Pharmaceutics- IV (Pharmaceutical Engineering – II) (PY-401)

Size Reduction and Size Separation- Definition objectives and significance of size reduction, Factors affecting size reduction, Standard of powders, Sieves and their usage in grading of powders, Laws governing energy and power requirements of a mill, Classification of size reduction machines, Study of various types of mill including ball mill, hammer mill fluid energy mill energy mill etc. Fluid classification methods.

Evaporation-Basic concepts, Factors affecting evaporation, Types of evaporators, Study of short tubs evaporators, Forced circulation evaporators and Film evaporators, Single and multiple effect evaporation, Evaporation under reduced pressure, Evaporation capacity, Heat and material balance, Scale formation, Foam and entrainment.

Distillation- General theory applied to binary mixtures, Boiling point and equilibrium diagrams, Raout's Law and Henry's Law, Constant boiling mixtures, Simple, steam and Equilibrium distillations, Rectification, Constructions of rectifying columns. Analysis of rectifying column: McCabe Thiel method and Lewis Sorel method for calculation of number of theoretical plates, Azeotropic and extractive distillations.

Drying- Introduction, Theory of drying Rate of drying curves, Classification of dryers, Study of dryers used in pharmaceutical industries, Special drying methods.

Extraction- Principles of solid-liquid and liquid- liquid extraction, Theories of extraction of drugs, Diffusion battery, Podbielnaik extractor, Continuous counter- current extraction system.

Crystallization-Importance of crystal purity, size, shape, geometry habit forms and types, Solubility curves and calculation of yields, Mier,s supersaturation theory and its limitations, Nucleation and crystal growth, Classification of crystallizers, Principles underlying the design and operation of Tank, Swenson-walker, Krystal and Vacuum

crystallizer, Crystallizer employed for producing large crystals, Caking of crystals and its prevention.

Mixing-Theory of mixing, Solid-solid; solid-liquid and liquid-liquid mixers used in pharmaceutical industries.

Filtration and Centrifugation- Theory of filtration, Factors affecting filtration, Filter media, Filter aids, Classification of filters, Industrial filters including Filter press, Rotary filter, Membrane filter etc.
Principles of centrifugation, Industrial filters and centrifugation sedimenters.

Compaction and Compression- Adhesion and Cohesion of particles, Strength of granules, Factors affecting strength of tablets, Physics of tablet compression.

Pilot Plant Scale Up Techniques- Concepts of pilot plant, scale up techniques in pharmaceutical industries.

Books recommended

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

12 Filtration in Pharma. Industry by Theodore H. Meltzer, Marcel Dekker Inc., New York, 1987.

13. A. R. Paradkar, Introduction to Pharmaceutical Engineering, Nirali Prakashan, 10th Ed. 2007.

List of practicals

PY401 Pharmaceutics – IV (any twelve)

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. Separate the constituents of the given a zeotropic mixture by the addition of third agent.
11. Study the rate of drying and determine EMC, CMC and FMC.
12. Study the effect of surface area, material bed thickness, temperature and moisture content on the rate of drying.
13. Compare the efficiency of single stage extraction with multiple stage extraction.
14. Determine the percentage of acetic acid extracted from the mixture of benzene and acetic acid using water as our extracting agent.
15. Prepare mier's super solubility curve for the given samples.
16. Determine the percentage purity of the given sample using crystallization technique.
17. Determine the mixing index for the mixing of give powders.
18. Determine the effect of surface area, thickness of filter medium, viscosity of liquid, temperature and filter aid on the rate of filtration.

Pharmaceutics –V (Dosage Form Design) (PY- 402)

Pharmaceutical preformulation: -

Definition and scope,

Establishment and importance of following physicochemical parameters

Solubility, pKa and selection of suitable salt, partition coefficient, dissolution, polymorphism, microscopy and powder properties, stability and drug-excipient compatibility Pharmaceutical factors influencing drug formulation.

Study of different types of formulation additives:
Diluents, Binders, Disintegrating agents, Lubricants, Solvents, Co-solvents and Vehicles, Preservatives, Suspending agents, Emulsifying agents, Antioxidants, Preservatives, colouring, flavoring and sweetning agents, Viscosity enhancers, ointment and suppositories bases

Polymers and biodegradable polymers:
Classification, Methods of synthesis, Properties, Characterization and evaluation.
Brief introduction of biodegradable polymers, pharmaceutical applications of polymers..

