wilson and Gisvold's textbook of organic medicinal and pharmaceutical chemistry. 11th ed. Baltimore: Lippincott Williams & Wilkins; 2004.
2. Lemke TL, Williams DA, editor. Foye's principles of medicinal chemistry. 6th ed. New Delhi: Wolters Kluwer and Lippincott Williams & Wilkins; 2008.
3. Kadam Dr. SS et al. – Principles of Medicinal Chemistry Vol. I and II. Nirali Prakashan, India.
4. Abraham DJ, editor. Burger's Medicinal Chemistry and Drug Discovery, 6th ed. Vol 1-6. New Jersey: John Wiley & Sons; 2007.
5. Hansch C, editor. Hansch's comprehensive medicinal chemistry, Delhi: Rajkamal Electronic Press; 2005.
6. Ariens EJ, editor. Drug design vol. I-X. Noida: Academic Press; 2009.
7. Roth HJ, Kleemann A. Pharmaceutical Chemistry. Vol-I. Drug synthesis. New York: Ellis Horwood Limited; 1988.
8. Lednicer D, Mitscher LA, The organic chemistry of drug synthesis, Volume-1-6. New York: A Wiley-Interscience publication; 2005.
9. Remington: The science and practice of pharmacy. 21st ed., vol. I & II, Lippincott Williams & Wilkins, New Delhi, 2005.
10. Smith & Williams. Introduction to principles of drug design-Harwood academic press.

PHAR 312 Pharmaceutical Technology I (45 hours)

Unit- 1. Liquid Dosage Forms: (13 hrs)

Liquid dosage forms and route of administration, advantages and disadvantages of liquid dosage forms. **(0.5 hrs)**

Solutions: Solvents, Buffers, Viscosity enhancers and density modifiers, Antioxidants, Reducing agents, Flavors and Fragrance, Isotonicity modifiers, Types of Oral solutions, General method of solution manufacturing. **(3.5 hrs)**

Suspension: Ideal properties of pharmaceutical suspension, Types, Theory of suspension, Theory of sedimentation, Electrical double layer and Zeta potential, DLVO theory of colloidal stability, flocculated and deflocculated suspension, Method of floccules formation, controlled flocculation, structured vehicle formulation, Wetting agents, suspending and thickening agents. Dispersing agents, flocculating agents. Taste mask of oral suspension. Quality control and pharmacopeial tests. Recent advances in suspension formulation – Sustain released suspension, Nanosuspension. **(6 hrs)**

Emulsion: Type, test for identification of emulsion type, emulsifying agents, stability of emulsion, preservation of emulsion, method of preparation, quality control including pharmacopeial tests. **(3 hrs)**

Unit- 2: Semisolid Dosage Forms (8 hrs):

Ideal properties of semisolid dosage forms, Types (Ointment, Cream, Gels- hydrogel, organo gel, oleo gel, stimuli responsive hydrogel, poultices, suppositories and passerines, Trans dermal patch). Percutaneous absorption, Factors affecting percutaneous absorption, Physiological and pathological condition of skin, formulation of semisolids, Bases types and gelling agents, method of manufacturing. Permeation enhancement (Physical and chemical permeation enhancers) and quality controls including pharmacopeial tests.

Unit -3: Suppositories (3 hrs):

Type, uses, Type of bases, Factor affecting drug absorption from rectal and vaginal suppositories ideal suppository base, Methods of manufacturing, , quality control including pharmacopeial tests.

Unit-4: Extraction and Galenical products (3 hrs):

Scope, importance, theory of extraction process, infusion, decoction. Digestion, maceration, Percolation. Factors affecting extraction process.

Unit- 5: Pharmaceutical aerosols (3 hrs)

– Advantage, component of aerosol, Manufacturing methods, filling (Cold filling, Pressure filling, compressed gas filling), stability testing, Quality control and pharmacopeial tests.

Unit- 6: Ophthalmic preparations (7 hrs):

Challenges of ocular drug delivery, pharmacokinetic consideration, formulation consideration, Physiochemical properties of drug used in ophthalmic dosage form, Buffer capacity, pH and isotonicity, instillation volume, Osmotic pressure, formulation approach, Classical dosage forms (solution, suspension, ointments). Introduction to polymeric

delivery system (viscosity enhancing polymers, Mucoadhesive polymer in situ gelling system), Introduction to colloidal drug delivery system (Nanoparticles, liposome, niosomes, microparticles), Introduction to delivery approach (Prodrug, penetration enhancers, cyclodextrin and ocular inserts).

Unit- 7: Cosmetology (8 hrs):

Definition (general and medical cosmetics), Types of cosmetics, Organ wise and body site wise cosmetics, Introduction to skin types. Sunscreens (mention UVA , UVB, drugs That Sensitize the Skin to Sunlight, mention ingredients, factors affecting the sunscreen the effectiveness of preparations), Moisturizers(methods of use, ingredients, toners(ingredients. Lipistics (ingredients and just idea of manufacturing). Hair (growth cycle and function, Shampoo and its ingredients, mention hair cream, dye and gel). Dentifrice (Defination, types- Tooth powder, Tooth paste, Mouth wash, and their ingredients).

Introduction to Manicure and Pedicure products.

PHAR 312 Lab Pharmaceutical Technology I Practical

1. Preparation, evaluation and packaging of liquid orals like solutions, suspensions and emulsions, ointments, suppositories, aerosols, eye drops, eye ointments etc.
2. Preparation of pharmacopoeial extracts and galenical products utilizing various methods of Extraction.
4. Formulation of various types of cosmetics preparations.

Books Recommended

1. Aulton, M.E. Pharmaceutics- The Science of Dosage Form Design. ELBS/Churchill Livingstone.
2. Lachman, L., Lieberman, H.A., and Kanig, J.L. The Theory & Practice of Industrial Pharmacy. Lea & Febiger, Philadelphia.
3. Sagarin & Balsam, M.S. Cosmetic Science & Technology. Vol. 1-3 2nd ed. John Wiley.
4. Poucher's Cosmetology.
5. Ansel, H.C. Introduction to Pharmaceutical Dosage Forms. V.M. Verghese & Co., Mumbai.
6. Banker, G.S. and Rhode, C.T. Modern Pharmaceutics. Marcel Dekker.
7. Carter, S.J. Cooper & Gunn's Tutorial Pharmacy. CBS Publishers, Delhi.
8. Jellinek, J.S. Formulation and Function of Cosmetics. John Wiley & Sons.
5. Kac Chensney, J.C. Packaging of Cosmetics and Toiletries. Newness Butter Worth, London.
6. Pharmaceutical Dosage Forms and Drug Delivery Systems. Lea and Febiger, Philadelphia.
7. Rawlins, E.A. Bentley's Textbook of Pharmaceutics. ELBS.

PHAR 313 Pharmaceutical Biotechnology

(45 hours)

Unit 1: Immunology and Immunological Preparations (10 hours)

Principles, antigens and haptens, immune system, cellular humoral immunity, immunological tolerance, antigen-antibody reactions and their applications. Hypersensitivity, Active and passive immunization; Vaccines- their preparation, standardization and storage.

Unit 2: Genetic Recombination (8 hours)

Transformation, conjugation, transduction, protoplast fusion and gene cloning and their applications. Development of hybridoma for monoclonal antibodies. Study of drugs produced by biotechnology such as Activase, Humulin, Humatrope, and HB.

Unit 3: Antibiotics (15 hours)

Historical development of antibiotics. Antimicrobial spectrum and methods used for their standardization. Screening of soil for organisms producing antibiotics, fermentator, its design, and control of different parameters. Isolation of mutants, factors influencing rate of mutation. Design of fermentation process. Isolation of fermentation products with special reference to penicillin, streptomycin tetracycline and vitamin B.

Unit 4: Microbial Transformation (6 hours)

Introduction, types of reactions mediated by microorganisms, design of biotransformation processes, selection of organisms, biotransformation process and its improvements with special reference to steroids.

Unit 5: Enzyme immobilization (6 hours)

Techniques of immobilization, factors affecting enzyme kinetics. Study of enzymes such as hyaluronidase, penicillinase, streptokinase and streptodromase, amylases and proteases etc. Immobilization of bacteria and plant cells.

PHAR 313 Lab Pharmaceutical Biotechnology Practical

1. Isolation of antibiotic producing microorganism from soil.
2. Enzyme immobilization by Ca-alginate method.
3. Determination of minimum inhibitory concentration of the given antibiotic. Antibiotic assay by cup plate method.
4. Collection, Processing, Storage and fractionation of blood.
5. Standardization of Cultures.
6. Microbiological assay of Antibiotics / Vitamins.
7. Production of alcohol by fermentation techniques.
8. Comparison of efficacy of immobilized cells.
9. Isolation of mutants by gradient plate technique.
10. Preparation of bacterial vaccine.

11. Extraction of DNA.
12. Separation techniques: Various types of Gel Electro Phoresis, Centrifugation.

Sample Experiments

Expt. 1: Immobilization by gel entrapment

1. Acrylamide, 2. Bis-acrylamide, 3. TEMED (N,N,N,N'-tetramethylenediamine)

Expt. 2: Protein estimation by Lowry Method

Sodium carbonate, Sodium hydroxide, Sodium potassium tartrate, Copper sulphate, Folin-Phenol and

Bovine Serum Albumin

Expt. 3: Estimation of glucose by DNS method

1. 3, 5 dinitrosalicylic acid, 2. Sodium hydroxide, 3. Phenol, 4. Rochelle salt (Sodium Potassium tartrate), 5. Sodium meta bisulphate, 6. Phenolphthalein, 7. 0.5 M HCl and 8. Glucose

Other experiments related to the topics covered in theory.

Books & other resources recommended

1. Wulf Crueger and Anneliese Crueger, Biotechnology, 2nd Ed, Publ- Panima publication co-operation, New Delhi.
2. P. F. Stanbury & A. Whitaker, Principles of fermentation technology, Pergamon Press
3. B.P. Nagori & Roshan Issari, Foundations in Pharmaceutical Biotechnology
4. Sambamurthy. K, Text Book of Pharmaceutical Biotechnology.
5. S. S. Kori, Pharmaceutical biotechnology.
6. Prescott and Dunne, "Industrial Microbiology" MC Caraw Hill Bool Company
7. 8. K. Kielslich "Biotechnology" Vol 6, Verlegchemic, Switzerland.
9. PF Standury & A. Whitaker, "Principles of fermentation Technology" Pergamon Press, Oxford
10. OP Ward "Fermentation Technology, Principles, Processes products" Open University press, Milton Keynes, UK.
11. A. M. Campbelli, Monoclonal antibody technology.
12. A. Wiseman, Handbook of enzyme biotechnology.
13. J. D. Watson, Recombinant DNA technology.
14. Smith and Hood, Molecular biology and biotechnology.
16. Brahamankar & Jaiswal- Biotechnology, SP Publication

PHAR 314 Pharmacology –II (45 hours)

Unit-1: Pharmacology of Cardiovascular System (15 hours)

- 1.1. MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of: Digitalis. Antihypertensive drugs (Hydrochlorothiazide, Calcium channel blockers as antihypertensive and
- 1.2. Antianginal: Nifedipine, Amlodipine, Verapamil, Diltiazem., Enalapril, Losartan, Telmesartan, Terazosin, Tamsulosin, Atenolol, Metoprolol, Hydralazine, Sodium Nitropruside, Antianginal- Nitroglycerine, Acebutolol, or non- cardioselectives beta blockers such as Sotalol.
- 1.3. Antiarrhythmic drugs (Quinidine, Procainamide, Propranolol, Amiodaron, Ibutilide, and Magnesium Sulphate).
- 1.4. Antihyperlipedemic drugs (Statins: Simvastatin, Atrovastatin, Rosuvastatin, Lovastatin. Fibrates: Clofibrate, Gemfibrozil Fenofibrate. Niacin, Bile acid sequestrants resins (chenodeoxycholic acid (CDCA) or ursodeoxycholic acid) and Orlistat.

