B. Pharma - IV Semester
Pharmaceutics- IV (Pharmaceutical Engineering – II)
(BPH-401)

Unit-I

Size Reduction and Size Separation - Definition, significance and factors affecting of size reduction, classification of size reduction machines, study of various types of mill including ball mill, hammer mill, fluid energy mill etc. standard of powders, sieves and their usage in grading of powders. Laws governing energy and power requirements of a mill.

Compaction and Compression - Adhesion and Cohesion of particles, strength of granules, physics of tablet compression.

Unit-II

Mixing - Definition and significance of mixing, solid-solid, solid-liquid, liquid-liquid and mixing of immiscible liquids, mixers used in pharmaceutical industries.

Extraction - Solid-liquid and liquid-liquid extraction-mechanism and method of extraction process and factors affecting extraction process, equipments employed in solid liquid and liquid –liquid.

Unit-III

Distillation - Raoult's law, volatility, boiling point diagrams, azeotropic mixtures, equilibrium diagrams, types of distillation, rectification, rectifying columns, material and energy balance of a rectifying column, reflux ratio and extractive distillations.

Evaporation - Introduction, heat transfer process in boiling liquids in evaporators, factors affecting evaporation. Study of pan evaporators, horizontal tube evaporator, short tube vertical evaporator, falling film evaporator and forced circulation evaporator.

Unit-IV

Crystallization - Crystal forms and crystal habits, crystallizer classification, principles underlying the design and operation of tank crystallizers, agitated tank crystallizers, swenson walker crystallizer, vacuum crystallizer and krystal or oslo crystallizer

Drying - Mechanism and theory of drying. study of dryer-tray dryer, vacuum tray dryer, tunnel dryer, rotary drum dryer, spray dryer, and freeze dryer, fluidised bed dryer.

Unit-V

Filtration - Theory of filtration, factors affecting filtration, Filter media, filter aids, classification of filters, study of Industrial filters including filter press, rotary filter, membrane filter etc.

Centrifugation - Principles and significance of centrifugation, design and operation of various centrifugation sedimenters.

Reference Books-

1. Elementary Chemical Engineering - Max S. Peters, Published by McGraw Hill Book Company, New York, 1954.
2. Walter L. Badger & Julius T. Bancherro, Introduction to Chemical Engineering, Mc. Graw Hill Inc., 1955.
3. A. R. Paradkar, Introduction to Pharmaceutical Engineering, Nirali Prakashan, 10th Ed. 2007.
4. Tutorial Pharmacy by Cooper & Gunn, ed. S.J.Carter, CBS Publishers & Distributors, Delhi, 6th Edition, 2000.
5. Unit Operations of Chemical Engineering, 5th edition – McCabe, Smith & Harriott, McGraw – Hill Inc., New York.
6. Pharmaceutical Engineering – K.Sambamurthy, 2002 NAI (P) Ltd., Delhi.
7. Pharmaceutics : The Science of Dosage Form Design - M.E. Aulton.
8. The Theory & Practice of Industrial Pharmacy – Lachman L., Lieberman H.A. & Kanjig J.L., 3rd edition, 1990 Varghese Publishing House, Bombay.
9. Alfonso G. Remington: The Science & Practice of Pharmacy. Vol.I & II. Lippincott, Williams & Wilkins Philadelphia.
10. Jani G. K., Pharmaceutics II (Unit Operations), B. S. Shah Prakashan, Ahmedabad.
11. Subramanyam C.V.S., Thimma J, Suresh S.S. et. al., Pharmaceutical Engineering : Principles and Practice, 2002, Vallabh Prakashan, Delhi.
12. Introduction to Chemical Engineering by Walter L. Badger & Julius T. Banchero, Mcgraw Hill International edition, New Delhi, 1955.
13. Filtration in Pharma. Industry by Theodore H. Meltzer, Marcel Dekker Inc., New York, 1987.
14. Perry's Chemical Engineer's Handbook - Robert H Perry, Green D.W., Maloney O.7th Edition, 1998, McGraw – Hill Inc., New York.