Dissolution 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.

Drug product design:
Stages of drug discovery and development process, Importance of product design, considerations.

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.

List of practicals:

(Any ten)

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 deurity (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 self life of the given drug
5. Study the effect of mesture content on chemical stability of aspirin.
6. Study the effect of temperation 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. Qice yihong, ChenY, Zhang G.G.Z., Developing solid Oral dosage forms-Pharmaceutical 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.
7. Rowe RC, Sheskey P.J., Owen S.C., Handbook of Pharmaceutical Excipents, Fifth edition, Pharmaceutical Pr.
8. Bugay D.E., Findlay W.P., Pharmaceutical Excipents, Marcel Dekker, Inc. Newyork.
9. Kim C.J., Advanced Pharmaceutics- Physiochemical Principle CRC Press, Florida.
10. Jan N.K., Pharmaceutical Product Development, CBS Publishers and distributors, New Delhi.
11. Shah D.H., "SOP Guidelines", Business Horizons Publishers, New Delhi.
12. Wachter A.H., Nash R.A., "Pharmaceutical Process validation, Marcel Dekker, Inc. Newyork.
13. Mazzo D.J., "International stability Testing" Interpha Press, Inc. Illinois.
14. Gibaldi M., Perriner D., "Pharmacokinetics:, Marcel Dekker Newyork.

BRANCH: PHARMACY-IV SEMESTER
COURSE: PY 403 PHARMACEUTICAL ANALYSIS (THEORY)

Fundamentals, Significance of quantitative analysis in quality control, Different techniques of analysis.

Theoretical considerations and pharmaceutical applications; with special reference to Indian pharmacopoeia; of the following analytical techniques -

1) Acid-Base titrations: Theoretical principles. Classification, Direct titration of strong acids, Strong bases, and weak bases, Back titrations, Acid –Base indicators, Choice of indicators and mixed indicators. Methods for determination of organically combined Nitrogen and in pharmaceutical applications.

2) Oxidation-Reduction titrations: Concepts of oxidation and reduction, redox reactions, strengths & equivalent weighs of oxidizing and reducing agents, redox indicators, potassium permanganate titrations, iodometry & iodometry, 9£dcammonium sulphate titrations, potassium iodate titrations. Pharmaceutical applications, preparation and standardization of redox titrants e.g. sodium thiosulphate etc.

3) Precipitation titrations: Detection of End Points in Precipitation reactions. Indicators used in Precipitation titrations, Preparation & standardization of titrants like silver nitrate, ammonium thiocyanate; titrations according to Mohr's and Volhard's methods; ammonium and potassium thiocyanate titrations; indicators; applications in pharmaceutical analysis

4) Gravimetric analysis: Fundamentals of gravimetry, Precipitation reagents precipitation techniques, Specific examples of gravimetric estimation like Aluminum as hydroxy quinolate, Barium on Barium Sulfate, Lead as Chromate and Magnesium as Magnesium Pyrophosphate.

5) 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.

6) Complexometric titrations: Theory of Complexometric analysis. Factor in influencing stability of complexes. pM indicators. Types of Disodium edetate titrations with suitable examples.

7) Conductometry: Ohm’s law and ionic conductivities, Apparatus used for conductimetric titrations. Application of conductimetry in acid-base, Precipitation and complexometric titrations with suitable examples.

8) Potentiometry: Theory and principles, Reference electrodes, Indicators electrodes and Ion selective electrodes. Instrumentation for potentiometric titrations. Application of potentiometry for end point determination in acid-base titration, redox titrations, precipitation titrations with suitable examples

9) Polarography & Amperometry: Introduction, theoretical principles, organic polarography, dropping mercury electrode, basic principles of polarographic instruments, methods of analysis, experiments including amperometric titrations.

10) Miscellaneous methods of analysis like diazotization titrations and Karl-fisher titrations.

List of Practicals:

A total of 15 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. A.H. Beckett and J.B. Stenlake: Practical Pharmaceutical Chemistry, Vol I and II, CBS Publishers and Distributors, New Delhi, India

2. H. H. Willard, L. L. Merritt and J. A. Dean: Instrumental Methods of Analysis, Van Nostrand Reinbold, New York.

3. L.M. Atherden: Bentley and Driver's Text book of Pharmaceutical Chemistry, Oxford UniversityPress, Delhi.

4. G.L. Jenldns, J.E. Christian, G.P. Hager: Quantitative Pharmaceutical Chemistry, McGrawHill, Company, New York.

5. Pharmacopoeia of India, Govt. of India, Ministry of Health, Delhi.

6. Bassett, R.C. Denney, G.H. Jeffery, J. Mendham: Vogel's Textbook of quantitative Inorganic Analysis, The ELBS and Longman, London.