Unit-2: Drugs used in Shock (2 hours)

Classifications of Shock, Signs and Symptoms, ABC management, Adrenaline, Dopamine, Dexamethasone and Sodium bicarbonate injection, Management of Septic Shock.

Unit-3: Drugs acting on the Hematopoietic System (8 hours)

- MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of following drugs: Erythropoietin, Iron Requirements and the Availability of Dietary Iron and Iron Salts, Folic acid and Vitamin B12, Therapy with Parenteral Iron.
- Hydroxyurea for sickle cell anemia. View of hemostasis: platelet function, blood coagulation and fibrinolysis. Heparin, Bivalirudin, Warfarin, Monitoring Anticoagulant Therapy: The INR (International Normalized Ratio). Phenprocoumon and Acenocoumarol. Aminocaproic Acid, Aprotinin, Abciximab, Aspirin, Dipyridamol, Ticlopedine, Clopidogrel, Etamsylate, Protamine sulphate, Traneximic acid and role of Vitamin K. Blood and plasma volume expanders (Albumin, Whole Blood, Dextran-70, Etherified starches, Polygeline).

Unit-4: Drugs acting on the urinary system (4 hours)

- a. Fluid and electrolyte balance. .
- b. Diuretics (Classification, MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of Acetazolamide, Hydrochlorothiazide, Frusemide, Spironolactone, Mannitol).

Unit-5: Autacoids and Autacoids Antagonists (6 hours)

- 1.1 Role of Histamine, Thromboxane and leukotrienes.
- 1.2 Therapeutic uses of prostaglandins, H1 antihistamins (Classification, MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of

Diphenhydramine, Pyrilamine, Pheniramine, Chlorpheniramine, Cetirizine, Promethazine, Cyproheptadine, Terfenadine, loratadine, and fexofenadine).
Leukotriene inhibitor (Montelukast).

1.3 H₂ receptor antagonists (MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of Cimetidine, Ranitidine and Famotidine).

1.4 5HT₃ antagonist (Ondansetron)

Unit-6: Drugs acting on the Respiratory System (5 hours)

- a. Anti-asthmatic drugs (Classification, MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of Salbutamol, Salmeterol, Formoterol, Theophylline, Etophylline, Steroids (Fluticasone, Budesonide),
- b. Mast cell stabilizer (Chromoglycate). Anti-tussives and expectorants (Codeine, Noscapine. Dextromethorphan, Promethazine, Triprolidine, Terpene hydrate, Bromhexine, Ammonium Chloride, Ambroxol).
- c. Respiratory stimulants (Doxapram, Caffeine citrate injection).

Unit- 7: Narcotic analgesics, NSAIDs and Anti-gout drugs: (5 hours)

- a. Classification, Mechanism of action, Side-effects, Contraindications, Precautions and doses of commonly used drugs :
- b. **Narcotic analgesics and antagonists:** Morphine, Methadone, codeine, Fentanyl, Pethidine, Naloxone
- c. **NSAIDs and Anti-gout drugs:** Aspirin, Ibuprofen, Paracetamol, Indomethacin, Nimesulide, Diclofenac, Naproxen, Allopurinol, Colchicine and Febuxostat, Probenecid, Sulfinpyrazone.

Books & other resources recommended

1. Goodman & Gillman's: The Pharmacological basis of Therapeutics- 11th Edn. (2006)
2. Pharmacology by Rang and Dale
3. Pharmacology and Pharmacotherapeutic by Satoshkar and Bhandarkar.
4. Essentials of Pharmacotherapeutic by F.S.K.Barar.
5. Lewis Pharmacology by Crosslan.
6. Textbook of Pharmacology by Bowman and Rand.
7. Martindale: The Complete Drug Reference, 36th edition.
8. Basic & Clinical Pharmacology tenth edition, 2007 edited by Bertram G. Katzung, MD, PhD
9. Lippincott's Illustrated Reviews: Pharmacology, 4th Edition, Copyright ©2009 Lippincott Williams & Wilkins

PHAR 316 Public Health Pharmacy (45 hours)

Unit-1: Introduction (2 hours)

Overview of Public Health & Pharmacy. Concept of health, disease, prevention and factors influence in health. Concepts of health and disease: Disease causing agents and prevention of disease.

Unit-2: Epidemiology and Pharmacoepidemiology (14 hours)

Definition, scope, concept and use of epidemiology disease transmission and control defense mechanism, immunity, immunization and occupational disease. Descriptive Studies (Case report, Case series and Ecological studies), Analytical Studies (Case control studies, Cohort studies), Experimental Studies (True experimental studies, Quasi experimental studies). Methods of quantifying drug interactions/ADR and adherence to drug therapy in pharmacoepidemiology. Spontaneous reporting, Global drug surveillance and role of pharmacists. Discuss different methods of quantifying adherence to drug therapy. Methods of quantifying drug interaction using principles of epidemiology, more specifically the Rothman principle of causation and the Rothman Synergy index. Discuss different methods of quantifying adherence to drug therapy.

Unit-3: Pharmacoeconomic methodologies (8 hrs)

Describe the Nepalese health care system with respect to: public and private sectors, persons and organizations that provide health services. Describe how characteristics of the Nepalese health care system influence prescribing, dispensing, and use of prescription medications, non-prescription medications, and complementary/alternative medicines. Describe the effect of self medication to public health. Cost Benefit Analysis (CBA), Cost Effectiveness Analysis (CEA), Cost Minimization Analysis (CMA), Cost Utility Analysis (CUA).

Unit-4: Health Promotion & Disease Prevention (8 hours)

.Principles, scope, planning and Method (individual, Group and Mass methods) of health education in Pharmacy. Describe stakeholders in and partnerships with public/private health professional and community groups that participate at the system, community, state, national and/or international levels to promote public health and safety. Planning of health education program (Rational use, Use of contraceptives, and health hazards of insecticides and pesticides).

Unit-4: Primary health care (10 hours)

Introduction, elements, Principles (explain 5 major principles), Implementation of PHC (in terms of WHO and government of Nepal). History of health care delivery system in Nepal. Health care delivery system in Nepal and health care management models.

Promotion of pharmacy related issues of health maintenance and disease prevention and treatment to the lay public and to health professionals.

Describe population level strategies for disease prevention, detection, wellness, promotion and for resolving identified public health problems in the context of pharmacy practice.

Role of pharmacist in PHC, Theory that approach to the health (biological system, psychological system, spiritual system, socio-cultural system). First aid treatment of poisoning, shock, snake bite, burns, fracture and drowning. Diarrhea, vomiting and dehydration, fluid replacement therapy.

Unit-5: Environmental Pollution (3 hours)

A brief description on environment, pollution, pollutant, waste, type of waste and waste from pharmaceutical activities, Classification of pharmaceutical waste. Safe disposal method of pharmaceutical wastes, WHO guidelines for the disposal of pharmaceutical waste

PHAR 316 Public Health Pharmacy Field Work

Conduct educational diagnosis survey (in hospital or HP or community)

Select topic of interest, Prepare KAP questionnaire, Collect data from patients, Analyze and interpret data, Find out problem and Prioritize problems.

- Write a plan for the development of a health education action project based on results of the health education survey
- Observation visit of pharmaceutical industry to know their waste disposal methods and make a report for the better solution if any.
- List hazards due to food additives and food adulteration
- Organize and conduct a health education action project and assess the effectiveness of health education in relation to Pharmacy, action project (1 day field)

Books and Other Resources recommended

1. Levin BL, Hurd PD, Hanson A. *Introduction to Public Health in Pharmacy*. Sudbury, MA: Jones and Bartlett, 2008.
2. *The Future of the Public's Health in the 21st Century*. Washington, D.C: National Academies Press;2003: 97, 417.
3. Bush PJ, Johnson KW. Where is the public health pharmacist? *Am J of Pharm Edu*. 1979;43:249-253.
4. Berger ML, Binglefors K, Hedblom EC et. al. International society for pharmacoconomics and outcomes research. Health Care Cost, Quality and Outcomes. 2003.
5. *Pharmacoeconomics and Outcomes: Applications for Patient Care*, American College of Clinical Pharmacy, Kansas City;1997.
6. Beaglehole R, Bonita R, Kjellstrom T. *Basic Epidemiology*. World Health Organization, Geneva, 1993.
7. MacMahon B, Trichopoulos D. *Epidemiology: Principles and Methods*. 2nd Edition.
8. Boston: Little, Brown, 1996.
9. Rothman KJ. *Epidemiology: an Introduction*. Oxford University Press, 2002

PHAR 317 Pathophysiology (45 hours)

Unit – 1: Basic Concepts of Pathophysiology - Cell injury, death and adaptation. (6 hours)

Occurrence of Cellular adaptations occurring in atrophy, hypertrophy, hyperplasia, dysplasia, and metaplasia.

Mechanism of cellular injury from hypoxia, free radicals, chemicals, unintentional and intentional injuries, infectious agents, immunologic and inflammatory responses, and genetic factors. Cellular accumulations occurring in response to injury and the subsequent manifestations of cellular damage. Major types of cellular necrosis, cite examples of the tissues involved in each type and compare necrosis to apoptosis. Compare the different theories of aging. Characterize somatic death and its manifestations.

Unit – 2: Acute and Chronic Inflammation. (3 hours)

Acute inflammation: vascular changes, leukocyte cellular events, chemical mediators of inflammation, outcomes of acute inflammation. Chronic inflammation. Role of lymphatics and lymph nodes in inflammation. Morphologic patterns in acute and chronic inflammation. Systemic effects of inflammation.

Unit – 3: Cell regeneration, fibrosis, and wound healing. (3 hours)

Regeneration. Control of cell growth and differentiation at sites of injury. Intracellular matrix and cell-matrix. Repair by connective tissue. Pathologic aspects of repair. Wound healing, Overview of the inflammatory-reparative response.

Unit – 4: Disorders of Immune System. (3 hours)

Cells of the immune system. Cytokines. Histocompatibility genes. Immune mechanisms of tissue injury. Autoimmune diseases. Immunodeficiency diseases.

Unit – 5: Neoplasia. (4 hours)

Characteristics of benign and malignant neoplasms. Epidemiology of neoplasia. Carcinogenesis-the molecular basis of cancer. Biology of tumor growth. Etiology of cancer-carcinogenic agents.

Host defense against tumors-tumor immunity. Clinical features of neoplasia.

Unit – 6: Hemodynamic disorders, thrombosis and shock. (3 hours)

Edema, hyperemia and congestion., Hemorrhage. Hemostasis and thrombosis. Embolism, infarction, shock. Congestive heart failure. Ischemic heart disease. Hypertensive heart disease and Shock.

Unit-7: Etiology, Pathophysiological features and symptoms of the following diseases. (27 hours)

Asthma, Chronic obstructive pulmonary diseases, Peptic ulcer. Chronic glomerulonephritis. Diarrheal diseases. Jaundice and cholestasis. Diabetes mellitus. Graves's disease. Diffuse nontoxic goiter and multinodular goiter. Osteomyelitis. Rheumatic and infectious arthritis. Myasthenia gravis. Epilepsy, Degenerative disorders (Alzheimer's disease, Parkinsonism disease), sexually transmitted diseases, tuberculosis, and anemias.

Books & Other Resources Recommended

1. Sue E. Huether and Kathryn L. McCance. Understanding Pathophysiology. Mosby. Latest Edition
2. Clayton, F. Parkinson. Study Guide and Workbook for Understanding Pathophysiology. Mosby. Latest Edition
3. Corwin E. Handbook of Pathophysiology 2nd edition, Lippincott, 2000 or most recent edition
4. Hogan, M & Hill, K Pathophysiology, Review & Rationales 2004 Prentice Hall publishing.
5. Muralitharan Nair and Ian Peate (2009) Fundamentals of Applied Pathophysiology: An Essential Guide for Nursing Students.
6. Kathryn L. McCance and Sue E. Huether (2009) - Pathophysiology: The Biologic Basis for Disease in Adults and Children.
7. Carol Mattson Porth and Glenn Matfin - Essentials of Pathophysiology: Concepts of Altered Health States (International Edition 2010).
8. Barbara E. Gould and Ruthanna Dyer (2010) - Pathophysiology for the Health Professions.
9. Robert A. Weinberg - The Biology of Cancer. Taylor & Francis -2006.