List of practical-

1. Study the effect of diameter of balls, No. of balls volume of balls or feed amount on the particle size reduction wing ball mill.
2. Calculate the energy requirement (as per Riltinger's law) for the powder milling.
3. Study the particle size distribution the given sample using standard sieve method.
4. Determine the particle size distribution of a given sample using microscopy.
5. Study the rate of sedimentation of the given sample.
6. Study the effect of suspending agents on the rate of sedimentation of the given sample.
7. Compare the efficiency of different suspending agents on the rate of sedimentation of the given sample.
8. Study the effect of temperature, surface area and viscosity of the liquid on the rate of evaporation.
9. Construct the boiling point diagram for the given mixture of alcohol and water.
10. Study the effect of surface area, material bed thickness, temperature and moisture content on the rate of drying.
11. Compare the efficiency of single stage extraction with multiple stage extraction.
12. Determine the percentage of acetic acid extracted from the mixture of benzene and acetic acid using water as our extracting agent.
13. Determine the percentage purity of the given sample using crystallization technique.
14. Determine the mixing index for the mixing of give powders.
15. Determine the effect of surface area, thickness of filter medium, viscosity of liquid, temperature and filter aid on the rate of filtration.

Dosage Form Design

Subject code: BPH 402 **Periods / week: 4**

Unit – I

Preformulation study: (a) Study of physical properties of drug like physical form, particle size, shape, density, wetting, dielectric constant, solubility, dissolution and organoleptic properties and their effect on formulation, stability and bioavailability.

(b) Study of chemical properties of drugs like hydrolysis, oxidation-reduction, racemization, polymerization etc. and their influence on formulation and strength of products, stabilization and stability testing protocol provision pharmaceutical products.

(c) Drug Discovery and drug design.

Unit – II

Polymer sciences: Introduction, classification and pharmaceutical applications of polymers, Polymers as thickening agents, and brief introduction of Biodegradable polymer.

Unit – III

Study of different types of formulation additives: Diluents, Binders, Disintegrating agents, Lubricants, Solvents, Preservatives, Suspending agents, Emulsifying agents, Antioxidants, Preservatives, coloring, flavoring and sweetening agents, Viscosity enhancers.

Unit – IV

Dissolution technology: Theories of dissolution, factors affecting dissolution, design of various dissolution apparatus, dissolution media, dissolution testing of different types of dosage formulations, data interpretation, mathematical models for predication of dissolution of profile

Unit –V

Stability And Degradation Study:Chemical stability, pathways of degradation, physical and phase transformation, stability testing protocols for various pharmaceutical dosage forms, determination of expiry date (shelf life) and overage calculations, stabilization of pharmaceutical formulations.

Practical **3hrs / week**

1. Establish the following preformulation parameters of the given drug sample. (a) Melting point (b) solubility (c) intrinsic solubility (d) pKa (e) Partition coefficient

2. Establish the following preformulation parameters of the given drug sample. (a) Particle size distribution (b) Flow proportion (c) Bulk density (d) Carr's index (e) Compression preparation.

3. Study the drug excipient compatibility of given drug with commonly used excipent by TLC technique.

4. Estimate the shelf life of the given drug

5. Study the effect of moisture content on chemical stability of Aspirin.

6. Study the effect of temperature on stability of given photosensitive drug.

7. Determine the molecular Mass of given polymer by viscometer.

8. Perform the in-vitro dissolution study of given the sample of tablet.

9. Study the effect of presence of surfactant in dissolution of tablet cantoning poorly soluble drug.

10. Study the effect of solvent / co-solvent hydrotropic agents on solubility of given drug.

11. Study the effect of pH of dissolution on in-vitro dissuasion study.

12. Compare the dissolution profile of two marketed tablet products.

References: 1. Swarbrick J., Boylan J.C., Encydopedia of Pharmaceutical Technology, Second edition, Volume-1,2,3, Marcel Dekker, Inc. Newyork.