Course Contents

Category of Course	Course Title	Course Code	Credit-4C			Theory Paper (ES)
	Pharmaceutical Chemistry-V (Biochemistry) (Theory)	**PY 404**	L	T	P	Max.Marks-70 Duration-3hrs.
			4	0	3	

Branch: Pharmacy-IV Semester
Course: PY -404 Pharmaceutical Chemistry-V (Biochemistry) Theory

Biochemical organization of the cell and transport processes across cell membrane.

The concept of free energy, determination of charges in free energy system from equilibrium constant and reduction potential, bioenergetics, production of ATP and its biological significance.

Structure and Functions of Proteins:

Amino acids and Peptides, Determination of Primary structure and higher orders of structure.

Enzymes:

Nomenclature, Kinetics ans its Mechanism of action, Mechanism of Inhibition,Isoenzymes, enzymes in technical diagnosis.

Co-enzymes:

Metals as coenzymes and their significance and Vitamins as coenzymes and their significance.

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 nucleotide in biosynthesis, pentosephosphate pathway.

The Citric acid cycle:

The significance, reaction and energetics of cycle, amphibolic role of cycle, Glyoxalic Acid Cycle.

Lipid Metabolism:

Oxidation of fatty acids, Beta Oxidation and energetic, alpha oxidation,omega oxidation, Biosynthesis of Ketone bodies and their utilisation, Biosynthesis of saturated and unsaturated fatty acids and eicosanoids, phospholipids, sphingolipids.

Biological oxidation:

Redox Potential, enzymes and co-enzymes involved in oxidation reduction and its control. The respiratory chain, its role in energy capture and its control, energetic of oxidative phosphorylation, inhibitors of respiratory chain and oxidative phosphyrlation, mechanism of oxidative phosphorylation.

Nitrogen & Sulphur Cycle:

Nitrogen fixation, ammonia assimilation, sulphur activation, sulphate reduction, incorporation of sulphur in organic compounds, release of sulphur from organic compounds

Metabolism of Ammonia and Nitrogen Containing monomers:

Nitrogen balance, biosynthesis of amino acids, catabolism of amino acids, conversion of amino acids to specialized products, assimilation of ammonia , urea cycle, metabolic disorders of urea cycle, metabolism biosynthesis, formation of bile pigment, hyperbilirubinemia, purine biosynthesis, purine nucleotide interconversion, pyrimidine biosynthesis, and formation of deoxyribonucleotides.

Disorders of Carbohydrate, Lipid and Protein Metabolism:

Biomedical Importance and Implications in Clinical Biochemistry. Diagnostic tests for detection of metabolic disorders.

Biosynthesis of nucleic Acids:

Brief introduction to genetic organisation, organisation of mammalian genome, alteration and rearrangement of genetic material, biosynthesis of DNA and its replication, mutation, physical and chemical mutagenesis/ carcinogenesis, DNA repair mechanism, biosynthesis of RNA.

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.

Course Contents

Category of Course	Course Title	Course Code	Credit		
	Pharmaceutical Chemistry-V (Biochemistry) Practical	**PY 404**	L	T	P
			4	0	3

Branch: Pharmacy IV Semester
Course: **PY- 404** Pharmaceutical Chemistry-V(Biochemistry) Practical

PY-404 PHARMACEUTICAL CHEMISTRY-V (BIOCHEMISTRY) PRACTICAL

1. Qualitative and Quantitative chemical examination of Urine ,Blood and Faeces.
2. Food Analysis – Analysis of Milk ,Butter, Flour, Honey and Starch.
3. Systemic analysis of water for pharmaceutical purpose.
4. Seperation of amino acids by two dimensional paper chromatography and gel electrophoresis.
5. Seperation of lipids by TLC.
6. Seperation of Serum protiens by electrophoresis on cellulose acetate.
7. Quantitative estimation of amino acids and proteins.
8. Determination of glucose.
9. Isolation and determination of RNA and DNA.