SIXTH SEMESTER

PHAR 321 Medicinal Chemistry II (60 hours)

Study of the following classes of compounds including their chemical classification, structure and nomenclature, physicochemical properties, mechanism of action, structure activity relationship (SAR), outline synthesis (of compounds with star)

Unit – 1: Drugs Acting on CNS (25 hours)

1.1. General anesthetics (3 hrs)

Classification of General anesthetics, Inhalation anesthetics: Ideal properties of volatile anesthetics, Nitrous oxide*, Halothane*, and Sevoflurane. Current intravenous anesthetic agents (non- opioid) Advantage, disadvantage and properties of Thiopental sodium*, Thiamylal, Propofol, Ketamine and Midazolam. Pre-anesthetic medication and Current intravenous reversal agents.

1.2. Local anesthetics: (3 hrs)

Procaine, Lignocaine* and Bupivacaine. Local anesthetics for eye surgery, eutectic mixture and its use, addition of vasoconstrictors in local anesthetic.

1.3. Sedative, Anxiolytics and Hypnotics: (4 hrs)

Barbiturates: Alprazolam, Diazepam*, Nitrazepam and Lorazepam. Barbiturates versus Benzodiazepines as hypnotic and sedatives. Miscellaneous: Paraldehyde* Glutethimide, Chloral Hydrate*, Zolpidem and Zaleplon.

1.4. Neuroleptics (Antipsychotics): (2 hrs)

Haloperidol*, Chlorpromazine*, Olanzapine, Quetiapine and Aripiprazole.

1.5. Anticonvulsants: (2 hrs)

Phenobarbitone, Carbamazepine*, Phenytoin, Clonazepam.

1.6. Antidepressants: (2 hrs)

MAO inhibitors, Tricyclic Antidepressants and Selective Serotonin Reuptake *Inhibitors*. Nortryptiline, Amoxepine, Fluoxetine, Citalopram, Sertraline, Amitryptiline, Imipramine, Doxepin, Bupropion, Lithium Carbonate.

1.7. Opioid Analgesics: (3 hrs)

Morphine, Codeine, Diacetyl morphine, Buprenorphine, Meperidine, Fentanyl, Pentazocine, Tramadol (structure and properties) and narcotic antagonists: Naloxone. Antitussive agents: Noscapine, Dextromethorphan, Terpin Hydrate.

1.8. Antiparkinsonics: (3 hrs)

Levodopa, Carbidopa and Amantidine only), Anticholinergics: Benhexol* (Trihexphenidyl), Catechol-O-methyl transferase inhibitors – Entacapone.

Cholinesterase inhibitors – Rivastigmine. Dopa decarboxylase inhibitors – Carbidopa. Dopamine precursor – Levodopa*, Dopamine agonist – Amantadine

1.9. CNS stimulants: (2 hrs)

Xanthine Derivatives: caffeine* theophylline, aminophylline and etofylline., Analeptics: Nikethamide, Doxapram and Bemegride. Miscellaneous Central Nervous System Stimulants. Mazindol

Unit-2: Antimicrobials (36 Hours)

2.1. Penicillin (4 hours)

β -Lactam antibiotics: Classification, Structure and nomenclature of penicillin's, MOA, classification and sources, General preparation of semi synthetic penicillin, SAR, Penicillin G* and its properties, Acid resistance (Penicillin v and ampicillin) β -Lactamase resistance (oxacillin, cloxacillin and flucloxacillin), Broad spectrum(ampicillin, amoxicillin* and carbenicillin). Combination with Prodrugs (pivampicillin) β -Lactamase inhibitors (sulbactam, clavulanic acid and imipenem) and MOA, Latent penicillin (penicillin G procaine and benzathine penicillin).

2.2: Cephalosporin & carbamapenams (3 Hours)

Cephalosporin structure and nomenclature, Cephalosporin C. 1st Generation (cephalexin and cephadroxil), 2nd Generation (cefaclor), 3rd Generation (Cepodoxime, cefotaxime and cefixime), 4th Generation (cefepime), Cephamycin (cefoxitin).

Carbamapenams: Imipenam & Meropenam

2.3. Tetracycline and Chloramphenicol (2 Hours)

Tétracycline, Demeclocycline, Oxytetracycline, Doxycycline, Minocycline. Structure, property and SAR of the Tetracycline. Structure, property, synthesis and SAR Chloramphenicol.

2.4. Aminoglycosides, macrolides & lincomycins (2 Hours)

Aminoglycosides: Members, Mode of Action and uses of Aminoglycoside. SAR of Streptomycin.

Macrolides- Members, Structure, Mode of action and uses.

Lincomycins: Lincomycin.

2.5. Quinolones: (3 Hours)

Classification, Structure, SAR and MOA of Fluoroquinolones. Structure and uses of Nalidixic acid, Norfloxacin, Ciprofloxacin* and Ofloxacin*

2.6. Antituberculars and Antileprotics: (4 Hours)

Tuberculosis and classification of anti T.B. drugs, INH* and its SAR, Ethambutol* and its SAR, Rifampin. Ethionamide, Pyrezinamide* aminosacylic acid, cycloserine and other 2nd line antitubercular drugs; Dapsone* and Clofazimine

2.7. Chemotherapy of Malaria (3hours)

Classification of antimalarial drugs in relation to plasmodium life cycle, properties and SAR of chloroquine, Mefloquine, Primaquine and Quinacrine. Artemisinin and derivatives.

2.8. Antifungal agents: (2 Hours)

Miconazole, Ketoconazole, Amphotericin B, Nystatin, Griseofulvin.

2.9. Antiprotozoal agents: (2 Hours)

Metronidazole, Tinidazole, Secnidazole. Diloxanide furoate,

2.10. Anthelmintics: (2 Hours)

Classification, Piperazine, Diethyl carbamazine, Pyrantel pamoate, Mebendazole, Niclosamide, Praziquantel, Albendazole*

2.11: Antiviral agents: (3 Hours)

Amantidine hydrochloride, Idoxuridine, Acyclovir, Lamivudine, Zidovudine and other Anti-HIV drugs.

2.13. Antineoplastic agents (6 Hours)

Alkylating agents: cyclophosphamide, chlorambucil, busulphan, uracil, mustard; Antimetabolites: mercaptopurine, flurouracil, methotrexate, azothioprine; Antibiotics: Doxorubicin, Mitomycin; Tubulin Inhibitors: Etoposide, Vincristine, Vinblastine, Taxol and Docitaxel. Miscellaneous: Cisplatin. Hormones: Mitotane, Tamoxifen. Immunotherapy: Interferon.

PHAR 321 Lab Medicinal Chemistry II Practical (Minimum 8 experiments)

Synthesis & pharmacopoeial analysis of some medicinal compounds:

- Benzyl from benjoin
- Benzanilide from aniline
- Salicylic acid from methyl salicylate
- Methyl salicylate from Salicylic acid
- Phenyton from Benzoin or Benzil
- Paracetamol from para- nitro phenol or para- aminophenol
- 1,4- di hydro pyridine from ethyl aceto acetate
- Quinazolinone from anthranilic acid via benzoxazinone
- Sulfanilamide from acetanilide
- Isoniazid from γ -picoline
- Benzocaine from para- nitro benzoic acid
- Methyl orange and methyl red
- Benzoic acid from toluene
- Acetophenone from Benzene

Books and other resources Recommended

1. Block JH, Beale JM, editor. Wilson and gisvold's textbook of organic medicinal and pharmaceutical chemistry. 11th ed. Baltimore: Lippincott Williams & Wilkins; 2004.
2. Lemke TL, Williams DA, editor. Foye's principles of medicinal chemistry. 6th ed. New Delhi: Wolters Kluwer and Lippincott Williams & Wilkins; 2008.
3. Kadam Dr. SS et al. – Principles of Medicinal Chemistry Vol. I and II. Nirali Prakashan, India.
4. Abraham DJ, editor. Burger's Medicinal Chemistry and Drug Discovery, 6th ed. Vol 1-6. New Jersey: John Wiley & Sons; 2007.
5. Hansch C, editor. Hansch's comprehensive medicinal chemistry, Delhi: Rajkamal Electronic Press; 2005.
6. Ariens EJ, editor. Drug design vol. I-X. Noida: Academic Press; 2009.
7. Roth HJ, Kleemann A. Pharmaceutical Chemistry. Vol-I. Drug synthesis. New
8. . Lednicer D, Mitscher LA, The organic chemistry of drug synthesis, Volume-1-6. New York: A wiley-interscience publication; 2005.
9. Remington: The science and practice of pharmacy. 21st ed., vol. I & II, Lippincott Willams & Wilkings, New Delhi, 2005.
10. Smith & Williams. Introduction to principles of drug design-Harwood academic press.

PHAR 322 Pharmaceutical Technology II

(45 hours)

Unit -1 – Capsules (6 hours)

Advantages and disadvantages of capsule dosage form, material for production of hard gelatin capsules, Manufacture of hard gelatin capsule, size of capsules, method of capsule filling (manual & semiautomatic), basic formulation(excipients), soft gelatin, Advantages and disadvantages of soft gel, capsule shell formulation and capsule content: Bloom strength, Viscosity & iron content, base absorption and minim per gm, Manufacturing of soft gels: Plate process & Rotary die process, factors in soft capsules, quality control, stability testing and storage of capsule dosage forms.

Unit 2 – Microencapsulation (6 hours)

Advantages and disadvantages, Pharmaceutical Application, Fundamental consideration: Nature of core & coating materials, Stability & release characteristic of coated materials, Microencapsulation method; Examples illustrating improved stabilization: Stabilization of Vitamin A Palmitate Oil; Stabilization of incompatible aspirin mixture; Microencapsulation Techniques: Pan Coating, Air suspension, Microorifice-Centrifugal Process, Solvent evaporation, Spray drying and spray congealing, Coacervation Phase separation; General mechanism of drug release from microencapsulated product Polymerization.

Unit -3 – Tablets (15 hours)

General Concept, Advantages & disadvantages, Types of Tablets, Formulation of Tablets: Excipients: Diluents with common examples, Binders with common examples , Disintegrants with common examples: mechanism of tablet disintegration, Factors affecting disintegration, superdisintegrants, Antifrictional Agents with common examples, Miscellaneous Excipients, **Operations involved in tablet manufacturing:** Dispensing, sieving, blending, granulation, drying, Lubrication, compression, coating, **Tablets Manufacturing methods:** Wet Granulation : Objective of granulation, Mechanism of wet granulation (Pendular State, Funicular State, Capillary State, Droplet or Suspension State), Dry Granulation (slugging & roll compaction), Direct compression : ideal DC excipients requirements,

Compression Machines or tablet press: List of Components or parts of tablet compression machines, General information of parts & MOC of punches & dies, Brief knowledge of Standard tooling of compression machines (D, DB, B, BB toolings), General Tablet press cycle (Filling zone, compression zone, Ejection Zone), general concept of Single station & multistation rotary compression machine, knowledge of shape & dimension of tablets & punches (concavity, breakline, embossing), Tablet processing problems & remedies: capping, lamination, cracking, chipping, sticking, picking, binding, mottling, double impression;

Tablet Coating: Objectives, components of coating, Tablet properties, Coating Process: Coating

Distribution: spray application system High pressure airless system, Low pressure air atomized system, Coating equipments, Parameters of coating process, Facility and ancillary equipments; Types of tablet coating: Sugar coating ; Film Coating : process variables, Pan variables. Process air variables, Spray variables, General Coating suspension Composition; Enteric coating : objectives, common enteric polymers;, Film defects: causes & remedies; Quality Control test for coated tablets (General Appearance, Size & shape, Organoleptic Properties, Assay, Content Uniformity test, Mechanical strength, Friability, Hardness or crushing strength, Disintegration, Dissolution).