2. Qiceyihong, ChenY, Zhang G.G.Z., Developing solid Oral dosage formsPharmaceutical Theory and Practice charon Tech Ltd

. 3. Allen L.V., Popovich N.G., Ansel H.C., Ansel's Pharmaceutics design and drug delivery systems, Eight edition, B.I. Publication Pvt. Ltd.

4. Aulton M.E. Pharmaceutics- The science of dosage form design" second edition., Churchill Livingstone Pvt. Ltd.

5. Banker G.S., Rhodes C.T., Modern Pharmaceutics" second edition, Marcel Dekker, Inc., Newyork.

6. Kanig J.J., Liebermen H.A., Lachman L. "The theory and Practics of Industrial Pharmacy, Varghese Publishing House, Bombay.

PHARMACEUTICAL ANALYSIS-I

B. Pharma (BPH – 403)

Significance of quantitative analysis in quality control different techniques of analysis, preliminaries and definitions, precision and accuracy. Fundamentals of volumetric analysis, methods of expressing concentration, primary and secondary standards.

Unit I

Acid base titrations: Acid base concepts, role of solvent, relative strengths of acids and bases,

ionization, law of mass action, common-ion effect, ionic product of water, pH, hydrolysis of salts, Henderson- Hasselbach equation, buffer solution, neutralization curves, acid base indicators, theory of indicators, choice of indicators, mixed indicators, polyprotic system.

Non-aqueous titrations: Scopes and limitations, Solvents used in non aqueous titrations, Acid-base equilibria in non-aqueous media, Titration of weak acids and weak bases with specific examples given in Indian Pharmacopoeia.

Unit II

Oxidation reduction titrations: Concepts of oxidation and reduction, redox reactions, strengths and equivalent weights of oxidizing and reducing agents, theory of redox titrations, redox indicators, oxidation reduction curves, iodimetry and iodometry, titrations involving ceric sulphate, potassium iodate, potassium bromate, potassium permanganate.

Unit III

Precipitation titrations: 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 indicators, Mohr's method, Volhard's method and Fajan's method.

Unit IV

Gravimetric analysis: Precipitation techniques, solubility products, the colloidal state, supersaturation, coprecipitation, post-precipitation, digestion, washing of the precipitate, filtration, filter papers and crucibles, Ignition, thermogravimetric curves, specific examples like barium as barium sulphate, aluminium as aluminium oxide, organic precipitants.

Unit V

Miscellaneous methods of analysis: Complexometric titrations, Conductometry, Potentiometry, Polarography & Amperometry, diazotization titrations and Karl-fisher titrations

PHARMACEUTICAL BIOCHEMISTRY

Subject code: BPH 404 **Periods / week: 4**

Unit – I

Biochemical organization of the cell and transport processes across cell membrane.
The concept of free energy, determination of free energy change from equilibrium constant and reduction potential, energy rich compounds, production of ATP and its biological significance.

Unit – II

Enzymes - Nomenclature & classification, Kinetics, mechanism of action and inhibition, clinical applications of enzymes, isoenzymes and coenzymes and their significance.
Structure and function of protein- amino acid and peptides, determination of primary structure and higher orders of structure.

Unit - III

Carbohydrate metabolism: - Glycolysis, gluconeogenesis, glycogenolysis, glycogen synthesis, metabolism of galactose, role of sugar nucleotides in biosynthesis; pentose phosphate pathway. TCA cycle, its significance, Effects of inhibitor and regulation of TCA cycle, Glyoxalate cycle.

Unit – IV

Lipid metabolism - Classification and properties, beta oxidation, oxidation of unsaturated fatty acids; synthesis of ketone bodies, biosynthesis of saturated and unsaturated fatty acids, cholesterol metabolism,eicosanoids, phospholipids and sphingolipids.