Books Recommended

1. Martin, D.W., Mays, P.A. and Redwell, V.M., Harper's Review of Biochemistry, Lange medical Publication.
2. Horrow, B. and Mazur, A., Text book of biochemistry, W.B. Saunders Co. Philadelphia.
3. Lehninger, A.L., Principles of Biochemistry, CBS Publishers and Distributors.
4. Lehninger, A.L., Biochemistry, Worth Publishers Inc.
5. Stryer, L., Biochemistry, W.H. Freeman and Co. San Franscisco.
6. Plumer, D.T., An Introduction to Practical Biochemistry, Tata McGraw Hill, New Delhi.
7. Jayaraman, J., Laboratory manual in Biochemistry, Wiley eastern Ltd., New Delhi.

Course Contents

Category of Course	Course Title	Course Code	Credit-4C			Theory Paper (ES)
	Pharmacology-I	**PY 405**	L	T	P	Max.Marks-70
			4	0	0	Duration-3hrs.

Branch: Pharmacy-IV Semester
Course: PY - 405 Pharmacology-I (Theory)

General Pharmacology

a. Introduction to pharmacology, sources of drugs, dosage forms and routes of administration, mechanism of action, combined effects of drugs, factors modifying drug action, tolerance and dependence, pharmacogenetics.

b. Absorption, distribution and excretion of drugs, principle of basic and clinical pharmacokinetics adverse drug reactions and treatment of poisoning, ADME drug interaction, bioassay of drugs and biological standardization, discovery and development of new drugs. Introduction to clinical trials.

Pharmacology of Peripheral Nervous System

a. Neurohumoral transmission (autonomous and somatic)
b. Parasympathomimetic, parasympatholytic, sympathomimetics, sympatholytics, neuron blocking agents.
c. Neuromuscular blocking agents
d. Local anaesthetic agents

Autocoids

a. Histamine, bradykinin 5- HT and their antagonists.
b. Prostaglandins, leukotrienes and platelet activating factors.

Analgesic, Antipyretic, Anti-inflammatory and Anti-Gout Drugs:
Drugs acting on Respiratory System and Pathophysiology of respiratory system:

a. Anti-asthmatic drugs including bronchodilators
b. Anti-tussives and expectorants

Books Recommended

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

Course Contents

Category of Course	Course Title	Course Code	Credit		
	Pharmacology-I	**PY 405**	L	T	P
			0	0	3

Branch: Pharmacy V Semester
Course: **PY 405** Pharmacology-I - Practical

V-P-1 PHARMACOLOGY I PRACTICALS

List of practicals:

1. Introduction to Experimental Pharmacology and various regulatory authorities.
2. Study of common laboratory animals and anesthetics used in animal studies.
3. Study of various routes of drug administration in experimental animals.
4. Preparation of various physiological salt solution and set up of isolated rat ileum preparation.
5. Study the effects of various agonists and antagonists on isolated rat ileum preparation.
6. Plot dose response curve of choline using isolated gunea pig ileum preparation.
7. Plot dose response curve of histamine using isolated guinea pig ileum preparation.
8. Study the effect of autonomic drugs mydriatic and miotic on rabbit eye.
9. Study the effect of local anesthetics on rabbit eye.
10. Study the peripheral analgesic activity of indomethacin using writhing test on mice.
11. Study anti- inflammatory activity of indomethacin using rat paw edema paradigm.
12. Study the neuromuscular effect of d-tubocurarine/ succinyl choline using rotarod apparatus.

Books recommended

1. 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.
2. Satoskar, R.S. and Bhandarkar, S.D., Pharmacology and Pharmacotherapeutics.
3. Tripathi, K.D., Essentials of Medical Pharmcology.
4. Kulkarni, S.K., Handbook of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
5. Crossland, J and Thomson, J.H., Essential of Pharmacology, Harper and Row, Publishers, New York.
6. Craig, C.R. and Stitzel, R.R., Modern Pharmacology, Little Brown and Company.
7. Rang, M.P. , Dale, M.M. and Riter, J.M., Pharmacology, Churchill Livingstone.
8. Paul, L., Principles of Pharmacology, Chamman and Hall.
9. Herfindal, E.T. and Hirschman, J.L., Clinical Pharmacy and Therapeutics, William and Wilkins. Katzung, B.G., Basic and Clinical Pharmacology, Prentice Hall International.