Unit -4 - Parenteral Products (8 hours)

Preformulation factors, routes of administration, water for injection, pyrogenicity, non-aqueous vehicles, isotonicity and methods of its adjustment. Formulation details, containers and closures and selection. Prefilling treatment, washing of containers and closures, preparation of solution and suspensions, filling and closing of ampoules, vials, infusion fluids, lyophilization & preparation of sterile powders, equipment for large scale manufacture and evaluation of parenteral products. Aseptic Techniques:- source of contamination and methods of prevention, design of aseptic area, laminar flow bench services and maintenance. Sterility testing of Pharmaceuticals.

Unit-5: Pharmaceutical Packaging: (10 hours)

Classification of Packaging; **Glass containers:** props, advantages & disadvantage, composition & manufacturing of glass, Types of glass, **Plastic Containers:** properties, advantages & disadvantages, list of plastic polymers, Drug Plastic interaction (Permeation, Leaching, Sorption, Chemical reaction, Modification of the materials properties), Environmental issues, resin identification codes; **Collapsible Tubes:** Metal, Foils (PVC, PVdC, Aluminum); **Closures:** Threaded screw cap, Crown cap, Pilfer proof closure, Lug cap, Roll On Closure (ROPP); **Liners:** Closure Liner, Homogenous liner, Heterogeneous liner, Torque testing of caps, Rubber stoppers, **Tamper resistant packaging:** Blister package, Strip package, Alu-Alu pack, bubble pack, shrink pack, Foil, paper or plastic pouch, Bottle seals, Breakable caps, Sealed tubes (Collapsible Tubes), Sealed Box (Printed carton duplex), Induction seal.

Brief concept of **Packaging equipments** (Blister packing machines, Strip packing machine, Alu-ALU packing machine, Shrink Packing machine, Induction Sealing Machine, Strapping Machine)

PHAR 322 Lab Pharmaceutical Technology II Practical

1. Experiments to illustrate preparation, stabilization, physical and biological evaluation of pharmaceutical products like powders, capsules, tablets, parenterals, micro-capsules (Sterile water for injection, Calcium gluconate injection, Sodium chloride injection, Formulation, isotonicity, packaging and quality control of the following LVPs as per British pharmacopoeia. Also explain industrial scale manufacturing processes, Contact lens solution, Sodium chloride and Dextrose infusion
2. Micro encapsulation (using one solid and one liquid drug) by coacervation and polymer incompatibility, evaluation of microcapsules.
3. Evaluation of materials used in pharmaceutical packaging.

Books and Other Resources recommended

1. Lachman, L. Lieberman, H.A. Kanig, J.L. The Theory & Practice of industrial Pharmacy. Lea & Febiger, Philadelphia.
2. Turco, S & King, R.E. Sterile Dosage Forms. Lea & Febiger, Philadelphia
3. Remington's the science and practice of Pharmacy Mack Publishing Co. Easton, PA.
4. Lieberman, H.A. Lachman, L. Sachwartz, J.B. Pharmaceutical Dosage Forms: Tablets Vols 1-3 Marcel Dekker, N.Y.
5. Lieberman, H.A. Rieger, M.M. & Banker, G.S. Pharmaceutical Dosage Forms: Disperse Systems. Vol 1-2 Marcel Dekker, N.Y.
6. Ridgway, K. Hard Capsules The Pharmaceutical Press, London.

7. Ansel, H.C. Introduction to Pharmaceutical Dosage Forms KM Verghese.
8. J. Swarbrick, J. Boylan; Encyclopedia of Pharmaceutical technology, 2nd ed, Marcel Dekker,2002.
9. Aulton, M.E. Pharmaceutics- The Science of Dosage form Design ELBS.
10. Avis, K.E. Lachman, L. & Lieberman, H.A. "Pharmaceutical Dosage Forms: Parenteral Medications" Vols. I & II Marcel Decker.
11. I. R. Berry; R.A. Nash; Pharmaceutical Process Validation; 2nd ed, Marcel Dekker, 1993.

PHAR 323 Pharmacology –III

(45 hrs)

Unit-1: Drugs Acting on GIT

(5 hours)

- 1.1 Anti-ulcer drugs (Classification, MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions-
- 1.2 H1 receptor Antagonists, Proton Pump Inhibitors, Ulcer healers, Antacids and treatment of H pylori ulcer).
- 1.3 Laxative (Classification, MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions),
- 1.4 Emetics and anti-emetics (Ipecac syrup, Apomorphine, prokinetics, Promethazine, Ondansetron, Ginger, Peppermint and Ajwain.).
- 1.5 Antispasmodics (Dicyclomine, Drotaverine, and Hyoscine Butylbromide)
- 1.6 Antidiarrhoeal drugs (ORS, causal treatment, Role of Zinc in diarrhea, Loperamide, treatment of traveler's diarrhea).
- 1.7 Appetite Stimulants and Suppressants.
- 1.8 Digestive Enzymes.

Unit-2: Pharmacology of Endocrine System

(4 hours)

- a. Hypothalamic and pituitary hormones, Thyroid hormones and anti thyroid drugs, parathormone, calcitonin and Vitamin D.
- b. Insulin, oral hypoglycaemic agents & glucagon.
- c. ACTH and corticosteroids.
- d. Androgens and anabolic steroids. Estrogens, progesterone and oral contraceptives.
- e. Drugs acting on the uterus.

Unit-3: Antimicrobials

(25 hours)

- 3.1 Selection and use of Antibacterial agents (Empirical therapy and definitive Therapy)
- 3.2 Rational of combination of antimicrobials (Antibacterial, antiviral, antiprotozoal).
- 3.3 Resistance of antimicrobials in example of β -lactamase and Mycobacterium).
- 3.4 **Sulfonamides** - Classification, MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of (Sulfacetamide, Silver sulfadiazine, sulfadimethoxin and Cotrimoxazole).
- 3.5 **Penicillin** - Classification, MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of (Benzyl penicillin, Procaine penicillin, Benzathine penicillin, Ampicillin + Cloxacillin, Ampicillin, Amoxicillin, Flucloxacillin, Methicillin, Azocillin).
- 3.6 **Beta-lactamase inhibitors:** Clavulanic acid, Sulbactam, Tazobactam.
- 3.7 **Cephalosporin** - Classification, MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of (Cephalexin, Cefadroxil, Cefaclor, Ceftriaxone, Cefotaxime, Cefixime, Cepodoxime, Cefepime, Cefpirome, cephalosporin combination with β -lactamase inhibitors).
- 3.8 **Monobactams :** (Aztreonam)
- 3.9 **Carbapenems :** (Imipenem, Meropenem, Faropenem)
- 3.10 **Tetracycline** - Classification, MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of (Tetracycline HCl, Doxycycline, Demeclocycline, Minocycline).
- 3.11 **Chloramphenicol-** MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions.
- 3.12 **Macrolides-** MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of (Erythromycin, Azithromycin, Roxithromycin and Clarithromycin).

- 3.12.1 **Aminoglycosides**- MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of (Streptomycin, Gentamicin, Kanamycin, Tobramycin, Amikacin, Netilmicin and Neomicin)
- 3.12.2 **Antitubercular and Antileprotics**- Classification, MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of (INH, Rifampicin, Pyrizenamide, Ethambutol, PAS, Cycloserine). WHO regimen for pulmonary and extrapulmonary tuberculosis, DOTS. Dapsone and Clofazemine.
- 3.12.3 Classification, MOA of **Fluoroquinolones**. Structure and uses of Nalidixic acid, Norfloxacin, Ciprofloxacin Levofloxacin, Ofloxacin, Gatifloxacin and other member.
- 3.13 **Miscellaneous Antibiotics drugs**: Vancomycin, Clindamycin, Colistin Sulphate.
- 3.13.1 **Anthelmintics**: Classification, Piperazine, Diethyl carbamazine, Pyrantel pamoate, Mebendazole, Niclosamide, Praziquantel, Albendazole.
- 3.14 **Antiamoebic**: Metronidazole, Tinidazole, Secnidazole, Diloxanide furoate.
- 3.14.1 **Antifungal**: Classification, MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of (Nystatin, Natamycin, Amphotericin B, Miconazole, Ketoconazole, Clotrimazole, Fluconazole, Flucytosine, Griseofulvin. Topical Antifungal (Terbinafine, Caspofungin, Benzoic Acid, Ciclopirox, Tolnaftate).
- 3.14.2 **Antiviral**: Classification, MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of (Acyclovir, Amantadine). Zidovudine and other anti HIV drugs.

Unit-4: Antineoplastic agents (4 hours)

Classification, MOA, Indication, Dosage, ADRs, Contraindication and Drug interactions of:

- 4.1 Alkylating agents**: (cyclophosphamide, chlorambucil, busulphan, uracil mustard).
- 4.2 Antimetabolites**: (mercaptapurine, flurouracil, methotrexate, azothioprine).
- 4.3 Antibiotics**: (Doxorubicin, Mitomycin).
- 4.4 Plant products** : (Vincristine, Vinblastine, Taxol). Cisplatin, Mitotane, Tamoxifen, Interferon alpha.

Unit-5: Immunosuppressant and Immunostimulants (3 hours)

- a. Glucocorticoids, calcineurin inhibitors (cyclosporine and tacrolimus).
- b. Antiproliferative and Antimetabolic Drugs (Sirolimus, Azathioprine), *Mycophenolate mofetil*, other cytotoxic and antimetabolic agents. Anti-CD3 Monoclonal Antibodies.
- c. Interferons, Interleukin-2, Levamisole. Thalidomide. Bacillus Calmette-Guerin (BCG).

Unit-6. Principles of Toxicology (4 hours)

- a. Definition of poison, general principles of management of poisoning with particular reference to barbiturates, opioids, organophosphates, Heavy metals and heavy metal antagonists.

PHAR 323 Lab Pharmacology –III Practical

1. Stages of chloroform and ether anesthesia with and without premedication.
2. Study of phenobarbitone induced hypnosis (Demonstration).
3. Determination of analgesic activity (codeine/aspirin).
4. Study of anticonvulsant activity.
5. Study of local anesthetic activity.
 - i) Surface anesthesia activity on rabbits.
 - ii) Infiltration anesthesia using guinea pigs.

6. Identification of unknown drugs using rat ileum.
7. Seminars on the drugs studied in theory.

For Practical

1. Pharmacological experiments on isolated preparations by Edinburgh University Pharmacology Staff, 1968.
2. Robert A. Turner and Peter Hebbom: Screening methods in Pharmacology, Vol.1 edited
3. S.K.Kulkarni: Handbook of experimental Pharmacology
4. M.N.Ghosh: Fundamentals of experimental pharmacology
5. Ian Kitchen: Text book of invitro Pharmacology
6. U.K.Sheth, N.K.Dadkar, Usha G.Kamat: Selected topics in Experimental Pharmacology
7. K. K. Pillai: Experimental Pharmacology, CBS, Delhi.

Books and Other Resources Recommended

1. C.R.Craig and R.E.Stitzel: Modern Pharmacology
2. Theodore W.Rall, Alan S.Nies and Palmer Taylor: Goodman Gilman's : The Pharmacological Basis of Therapeutics by Alfred Goodman Gilman.
3. D.R.Laurence and P.N.Bennett: Clinical Pharmacology.
4. K.D.Tripathi: Essentials of Medical Pharmacology.
5. R.S.Satoskar and S.D.Bhandarkar: Pharmacology and Pharmacotherapeutics.
6. F.S.K. Barar: Essentials of Pharmacotherapeutics.
7. H.P.Rang and M.M.Dale: Pharmacology.
8. James Crossland: Lewis's Pharmacology, revised.
9. Pharmacology by Lippincott.

PHAR 324 Biopharmaceutics & Pharmacokinetics (45 hours)

Unit-1: Concept, definition and Introduction: (3 hours)

Biopharmaceutics and Pharmacokinetics and their role in formulation development and clinical setting. Pharmacokinetics Pharmacodynamics and clinical Pharmacokinetics with respect to design of dosage regimens. Plasma drug concentration Profile.