Unit – V

Electron transport and biological oxidation.Nitrogen balance, metabolism of amino acids; biosynthesis of purine, pyrimidines and their nucleotides, formation of uric acid.
Biosynthesis of RNA and DNA, Physical and chemical mutagenesis, DNA repair mechanism, recombinant DNA, mechanism of protein synthesis and its regulation.

Text Books

1. Text Book of Biochemistry, by B.Harrow&A.Mazur, W.B.Saundors Co., Philadelphia.
2. Principles of Biochemistry, A.L.Lehninger, CBS publishers, New Delhi.
3. Fundamentals of Biochemistry by Dr.A.C.Deb (New Central Book Agency, Calcutta)
4. Text Book of Biochemistry by Dr.A.V.S.S.RamaRao (UBS Publishers & Distributors, New Delhi). 5. Text Book of Biochemistry by Dr.Satyanarayana, Elsevier 4thed.

Reference Books

1. E.E.Conn and P.K.Stumpf. "Outlines of Biochemistry" John Wiley & Sons, New York.
2.D.T.Plumer, "An Introduction to Practical Biochemistry" Tata McGraw Hill, New Delhi.

Practicals **3hrs / week**

1. Identification of carbohydrates, proteins and fats.

2. Effect of enzyme on protein using papain enzyme.

3. Titration curve for amino acids.

4. Separation of amino acids by two dimensional paper chromatography and gel electrophoresis.

5. The separation of lipids by TLC.

6. Qualitative & Quantitative estimation of amino acids.

7. Quantitative estimation of proteins.

8. The estimate the amount of glucose present.

9. The isolation and determination of RNA and DNA.

10. Quantitative estimation of uric acid in Blood sample.

11. Identification of abnormal constituents of urine.

12. Food analysis of milk ,butter,flour,honey and starch.

Practicals:

A total of 10 experiments should be performed on the topics mentioned below

1. Acid base titrations: Preparation and standardization of acids and bases, some exercises related to the determination of acids and bases separately and in mixture form. Some official assay procedures of boric acid, ascorbic acid shall also be covered.

2. Oxidation-reduction titration: Preparation and standardization of some redox titrants, e.g., potassium permanganate, potassium dichromate, iodine, sodium thiosulphate etc. Some exercises related to the determination of oxidizing and reducing agents in the sample shall be covered. Exercises involving use of potassium iodate, potassium bromate, ceric ammonium sulphate shall be performed.

3. Precipitation titrations: Preparation and standardization of titrants like silver nitrate and ammonium thiocyanate, titrations according to Mohr's and Volhard's methods.

4. Gravimetric analysis: Determination of water of hydration, some exercises related to Gravimetric estimation of metal ions such as barium, magnesium and calcium shall he covered.

5. Diazotization reaction: Assay of sulphonamides.

6. Complexometric titration: Any two official assays done by this method.

7. Non-aqueous titrations: preparation and standardization of some non aqueous titrants, e.g., Perchloric acid, tetrabutyl ammonium hydroxide. Any two official assay given in Pharmacopoeia of India.

BOOKS RECOMMENDED:

1. Mendhanm J., Denny R.C., Barnes J.D., Thomas M, Jeffery G.H., Vogel's Textbook of Quantitative Chemical Analysis, Pearson Education Asia.
2. Conners K.A., A Text book of Pharmaceutical Analysis , Wiley Inter-science.
3. Beckett A.H., and Stenlake J.B., Practical Pharmaceutical Chemistry, Vol. I&II. The Atherden Press of the University of London.
4. British Pharmacopoeia, Her Majesty's Stationary Office, University Press, Cambridge.
5. Alexeyev V. Quantitative Analysis. CBS Publishers & Distributors.
6. H. H. Willard, L. L. Merritt and J. A. Dean: Instrumental Methods of Analysis, Van Nostrand Reinbold, New York.
7. G.L. Jenldns, J.E. Christian, G.P. Hager: Quantitative Pharmaceutical Chemistry, McGrawHill, Company, New York.
8. Pharmacopoeia of India, Govt. of India, Ministry of Health, Delhi.

Pharmacology-I

Subject code: BPH 405 **Periods / week: 4**

Unit – I

General Pharmacology

Definition,Scope and General Principles of Pharmacology, Nature and Sources of drugs, Drug Nomenclature, Essential Drug (Medicine) Concept, Detail discussion, Merits and Demerits of various Routes ofDrug Administration.
Bioassay of drugs and biological standardization, discovery and development of new drugs. Introduction to clinical trials.

Unit – II

Pharmacokinetics
Biological Membranes- Structure, Types, Properties and Functions of Biological Membranes, Physio-Chemical Factors and Process in transfer of Drug across the biological membrane.

Unit - III

Pharmacodynamics
Site and Mechanism of Drug Action, Structure Activity Relationship (SAR),
Drug Receptors- Basic Discussion, Classification, Structure and Family of Receptors, Drug Effects and Regulation of Receptors.
Drug Receptor Interactions and their effects, Dose Response Relationships and Therapeutic Index.

Unit – IV

Priciples of Therapeutics
Concept of Drug Summation, Synergism, Drug Antagonism and its types.
Adverse Drug Reactions & Drug Toxicity(Teratogenicity, Carcinogenicity Mutagenicity)
Contraindications, Therapeutic Uses, Drug Interactions .
Dose , Symptoms and Treatment of Poisoning.
Drug-Food Interactions, Classification of Drug-Drug interaction.

Unit – V

Pharmacology of Peripheral Nervous System
Autonomic Nervous System: General Considerations.
Parasympathomimetic andParasympatholytic,
Sympathomimetic and Sympatholytic ,
Neuromuscular blocking agents
Ganglion Stimulants and Blockers.

Text Books

1. Satoskar, R.S. and Bhandarkar, S.D., Pharmacology and Pharmacotherapeutics.
2. Tripathi, K.D., Essentials of Medical Pharmacology.
3. Kulkarni, S.K., Handbook of Experimental Pharmacology, Vallabh Prakashan, NewDelhi.

Reference Books

4. Crossland, J and Thomson, J.H., Essential of Pharmacology, Harper and Row, Publishers, New York.
5. Craig, C.R. and Stitzel, R.R., Modern Pharmacology, Little Brown and Company.
6. Rang, M.P. , Dale, M.M. and Riter, J.M., Pharmacology, Churchill Livingstone.
7. Paul, L., Principles of Pharmacology, Chamman and Hall.
8. Herfindal, E.T. and Hirschman, J.L., Clinical Pharmacy and Therapeutics, William and Wilkins.
9. Katzung, B.G., Basic and Clinical Pharmacology, Prentice Hall International.
10. Hardmen, J.G., Limbired, L.E., Molinoss, P.B., Ruddon, R.W. and Gil, A.G.,Goodman and Gillman's The Pharmacological basis of Therapeutics, Pergamon Press.

List of practicals: **3hrs / week**

1. Introduction to commonly used instruments in experimental pharmacology.
2. Care and Handling of common laboratrory animals, animal welfare and introduction of CPCSEA and its guidelines, OECD guidelines.
3. Introduction to animal physiology with their biochemical reference values in various animal species.
4. Study of various anesthetics employed to anesthetize laboratory animals.
5. Study of various routes of Drug Administration.
6. Study of physiological salt solutions, Drug solutions and use of Molar solution in various animal experiments.
7. Introduction to techniques of Euthenesia, Stunning and Pithing.
8. Study of various methods for collection of Blood, Body fluids and urine form experimental animals.
9. Computer Simulations of Following experiments through computerized software programs using software such as X-Pharma, X-cology etc.
   a) Record and interpret the concentration response of acetylcholine using suitable isolsted tissues.
   b) Study of Synergism using isolated tissues.
   c) Study of Drug Antagonismusing isolated tissues
   d) Study of Miotic and Mydriatic effects of drugs on rabbit eyes.
10. Bioassay of Acetylcholine and Histamine using suitable animal preparation.
11. Study of locomotor activity of Drug using Actophotometer.