Unit-2: Review of Pharmacokinetics: (10 hours)

Absorption of Drug (Physicochemical. Physiological. Pharmaceutical. pH partition hypothesis, Pharmacokinetics of drug absorption-Zero order and first order absorption rate constant using Wagner – Nelson and Loo-Reigelman method).**Drug distribution**(Protein binding (intravascular and extravascular). Significance of drug-protein binding and drug displacement interactions. Kinetics of protein binding).**Drug metabolism.** (Study of factors affecting metabolism. Bioactivation and first pass effect).**Excretion:** (Introduction, types of drug excretion, Clearance concept, Mechanism of renal clearance, clearance ratio, determination of renal clearance. Extraction ratio, hepatic clearance, biliary excretion, Extrahepatic circulation).

Unit-3: Bioavailability and Bioequivalence (8 hours)

Definition and concept of absolute & relative bioavailability. Methods of assessing bioavailability. Measures of bioavailability (C_{max}, t_{max}. AUC etc.) Bioequivalence study and introduction to various study designs. Single dose bioequivalence study and relevant statistics, Review of regulatory requirements for conducting bioequivalence study in Nepal and international perspective. Methods for enhancement of bioavailability. Clinical significance of bioavailability and bioequivalence.

Unit-4: Dissolution studies. (5 hours)

Introduction to Biopharmaceutical classification system, Mechanism of dissolution, In-vitro studies, and all latest models: Zero order, Matrix, First order, Higuchi. In-vitro in-vivo correlation: Definition, objectives & methods. Introduction to pharmacokinetic models. Physiologic versus compartment approach.

Unit-5: Compartment models (4 hours)

Concepts and their importance in the study of pharmacokinetics. One compartment open model. Assessment of pharmacokinetic parameters from plasma and urine data after i. v. bolus, i.v. infusion, i. v. injection with loading dose and oral administration. Percent absorbed time plot and determination of absorption rates based on one compartment model. Introduction to ‘Two compartment model.’

Unit-6: Non-Linear Pharmacokinetics (4 hours)

Causes of nonlinearity, Detection of non-linearity (saturation mechanism).Michaelis Menten equation. Definition of V_{max} and K_m. Determination of V_{max} and K_m. Significance of Non-Linear Pharmacokinetics: Case studies.

Unit-7: Clinical Pharmacokinetics (4 hours)

Definition and scope, Therapeutic drug monitoring. Case study of Digoxin and theophylline. Individualization of Dosage. Dose adjustment in patients with and without renal and hepatic failure. Design of single dose bio-equivalence study and relevant statistics. Pharmacokinetic drug interactions and their significance in combination therapy.

Unit-8: Numerical (7 hours)

Based on AUC, Elimination half life ($t_{1/2}$), Volume of distribution (V_d), Clearance (Cl), elimination rate constant (k_e) and amount of drug (X). Dose adjustment in Renal Failure.

PHAR 324 Lab Biopharmaceutics & Pharmacokinetics Practical

Experiments designed for the estimation of various pharmacokinetic parameters with given data.

In *vitro* evaluation of different dosage forms for drug release.

Absorption studies – in *vitro*.

Statistical treatment of pharmaceutical data.

Suggested Practical

1. In-vitro drug release study of the given powder dosage form using various dissolution media.
2. In-vitro drug release study of the given uncoated tablet dosage form using different dissolution media.
3. In-vitro drug release study of the given capsule dosage form using various dissolution media.
4. In-vitro drug release study of the given film coated dosage form using various dissolution media.
5. In-vitro dissolution study of the given sustained release dosage form.
6. In-vitro dissolution study of the given fast release (M.D, Dispersible etc.) dosage form.
7. To study the effect of hardness of tablet on dissolution rate.
8. To study the effect of various diluents on dissolution rate of dosage form (Tablets, Capsules, Ointment etc.).
9. To study the effect of formulation on drug release (powder, suspension etc.).
10. To determine the % protein binding of the given drugs.
11. To determine the effect of protein binding on drug bioavailability.
12. To calculate various Pharmacokinetic parameters from the given zero order drug release data.
13. To calculate various Pharmacokinetic parameters from the given first order drug release data.
14. To calculate the various Pharmacokinetic parameters from the given blood data of I.V bolus injection(one compartment model).
15. To calculate various Pharmacokinetic parameters from the given urinary excretion data of I.V bolus.injection using both methods (Rate of elimination & sigma minus method one compartment model).
16. To study the in- vitro drug- drug interaction.
17. To study the passive diffusion of the given drug using cellophane membrane.
18. To study the passive diffusion of the given drug using egg or goat membrane.
19. To determine the various Pharmacokinetic parameters from the given blood data of oral administration of dosage form.
20. DEMONSTRATION EXPERIMENTS
 - a) Dissolution Apparatus.
 - b) Preparation of Buffers & membranes.

- c) Use of semilog paper.
- d) Operation of colorimeter & U.V spectrophotometer.

Books and Other Resources Recommended

1. Brahmkar and Jaiswal; Biopharmaceutics and Pharmacokinetics: A treatise; 2nd Edition; CBS Publication; 2009
2. Leon Shargel and Andrew B. C. Yu: Applied Biopharmaceutics and Pharmacokinetics 5th Edition; McGraw Hill; 2005.
3. Rowland and Tozer Text book of Clinical Pharmacokinetics 2nd edition, Lippincott Williams & Wilkins; 1995
4. Robert E. Notari, Biopharmaceutics and Clinical Pharmacokinetics: An Introduction Fourth Edition, Revised and Expanded. Marcel Dekker, New York. 2005
5. Remington: The Science and Practice of Pharmacy, 21st Edition. Philadelphia, PA: Lippincott Williams & Wilkins, 2005
6. J Swarbrick, Current Concepts in the Pharmaceutical Sciences: Biopharmaceutics, Lea & Febiger, Philadelphia (1970)
7. Javed Ali, Roop.K.Khar and Alka Ahuja: Textbook of Biopharmaceutics and Pharmacokinetics: 1st edition; Birla Publication, 2001-2002
8. Robinson, J.R.Lee, V.H.L. Controlled Drug Delivery: Fundamentals and Applications 2nd edition, Marcel Dekker, New York, 1987
9. H.F.Lodish and J.E.Rothman "The assembly of cell membranes Sci. Am. 240: 48-63, 1979
10. R.I.Oberle, G.L.Amidon; J. Pharmacokinetics and Biopharmaceutics, 15:529-544, 1987
11. A.Rubinstein, V.H.K.Li and J.R. Robinson In oral sustained release formulation, Design and Evaluation, New York, Pergamon, 1988 cap. 6
12. Notari, R.E, Biopharmaceutics and Pharmacokinetics – An introduction Marcel Dekker Inc. N.Y.
13. Wagner J.G. Fundamentals of Clinical Pharmacokinetics, Drugs Intelligence Publishers, Hamilton.
14. Wagner J.G. Pharmacokinetics for the Pharmaceutical Scientist, Technomic Publishing A.G. Basel, Switzerland.

PHAR 325 Biostatistics (45 hours)

Unit-1: Basic concepts of Statistics (10 hours)

Data, Data Graphic, frequency distribution measures of central tendency (Mean, Median, Mode, Harmonic mean, Geometric mean and scattering of data, range, Mean, Deviation, Standard deviation, SEM Applications in Pharmaceutical Validation)

Unit-2: Introduction to probabilities (10 hours)

Binomial and Normal Probabilities distribution.

Unit-3: Sample and sampling method (5 hours)

Sample size and its significance. Sampling techniques and their application in pharmacy.

Unit-4: Hypothesis testing (5 hours)

[T-statistics (Application in dissolution testing of solid dosage forms) chi-square test]

Unit-5: Correlation and Regression (10 hours)

Correlation analysis, Correlation coefficient, Spearman's rank correlation coefficient. Linear regression analysis (applications in Beer's Lambert's Curve, stability study), Introduction to curve fitting techniques. Analysis of variance: Introduction and application of the test in the pharmacokinetic study.

Unit-6: Introduction to Software (5 hours)

SPSS and EPI info.

Books and Other Resources recommended

1. Health Research Methodology- A guide for Training in Research methods. WHO.
2. Green, J. 2004. Qualitative methods for health research. 2nd ed. London: Sage.
3. Methodology and Techniques of Social Research by Bhandarkar and Wilkinson. Himalyan Publishing House
4. Research methodology- Methods and Techniques By CR Kothari- Wiley Eastren limited.
5. Polagar, S. 1995. Introduction to research in the health sciences. 3rd ed. Edinburgh: Churchill Livingstone.
6. A guide for Research proposal writing, National science Foundation.
7. Mike Saks and Judith Allsop. Researching Health Qualitative, Quantitative and Mixed Methods. Sage. ISBN: 978-1-4129-0364-6. Required.
8. Dr Katherine Jones and Katherine Hooper. Researching Health Companion. Sage.
9. S. Polgar and S.A. Thomas Introduction to Research in the Health Sciences, 5th edition. Churchill Livingstone Elsevier, New York (2008).

10. Denise F Polit and Cheryl Tatano beck- Nursing Research- Principles and Methods.7th edition.
11. Albert P.S., and Borkowf, C.B., 2002. “An introduction to biostatistics: randomization, hypothesis testing and sample size,” in John I. Gallin (ed.), *Principles and practice of clinical research*, San Diego: Academic Press,
12. Brody, B.A., 1998. *The Ethics of Biomedical Research: An International Perspective*, Oxford: Oxford University Press.
13. Council for International Organizations of Medical Sciences, 2002. *International ethical guidelines for biomedical research involving human subjects*. Geneva: CIOMS.
14. Brett A, Grodin M (1991). Ethical aspects of human experimentation in health services research. *JAMA* 265:1854-57.

PHAR 326 Engineering Drawing

1. Isometric and orthographic projections
2. Basic Engineering Drawing Practice - Bolts, nuts, rivetted fronts, screws, worn screws as per specification.
3. Drawing of simple pharmaceutical machinery parts.
4. Layout designing of pharmaceutical production units, retail shops and wholesale

SEVENTH SEMESTER

PHAR 411 Dosage Form Design

[45 hours]

Unit- 1. Preformulation studies: (13 hours)

- a) Introduction, goals of preformulation, Study of physical properties of drug and their effect on formulation, stability and bioavailability.
 - **Bulk characterization:**-Crystallinity and polymorphism, hygroscopicity, Fine particle characterization, Bulk density and study of powder flow properties (Carr's index, Hausner index, Angle of Repose).
 - **Solubility Analysis:** Ionization constant $-pK_a$; pH solubility profile and common ion effect $-K_{sp}$; effect of temperature; Solubilisation; Partition Coefficient and dissolution.
 - **Stability Analysis:** Stability in toxicology formulation; Solution stability; PH rate profile ; solid state stability; bulk stability ; compatibility studies with excipient.
- b) Study of chemical properties of drugs like hydrolysis, oxidation, reduction, racemization, polymerization etc., and their influence on formulation and stability of products.
- c) Study of pro-drugs in solving problems related to stability, bioavailability and elegance of formulations.
 - Rationale for prodrug formation, potential prodrug candidates, Design and bioactivation, classification of prodrug (carrier linked prodrug, metabolic prodrug), pharmaceutical application of prodrug (Improvement of taste, odour, reduction of GI irritation, reduction of pain at site of injection, enhancement of solubility and dissolution of drug, chemical stability, prolonged duration of action, site specific drug delivery)

Unit 2: Design, development and process validation methods for pharmaceutical operations involved in the production of pharmaceutical products with special reference to tablets, suspensions. (5 hours)

- Introduction to validation, importance of validation, process validation, types of process validation (Prospective, Concurrent, Retrospective and Revalidation), validation team responsibility, elements of validation (DQ, IQ, OQ and PQ)
- Process validation: Process validation activities (process design, process qualification and verification), change control, phases of process validation (Pre-Validation Phase or the Qualification Phase, Process Validation Phase, Process Qualification phase and Validation Maintenance Phase); Required Validation Documents: validation master plan (VMP), Validation protocol (VP), Validation report (VR) and Standard Operating procedure (SOP).
- Process validation method of solid dosage form (Tablet): Process overview of tablet manufacturing process, validation of process parameters in tablet manufacturing (Focus on process critical parameters of process stages of dry

- mixing, granulation, wet milling, drying, dry milling, lubrication, compression, coating and packing)
- Process validation method of suspension dosage form: Process overview; validation of process parameters of suspension manufacturing (mixing, size reduction, filling)

Unit-3. Stabilization and stability testing protocol for various pharmaceutical products (6 hours)

- Brief introduction of rate kinetics and methods of determination of shelf
- Protection against hydrolysis, oxidation and photochemical degradation.
- Stability testing: Accelerated analysis for chemical stability and limitation (Arrhenius plot)
- Stability testing protocol: ICH guidelines for storage conditions, concept of climatic zone as per ICH, stress testing, accelerated and long term stability testing and on-going testing (focus on drug substance and drug product).
- DDA guidelines for stability testing 2007

Unit 4. Performance evaluation methods (6 hours)

- a) **In-vitro dissolution studies for solid dosage forms methods, interpretation of dissolution data:** Introduction, Noyes Whitney equation, factors affecting dissolution rate relating to the solid dosage form (effect of formulation factors and effect of processing factors), basic knowledge about dissolution apparatus (USP apparatus I and II).
- b) **Bioavailability studies and bioavailability testing protocol and procedures:** Bioavailability and bioequivalence, purpose of bioavailability studies, relative and absolute bioavailability, Methods of assessing bioavailability (Pharmacokinetic methods and pharmacodynamic methods).
- Pharmacokinetics methods: Plasma data (t_{max} , C_{max} , AUC), urine data
- pharmacodynamic methods: Acute pharmacological effect and clinical response.
- c) In-vivo methods of evaluation and statistical treatment:

Unit 5. GMP and quality assurance, Quality audit (5 hours)

- GMP – Introduction, Relationship among Quality Elements (Quality Assurance, Good Manufacturing Practices (GMP) for Drugs and Quality control). Short description of Premises, Personnel and equipments. GMP regulation in Nepal including “*Ausadi Utpadan Samhita*”.
- Quality Audit (Types: 3rd Party Audit, 2nd Party Audit, 1st Party Audits, Audit Categories: System Audit, Conformance Audit, Compliance Audit, Process Audit, Product Audit and Department Audit. Benefits of audit). Site Master File, GMP certification: Audit of Hardware, software and Practice.
- Quality Assurance: Concept, function and organizational Approach.

Unit 6. Design, development, production and evaluation of controlled released formulations (10 hours)

- Introduction to CR/SR preparations, concept of controlled release formulation, challenges of CR drug delivery system, advantages and disadvantages, Factors influencing the design and performance of CR products (**physiochemical properties**: molecular size and diffusivity, aqueous solubility, ionization constant, partition coefficient, stability, **pharmacokinetic and pharmacodynamic considerations**: release rate and dose, **Biological factors**: Absorption, distribution, metabolism and elimination half life, therapeutic index, duration of action.
- Kinetics of drug release from CRDS: Zero order, first order, Hixson-Crowell Release Model, Higuchi Release Model and Korsmeyer-Peppas Release Model
- Oral controlled release systems: Dissolution controlled release (Matrix and encapsulated dissolution), diffusion controlled release (Reservoir and matrix system), dissolution and diffusion controlled release, Osmotically controlled release, pH independent formulations, Ion exchange resins.
- Evaluation of CR formulations: Quality control methods(Identity, purity, strength, stability of the dosage form and drug in the dosage form, disintegration and dissolution, dosage form appearance, bioavailability of the drug from dosage form.

PHAR 411 Lab Dosage Form Design Practical

1. Preformulation studies including drug-excipient compatibility studies, effect of stabilizers, preservatives etc. in dosage form design.
2. Experiments demonstrating improvement in bioavailability through prodrug concept.
3. Stability evaluation of various dosage forms and their expiration dating.
4. Dissolution testing and data evaluation for oral solid dosage forms.
6. In-vivo bioavailability evaluation from plasma drug concentration and urinary excretion curves.
7. Design, development and evaluation of controlled release formulations.

Books and Other Resources Suggested

1. N.K. Jain , Controlled and Novel drug delivery., CBS Publishers and distributors. New Delhi.
2. Leon Lachman ,Theory and Practice of Industrial Pharmacy , Varghese publishing house, 3rd edition.
3. Remington's, The Sciences and practice of pharmacy- Volume I, II., Lippincott Williams and Wilkins London, 20th edition.
4. Hillery and loyed, Drug delivery and targeting., Tylor and francis London. 1st edition.
5. Yie W. Chien, Novel drug delivery systems., Mareel Dekker Inc.

6. Ansel, Howard, *Pharmaceutical Dosage Forms and Drug Delivery Systems*, Lippincott Williams and Wilkins London, 7th edition.
7. Hamed M. Abelson, *Dissolution, Bioavailability and Bioequivalence*, Mack Publishing Company, Pennsylvania.

PHAR 412 Pharmaceutical Management

[45 hours]

Unit-1: Concept of Management (12 hours)

Administrative Management (Planning, Organizing, Staffing Directing and Controlling). Entrepreneurship development, Operative Management (Personnel, Materials, Production, Financial, Marketing, Time/space, Margin/ Morale) Principles of Management (Coordination, Communication, Motivation, Decision making, leadership, Innovation Creativity, Delegation of Authority / Responsibility. Record Keeping), Identification of key points to give maximum thrust for development and perfection. Total Quality Management (TQM).

Unit-2: Pharmaceutical Marketing (6 hours)

Functions, buying, selling, transportation, storage financed. Feedback information, channels of distribution, wholesale, retail, department store, multiple shop and mail order business.

Unit-3: Salesmanship and Market Research (6 hours)

Principle of sales promotion, advertising, ethics of sales, merchandising, literature, detailing, Recruitment, training, evaluation, compensation to the pharmacist. Measuring & Forecasting Market Demand - Major concept in demand measurement, Estimating current demand Geo-demo- graphic analysis. Estimating industry sales, Market share and future demand. Market segmentation & Market targeting.

Unit-4: Introduction to Accountancy (5 hours)

Introduction, Accounting Process, Bank Reconciliation, Trail Balance, Profit & Loss Account, Depreciation, Inventory management & Accounting, Long Lived Assets and Long term liabilities.

Unit-5: Material Management (4 hours)

A brief description of basic principles of material management, major areas, scope, purchase, stores, inventory control and evaluation of materials management.

Unit-6: Production Management (6 hours)

A brief description of the different aspects of Production Management. Visible and Invisible inputs, Methodology of Activities Performance Evaluation Technique Process, Flow, Process Know-how, Maintenance Management.

Unit-7: Introduction to Microeconomics (6 hours)

Introduction, Supply/Demand and Elasticity, types of market (Monopoly, Competitive, Oligopoly, and Monopolistic Competition).

BOOKS RECOMMENDED:

1. Beri, Market Research – Tata Mc Graw Hill
2. Chary S.N, Production and Operative Management / Tata Mc Graw Hill.
3. Datta A.K., Material Management / PHI.
4. Chadwick Leslie, The essence of management accounting / PHI.
5. Massie L. Joseph Essentials of Management / PHI.
6. Barthwal R.R, Industrial Economics –. / New Age International.
7. Shreenivasan K.R., An Introduction to Industrial Management –/ Vikas.
8. Daver Rustam S. Salesmanship and Publicity –/ Vikas.
9. Mukopadhyay Sekhar, Pharmaceutical Selling, Sterling Publishers.
10. Koontz H, Wehrich H, Essentials of Management, Tata Mc Graw Hill.
11. Vidya sagar Pharmaceutical Industrial Management, Pharma Book Syndicate

PHAR 413 Pharmacotherapeutics [45 hrs]

1. Basic Concepts of Pharmacotherapy.(1 hr)
2. Important Disorders of Organ Systems and their Management: (44 hrs)
 - 2.1. Cardiovascular Disorders – Hypertension, Congestive Heart Failure, Angina, Acute Myocardial Infarction, Cardiac arrhythmias (8hrs)
 - 2.2 .CNS Disorders: Epilepsy, Parkinsonism, Schizophrenia, Depression (7hrs)
 - 2.3 .Respiratory Disease- Asthma, COPD (4hrs)
 - 2.4. Gastrointestinal Disorders-Peptic ulcer, Ulcerative colitis, Hepatitis, Cirrhosis (8hrs)
 - 2.5 Endocrine Disorders-Diabetes mellitus and Thyroid Disorders (3hrs).
 - 2.6 Infectious Diseases-Tuberculosis, Urinary Tract Infection, Enteric Infections, Upper Respiratory Infection (5hrs).
 - 2.7 Hemopoietic Disorders-Anemias (6hrs)
 - 2.8 Joint and Connective Tissue Disorders-Rheumatic Diseases, Gout and Hyperuricaemia (1hrs)
 - 2.9 Neoplastic Diseases- Acute Leukaemias, Hodgkin's diseases (2hrs)

Books and Other Resources Recommended

1. Sathoskar, Pharmacology and pharmacotherapeutics, Vol. 1 & 2, Publ by Popular Prakashan, Mumbai.
2. Roger Walker and Cleve Edwards: Clinical Pharmacy and Therapeutics.
3. Current Medical Diagnosis and Treatment(CMDT)
4. Washington Manual and Medical therapeutics, 32nd Edition.
5. Bertram. G. Katzung, Basic and clinical pharmacology
6. J.G. Hardman and Lee E. Limbard, Good Mann & Gilman: The Pharmacological basis of therapeutics, Mc Graw hill, Health Professions Dvn.
7. Lippincott Williams and Wilkins: Remington Pharmaceutical Sciences, 20th Edition. Hamsten, Drug interaction, Kven Stockley.
8. Laurence, DR and Bennet PN. Clinical Pharmacology, Scientific book agency
9. Dr. D.R Krishna, V. Klotz, Clinical pharmaco kinetics, Publ Springer Verlab
10. M Rowland and T N Tozer, "Clinical Pharmacokinetics" 2nd ed Lea & Febiger, NY.
11. Grahame smith and Aronson, Clinical pharmacology and drug therapy
12. Richard A Helms, Text Book of Therapeutics Drug and Disease Management Hardbound.
13. Herfindal E T and Hirschman JL, Williams and Wilkins, Clinical Pharmacy and therapeutics
14. Applied Therapeutics, The clinical uses of Drugs applied therapeutics INC

PHAR 414 Research Methodology [45 hours]

1. Introduction, meaning and nature of research, scope and objective of research, type of researches, health research and its benefits. Research Ethics and plagiarism. Health research, policy and priorities, pharmaceutical researches, indicators in health researches, pharmaceutical researches, laboratory and survey research **(4 hrs)**
2. Introduction, significance of valid design **(1hr)**
3. Research design: Observational Study – types, design, example. Interventional study – types, design, example. Qualitative Research, meta-analysis, small topics. Foundations of Quantitative and qualitative Research Design. Identify different types of study design, including observational, pre-experimental and experimental designs, and their inherent threats to internal and external validity, **(5 hrs)**
4. Variables – types, example. Describe the basic issues related to measurement of variables. (2hours)
5. Confounders and Bias: Confounding, control of confounding. Bias- types, control; blinding- types, double dummy technique; randomisation – methods, measurement levels (3 hrs)
6. Data Analysis and Interpretation: (20 hours)
 - 6.1. Gaussian curve, hypothesis testing **(1hr)**
 - 6.2. Confidence interval, p-value, effect size, power **(1hr)**
 - 6.3. Types of error, reducing error in test **(1 hr)**
 - 6.4. Parametric and non-parametric tests for difference between groups: data required, example (2 hrs)
 - 6.5. Chi-square test, Mc Nemar test- Assumption, example, interpretation **(2 hrs)**
 - 6.6. Tests for ordinal data- Assumption, example, interpretation **(2 hrs)**
 - 6.7. Central limit theorem, t-distribution, different t-tests- Assumption, example, interpretation (2 hrs)
 - 6.8. One way Anova- Assumption, example, interpretation, source of variation, post hoc tests (2 hrs)
 - 6.9.2 and n- way Anova, multivariate Anova- Assumption, example, interpretation **(2 hrs)**
 - 6.10. Relative risk, odds ratio, survival studies **(1 hr)**
 - 6.11. Correlation- Types, Assumption, example, interpretation **(2 hrs)**
 - 6.12. Regression- Types, Assumption, example, interpretation **(2 hrs)**
 - 6.13. Topic selection, defining objective and research question, research hypothesis (1 hour)
 - 6.14. Research report writing, types of report, draft report and presentation and dissemination plan **(2 hours)**
7. Data entry in SPSS and other softwares – Lab Practice **(2hrs)**.
Non-parametric tests (SPSS)- 2hrs,
T- tests, One- way Anova (SPSS)- **2 hrs**
Correlation, Regression (SPSS)- **2hrs**

PHAR 414 Lab Literature Survey and Project Design Practical

Write a project proposal for 8th semester project work and conduct literature survey.

Books and Other Resources Recommended

1. Health Research Methodology- A guide for Training in Research methods. WHO.
2. Green, J. 2004. Qualitative methods for health research. 2nd ed. London: Sage.
3. Methodology and Techniques of Social Research by Bhandarkar and Wilkinson. Himalyan Publishing House
4. Research methodology- Methods and Techniques By CR Kothari- Wiley Eastren limited.
5. Polagar, S. 1995. Introduction to research in the health sciences. 3rd ed. Edinburgh: Churchill Livingstone.
6. A guide for Research proposal writing, National science Foundation.
7. Mike Saks and Judith Allsop. Researching Health Qualitative, Quantitative and Mixed Methods. Sage. ISBN: 978-1-4129-0364-6. Required.
8. Dr Katherine Jones and Katherine Hooper. Researching Health Companion. Sage.
9. S. Polgar and S.A. Thomas Introduction to Research in the Health Sciences, 5th edition. Churchill Livingstone Elsevier, New York (2008).
10. Denise F Polit and Cheryl Tatano beck- Nursing Research- Principles and Methods. 7th edition.
11. Albert P.S., and Borkowf, C.B., 2002. "An introduction to biostatistics: randomization, hypothesis testing and sample size," in John I. Gallin (ed.), *Principles and practice of clinical research*, San Diego: Academic Press,
12. Brody, B.A., 1998. *The Ethics of Biomedical Research: An International Perspective*, Oxford: Oxford University Press.
13. Council for International Organizations of Medical Sciences, 2002. *International ethical guidelines for biomedical research involving human subjects*. Geneva: CIOMS.
14. Brett A, Grodin M (1991). Ethical aspects of human experimentation in health services research. JAMA 265:1854-57.
15. BEVERLEY HANCOCK - Trent Focus for Research and Development in Primary Health Care: An Introduction to Qualitative Research. Division of General Practice , University of Nottingham.
16. NATASHA MACK • CYNTHIAWOODSONG, KATHLEEN M.MACQUEEN • GREG GUEST • EMILY NAMEY - Qualitative Research Methods: A DATA COLLECTOR'S FIELD GUIDE. Family Health International.

PHAR 415 Forensic Pharmacy

[45 hrs]

Unit – 1: Introduction (2 hours)

History of pharmaceutical legislation, Pharmaceutical industry and pharmaceutical education in Nepal and Global Perspective.

Unit – 2: An elaborate study of the following: (30 hours)

- Drugs Act, 1978
- Drug Registration Regulation
- Drug Consultative Council and Drug Advisory Regulations
- Drug Standard Regulation
- Drug Inspection Regulation
- Drug Manufacturing Codes
- Good Manufacturing Practices
- Drugs Sale and Distribution Codes
- Pharmacy Council Act

Unit – 3: A brief account on the following: (13 hours)

- Regulatory provisions for veterinary, ayurvedic and other system of medicines
- Company Act of Nepal
- Patents Act 1970.
- National Health Research Council Act
- Professional councils
- Narcotic drugs control act relating to pharmaceutical product and the relation of act with Drugs Act, 1978
- Drugs banned in Nepal and the reason of drug banning
- Introduction Regulatory affairs in INDIA(Pharmacy act 1948, Drugs and cosmetics act 1940, Narcotic drugs and ptychotropic substances act 1985)
- A brief account about the Drug & Cosmetic Act of UK, Australia and USA.

Books and Other Resources Recommended

1. Drug Act of Nepal and Regulations under it.
2. Forensic Pharmacy by B.M. Mithal
3. Laws of drugs in India – Hussain
4. Intellectual Property Law by R.K. Nagarajan
5. Text book of forensic pharmacy by C.K.Kokate and S.B.Gokhale published by Pharma book syndicate.

PHAR 416 Dispensing and Community Pharmacy [45 hours]

Unit-1: Community Pharmacy (4 hours)

1.1. Definition, Scope of community pharmacy, different types of community pharmacy.

1.2. Professionalism in the Community Pharmacy Setting.

1.3. Roles and responsibilities of Community pharmacist, Code of Ethics.

Unit-2: Entrepreneurship in Community Pharmacy and developing business plan. **(2 hrs)**

Unit-3: Pharmaceutical care: Definition and Principles of Pharmaceutical care. **(2 hrs)**

Unit-4: Community Pharmacy Management (12 hrs)

4.1. Selection of site, Space layout, and design, Pharmacy workflow

4.2. Staff, Materials- coding, stocking

4.3. Legal requirements and legal structure of ownership.

4.4. Maintenance of various registers

4.5. Computerization of Pharmacy

4.6. Documentation in Community pharmacy

4.7. Patient care process in Community pharmacy

Unit-5: Inventory Control: Purchasing and Inventory control in community pharmacy. **(3hrs)**

ABC, VED, EOQ, Lead time, safety stock

Unit-6: Prescription: Handling of prescription, source of errors in prescription, care required in dispensing procedures including labeling of dispensed products. **(2 hrs)**

Unit-7: Pharmaceutical calculations (3 hrs)

Posology, calculation of doses for infants, adults and elderly patients; Enlarging and reducing recipes percentage solutions, allegation, alcohol dilution, proof spirit, isotonic solutions, displacement value etc.

Unit-8: Communication skills in Patient counselling (6 hrs)

Need for good communication, Key communication skills, strategies to overcome barriers. Patient compliance: Definition, Factors affecting compliance, role of pharmacist in improving the compliance. Patient information leaflets- content, design, & layouts, advisory labels.

Unit-9: Health screening services: (8 hrs)

Definition, importance, methods for screening, responding to symptoms. Role of Pharmacist in OTC drugs, Immunization, Nutrition and Dietary supplements. Smoking cessation, Obesity, Hypertension, Diabetes mellitus (TYPE II) and Family planning.

Unit-10: Good Community Pharmacy Practice: (3 hrs)

Requirements of premises/layout, equipments, manpower, of material, storage and inventory control services, documentation.

PHAR 416 Lab Community Pharmacy Practical

1. Categorization and storage of Pharmaceutical products bases on legal requirements of labeling and storage.
2. Prescription handling and identification of drug interactions, incompatibilities.
3. Health screening services and study of equipments for:- Blood glucose determination (Glucometer), Blood pressure (BP apparatus) and Lung function test (Peak flow meter)
4. Layout and Design of community pharmacy to incorporate all pharmaceutical care services.
5. Study of OTC medications List & Available brands.
6. Interpretation of various pathological reports of blood and urine.
7. Techniques of administration of special dosage forms of drugs : Discussion and overhead picture presentation on proper techniques of administration of :-Inhaler, Eye drops and ointment, Ear drops, Nose drops, Dry syrups, Suppositories and Vaginal pessaries (Demonstration of these actual dosage forms and hands on experience at using them)
8. Problem solving / patient care analysis in pharmacy practice, taking drug history, patient counselling role play.
9. Project report on visit to the nearby Community for Counseling on the rational use of drugs and aspects of health care.

Books and Other Resources Suggested

1. Churchill Livingstone, Edalker and Edwards- Clinical Pharmacy and Therapeutics 2nd ed. 1999
2. Clive Edwards and Paul Stillman - Minor Illness or Major Disease? Responding to symptoms in the Pharmacy, Pharma Press 1995.

3. Robinson Harma - Patient Care in Community Practice, A Handbook of Non Medical Healthcare, Pharma Press 1989.
4. Melanie J. Rantucci- Pharmacists talking with Patinents, A guide to Patient Conseling. Williams and Wilkins. 1997.
5. Cynthia Knapp Dlugosz, The Practitioner's quick reference to Non Prescription Durgs. American Pharmacists Association. 2009.
6. Jean Venable, Lynne Roman, Kristin Weitzel, Community Pharmacy Practice. American Pharmacists Association. 2009.
7. WHO Publications: Role of Pharmacist in Health Care, Good Pharmacy Practice, Operational principle for good procurement practice and WHO Revised drug strategies

EIGHTH SEMESTER

PHAR 421 Hospital Pharmacy

(45 hours)

- 1) History and Development of Hospital, Hospital pharmacy and Clinical Pharmacy in Nepal. 1 hr
- 2) Organization and Structure 1 hr
 - Hospitals: Definition, Objectives and Functions, Classifications based on various criteria, Organization, Management and health delivery system in Nepal.
- 3) Hospital Pharmacy: 4 hr
 - a) Hospital Pharmacy, Definition, functions and objectives of hospital pharmacy, organization, planning and administration of modern hospital pharmacy services, Location, Layout & flow chart of material and men, personnel, and facilities required, including equipments,
 - b) Minimum Standards of practice in Hospital pharmacy.
 - c) Qualifications, requirements, abilities and evaluation of hospital pharmacist, responsibilities required for Hospital Pharmacists, workload and remuneration of hospital pharmacist, pharmacist assistants and supporting staffs, Job descriptions.
- 4) Drug Store Management and Inventory Control 4 hr
 - a) Organization of drug store, Types of material stocked, Storage Condition, Budgeting for Drugs.
 - b) Purchase and Inventory Control Principles, Purchase procedures, Estimation of drug requirements, Determining drug types and quantities required, Lead time, Monthly consumption, Purchase Specifications, Requisition, Purchase order, Purchase record, Procurement and Stocking. Control on Purchase, Vendor selection, ABC analysis, VED analysis.
- 5) Drug Distribution Systems In Hospitals 5 hr
 - a) Outpatient Dispensing; Method adopted, Guidelines for Hospital Drug Distribution Systems.
 - b) Inpatients Dispensing; Type of drug distribution systems; Individual prescription order, Floor stock system, Unit dose dispensing system (centralized and decentralized system), Satellite pharmacy services, Bed side pharmacy, charging policy, labeling.

- c) Dispensing of controlled drugs, record keeping and stock maintenance.
- d) New dispensing systems: Mechanical Drug Dispensing, Computerized Drug Dispensing.
- 6) Central Sterile Supply Unit and its management: Type of materials for sterilization, packaging of materials prior to sterilization, sterilization equipments, supply of sterile materials. 2 hr
- 7) Hospital manufacturing and pre-packaging in the Hospital: 6 hr
 - a) Economic Considerations, Factors affecting make or buy decision, sterile manufacture and non sterile manufacture, facilities and requirements.
 - b) Nutritional problems in hospitalized patients, Nutritional assessment and metabolic requirements, Disease specific support, Home parenteral nutrition with calculations
- 8) Hospital committees: 6 hrs

Role of Pharmacists in different hospital committee and rational use of drugs

 - a) Drug and Therapeutic committee: Goals and Objectives, functions, role of DTC in drug management Cycle, Structure and organization of DTC
 - b) Infection control committee
 - c) Antibiotic monitoring committee
 - d) Research and Ethics committee
- 9) Nomenclature and uses of surgical Instruments, Surgical supplies and Surgical Dressings. 2 hrs
- 10) Managing Formulary process
The Formulary process, The formulary list, Formulary manual, Standard Treatment Guidelines, Assessing New medicines 4 hrs
- 11) Radiopharmaceuticals 8 hr

Type of radio Pharmaceuticals, Radioactive half life, Units of Radioactivity and Dose, Facilities required for the production of radiopharmaceuticals, Production of ^{99m}Tc, Measurement of radioactivity (Geiger- Miiller counting, Liquid scintillation counting, Measurement of gamma radiation), Dosing, Radiation Hazards and role of pharmacist
- 12). Computer application in hospital pharmacy 2 hrs

PHAR 421 Lab Hospital Pharmacy Practical

1. Organizational chart of Hospital and hospital Pharmacy.
2. Layout design and workflow of hospital pharmacy.
3. Demonstration of surgical equipments and surgical dressings.
4. Drug List, Emergency Drug list.
5. Adverse Drug Reaction with causality assessment.
6. Drug dose calculation in Children, pregnancy and geriatric patients.
7. Case studies involving different diseases.
8. Prepare formulary of selective drugs.
9. Visit to Hospital pharmacy and prepare a report. (optional)

Books and Other Resources recommended

1. Lea and Gebiger, William E. Hassan- Hospital Pharmacy 3rd ed. 1974.
2. Birla Publications, Pratibha Nand and RK Khar- A textbook of Hospital and Clinical Pharmacy 1st ed. 2001.
3. Vallabh Publications, PC Dandiya and Mukul Mahur- A textbook of Hospital and Clinical Pharmacy 4th ed. 2005.
4. Churchill Livingstone, Edalker and Edwards- Clinical Pharmacy and Therapeutics 2nd ed. 1999
5. American Pharmaceutical Association, John Rovers and Jay Currie- A Practical Guide to Pharmaceutical Care 3rd ed. 2007.
6. Green and Harris - Pathology and Therapeutics for Pharmacists , Chapman and Hall ISBN 0-412-36000-4
7. Winfield and Richanrds - Pharmaceutical Practice , Churchill Livingstone 1998.
8. Diane M.Collett and Michael E.Aulton, Churchill Livingstone 1990.
9. Clive Edwards and Paul Stillman - Minor Illness or Major Disease ? Responding to symptoms in the Pharmacy, Pharma Press 1995.
10. Alison Blenkinshopp and Paul Paxton - Symptom in Pharmacy, Blackwell Science 1995.
11. WHO Publications: Role of Pharmacist in Health Care, Good Pharmacy Practice, Operational principle for good procurement practice and WHO Revised drug strategies.

12. Preparation and characterization of niosomes.
13. Study of in vitro dissolution of various sustained release formulations of marketed products.
14. Demonstration of skin sensitivity testing of TDDS on a suitable animal model.

DRUG DELIVERY SYSTEMS

1. Preparation and Evaluation of Matrix Tablets
2. Formulation and Evaluation of Film Coated Tablets.
3. Formulation and Evaluation of Enteric Coated Tablets.
4. Preparation and Evaluation of Transdermal Drug Delivery Systems.
5. Formulation and Evaluation of Mucoadhesive Delivery Systems.
6. Evaluation of Market SR Formulations.
7. Preparation and Evaluation of Alginate Beads.
8. Analytical Method Validation.

Books and Other Resources recommended

1. Fried J.R. Polymer Science & Technology, 2nd edition. Prentice-Hall India Pvt. Ltd.
2. Coleman M.M., Painter P.C. Fundamentals of Polymer Science: An Introductory Text. CRC Press.
3. Liun Lisbeth, Davis Stanley S. Polymers in Controlled Drug Delivery. Wright Bristol.
4. Robinson J.R., Lee V.H.L. Controlled Drug Delivery. Marcel Dekker, Inc.
5. Juliano R.L., Drug Delivery Systems: Characteristics and Biomedical Applications. Oxford University Press.
6. Chien Y.W. Novel Drug Delivery Systems. Marcel Dekker, Inc.
7. Vyas S.P., Khar R.K. Controlled Drug Delivery-Concepts and Advances. Vallabh Prakashan.
8. Mathiowitz E. Encyclopedia of Controlled Delivery. John Wiley & Sons, Inc.
9. Jain N.K. Controlled and Novel Drug Delivery. CBS Publishers & Distributors.
10. Carstensen J. T. Drugs and Pharm.Sci. Series, vol. 43, Marcel Dekker Inc.
11. Johnson P., Lloyd-Jones, J.G. Drug Delivery Systems: Fundamentals and Techniques. VCH.
12. Audus K.L., Juliano R.L. Targeted Drug Delivery. Springer-Verlag.
13. Lee V.H.L. Peptide and Protein Drug Delivery. Marcel Dekker, Inc.
14. Guy R.H., Hadgraft G. Transdermal Drug Delivery. Marcel Dekker, Inc.
15. Edith Mathiowitz, Donald E. Chickering, Claus-Michael Lehr. Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches and Development. Marcel Dekker, Inc.
16. Kasliwal N. Liposomes/Niosomes As a Drug Delivery System. Lambert Academic Publishing.
17. Dietrich G., Goebel W. Vaccine Delivery Strategies. Horizon Scientific Press.
18. Kaufmann S.H.E. Novel Vaccination Strategies. Wiley-VCH.

PHAR 423 Quality Assurance & Instrumental Analysis (60 hours)

Unit – 1: Quality assurance (10 hrs)

- 1.1. GMP concept and its components, comparison of requirements of WHO guidelines, US FDA guidelines,
- 1.2. GLP concept and its components,
- 1.3. Concept of ISO, difference of GMP guidelines with ISO
- 1.4. Concept of TQM, Quality Review and Quality Documentation.
- 1.5. Validation, validation of equipment, validation of analytical procedures.

Unit-2: Instrumental Analysis (50 hours)

- 2.1. Ultraviolet and visible spectrophotometry: Introduction, absorption laws, instrumentation, types of electronic transition, chromophore concept, auxochrome, absorption & intensity shifts, types of absorption bands, choice of solvent & solvent effects, Woodward-Feiser & Feiser-Kuhn rules for calculating absorption maxima, applications of UV spectroscopy.(12 hrs)
- 2.2. Fluorimetry: Introduction, principle, factors affecting fluorescence intensity, instrumentation & applications of fluorimetry.(3hrs)
- 2.3. Infrared spectrophotometry: Introduction, theory of IR spectroscopy, modes of vibration, factors affecting vibrational frequencies, instrumentation, position & intensity of absorption bands, sampling methods, applications of IR spectroscopy, interpretation of IR spectra, limitations of IR spectroscopy.(10 hrs)
- 2.4. Nuclear Magnetic Resonance spectroscopy including ^{13}C NMR: Introduction, principle, instrumentation, number of signals, chemical shift & factors affecting chemical shift, internal standards, shielding & deshielding effects, solvents in nmr, splitting of signals, spin-spin coupling, coupling constant, double resonance (spin decoupling), nuclear overhauser effect (NOE), introduction to ^{13}C NMR, applications of NMR spectroscopy, interpretation of NMR spectra.(12 hrs)
- 2.5. Mass Spectrometry: Introduction, principle, instrumentation, mass spectrogram, types of ion produced in mass spectrometer, index of hydrogen deficiency, nitrogen rule, ring rule, interpretation of molecular spectra & applications of mass spectroscopy. (7 hrs)
- 2.6. Flame Photometry: Introduction, principle, instrumentation, effect of solvent, applications in qualitative & quantitative analysis, methods of quantitative analysis, interferences in flame photometry & limitations of flame photometry.(3 hrs)
- 2.7. Emission Spectroscopy: Introduction, theory, instrumentation, advantage & disadvantage of emission spectroscopy, applications. (2hrs)
- 2.8. Atomic Absorption Spectroscopy: Introduction, theory, instrumentation, detection limit & sensitivity, interference, applications of AAS. (2hrs)
- 2.9. X-ray Diffraction: Introduction, theory, instrumentation, applications.(2hrs)
- 2.10. Thermal methods: Introduction to thermal methods; principle, instrumentation & application of differential thermal analysis (DTA), differential scanning calorimetry (DSC) & thermogravimetry (TG). (5hrs)
- 2.11. Radioimmunoassay (3 hrs)

Phar 423 Lab Quality Assurance and Instrumental Analysis Practical

1. Quantitative estimation of formulations containing single drug or more than one drug, using uv-visible spectroscopy.
2. Estimation of Na, K, Ca ions using flame photometry.
3. Estimation of riboflavin, quinine using flame fluorimetry.
4. Workshop to interpret the structure of simple organic compounds using UV, IR, NMR and MS.

Books and Other Resources recommended

1. Skoog, et al : Fundamentals of analytical chemistry, Thomson Brooks/Cole
2. William Kemp: Organic Spectroscopy (3rd Ed.) 1991, Macmillan Press Ltd., London.
3. R. M. Silverstein, G. C. Baller and T. C. Morrill: Spectrometric Identification of Organic Compounds. (5thEd.) 1991, John Wiley and Sons, Inc. London.
4. John R. Dyer: Applications of Absorption Spectroscopy of Organic Compounds, 1965, Prentice-Hall, Inc., London.
5. BK Sharma: Instrumental & Chemical Methods of analysis: Goel Publication
6. Chatwal & Anand: Instrumental & Chemical Methods of analysis: Himalayan Publication
7. Beckett A H and Stenlake J B, Practical Pharmaceutical Chemistry Vol. II, The Athlone Press of the University of London.
8. G. Gauglitz and T. Vo-Dinh; Handbook of Spectroscopy; Wiley-VCH

PHAR 424 Clinical Pharmacy (30 hours)

- 1) Introduction to Clinical Pharmacy, Objectives of clinical pharmacy, Scope of Clinical pharmacy, Role of Clinical pharmacists (1 hr)
- 2) Patient data analysis and Prescribing guidelines: (5 hrs)
Interpretation of Clinical laboratory tests used in the evaluation of common disease states, Haematological parameters, Urine examination, Stool Examination, liver function tests, pulmonary function tests. Patient's Data collection. Paediatric patients, Geriatric patients, Pregnant and breast feeding women.
- 3) Adverse drug reactions: ADRs with special emphasis on epidemiology, classification, risk factors, monitoring and detecting ADR, assessing causality, reporting ADRs. (4 hrs)
- 4) Drug interactions: Define drug-drug and drug-food interactions. Classify and explain mechanism of drug-drug interactions. (5 hrs)
- 5) Drug dependence and Drug abuse (1 hr)
- 6) Describe the investigational drugs and phases of clinical trials, pharmacist's role in clinical trials, statistical methods of interpretation, legal and ethical considerations. (4 hrs)
- 7) Therapeutic drug monitoring and role of pharmacist. (4 hrs)
- 8) Drug and poison information services: (6 hrs)
Introduction of drug information, Resources available, Design of literature searches, Critical evaluation of drug information and literature, Preparation of written and verbal reports and Development of a drug information data base and emergency treatment of poisoning.

Books and Other Resources recommended

1. Birla Publications, Pratibha Nand and RK Khar- A textbook of Hospital and Clinical Pharmacy 1st ed. 2001.
2. Vallabh Publications, PC Dandiya and Mukul Mahur- A textbook of Hospital and Clinical Pharmacy 4th ed. 2005.
3. Churchill Livingstone, Edalker and Edwards- Clinical Pharmacy and Therapeutics 2nd ed. 1999
4. American Pharmaceutical Association, John Rovers and Jay Currie- A Practical Guide to Pharmaceutical Care 3rd ed. 2007.

5. Green and Harris - Pathology and Therapeutics for Pharmacists , Chapman and Hall ISBN 0-412-36000-4
6. Winfield and Richards - Pharmaceutical Practice , Churchill Livingstone 1998.
7. Clive Edwards and Paul Stillman - Minor Illness or Major Disease ? Responding to symptoms in the Pharmacy, Pharma Press 1995.
8. Current Medical Diagnosis & Treatment Lawrence M. Tierney,Jr.Stephen J. McPhee,Maxine A. Papadakis

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