Pharmaceutics-X (Pharmaceutical Technology-II)

(BPH-801)

Unit-I

Granulation Technology

Production of granules on large scale by various techniques, evaluation of granules. Compression and consolidation of powdered solids. Heckel plots. Force displacement (F-D) Curves.

Unit-II

Microencapsulation Techniques

Coating of particles. Fluidized bed and air suspension coating. Phase separation co-acervation, multiorifice centrifugal, spray drying, spray congealing, polymerization complex emulsion techniques. Top bottom and tangential spray coating machines. Evaluation of microcapsules.

Unit-III

Sustained and Controlled Drug Delivery Systems

Concept of sustained release, designing of sustained release products, zero order and first order approximation concept. Matrix and reservoir based techniques. Product evaluation and testing.

Novel Drug Delivery Systems

Transdermal drug delivery systems. Osmotic drug delivery systems. Liposomes and implants.

Unit-IV

Packaging of Pharmaceutical Products

Objective of packaging, packaging components, types, functions, containers and closures, foil and blister packaging. Packaging equipment, legal and official requirements for containers and closures. Package testing.

Unit-V

Pilot Plant Scale-Up Techniques

General considerations, personnel requirements, space requirements, review of formula and raw materials. Processing equipments. Process evaluation. GMP considerations.

Suggested Books:

1. Leon Lachman, Herbert A. Liebermann and Joseph L.Kanig., The Theory and Practice of Industrial Pharmacy.
2. Banker G.S. and Rhodes C.D., Modern Pharmaceutics.
3. Remington's Pharmaceutical Sciences.
4. Aulton M. E., The Science of Dosage Form Design.

LIST OF PRACTICAL'S

1. To perform comparison of the tablet by HPMC and PGs Binders.
2. To perform the punching of tablet by slugging process.
3. To prepare and evaluate the floating tablet of paracetamol.
4. To Perform and evaluate the fast deliver tablet of diclofenac sodium.
5. To prepare and evaluate diclofenac sodium emulgel formulation.
6. To study the effect of various suspending agents on CaCo3 suspension.
7. To perform the dissolution study of given tablet with curve fitting (zero & first order)
8. To prepare and microsphere by pan coating
9. To preparation and Characterization of Paracetamol Loaded Liposomes.
10. To prepare and submit waxes containing microsphere.
11. To perform phase separation coacervation used for microencapsulation (polymer-polymer interaction).
12. To prepare and submit Carbopol gel
13. To stability evaluation of various dosage forms and their expiration dating.
14. To formulation of oral S. R. Products & their evaluation by in-vitro dissolution profile
15. To evaluation of marketed parenteral suspension and emulsion for parameters like particle size, sterility and rheological parameters.
16. To evaluation of given packaging material (Primary & tertiary packaging).
17. To preparation, filling, sealing, sterilization and evaluation of the injections.
18. To formulation and evaluation of transdermal patch of given drug.
19. To prepare and study of TDDS using different polymer.
20. To prepare and submit buccal patches.
21. To prepare & evaluate gastro retentive floating matrix tablet of atenolol.
22. To prepare and evaluate multiple emulsion .
23. To design and evaluation of mucoadhesive buccal film of paracetamol using aluminum foil and mercury casting method.
24. To design and evaluation of diclofenac sodium ocusert.

Pharmaceutics –XI (Pharmaceutical Jurisprudence)

(BPH-802)

Unit-I

An Introduction to Pharmaceutical Jurisprudence

Review of Indian regulatory legislations for drug and pharmaceutical industries, and Pharmaceutical education.

Unit-II

An Elaborated Study of the Following

A. Medicinal and Toilet Preparations (Excise Duties) Act 1955.
B. Pharmacy Act 1948.
C. Drugs and Cosmetics Acts 1940 and Rules 1945.
D. Narcotic Drugs and Psychotropic Substances Act 1985 and Rules.
E. Patent Act 1970.
F. Essential Commodities and Drug Price Control Order.

Unit-III

A Brief Study of the Following

A. Medical Termination of Pregnancy Act 1970 and Rules 1975.
B. AICTE Act 1987.
C. Prevention of Cruelty to Animal Act 1960.
D. Poison Act and rules.
E. MRTP Act.

Unit-IV

A Brief Study of the Following

A. Minimum Wages Act 1948.
B. State Shops and Establishment Act and Rules.
C. Factories Act 1948.
D. Insecticides Act 1968.
E. Drugs and Magic Remedies Act (Objectionable Advertisement Act 1954).

Unit-V

A Brief Study of the Following

A. Various prescription and non-prescription products.
B. Medical and surgical accessories.
C. Diagnostic aids and appliances marketed in India.

Suggested Books:

1. Jain N. K., A Textbook of Forensic Pharmacy.

2. Mittal, B.M., A Textbook of Forensic Pharmacy.

3. Malik V., Drug & Cosmetic Act.

4. The Gazette of India. The Drugs and Cosmetics act and rules.

5. The Gazette of India. The Patent act 1970 and its latest amendments.

PHARMACEUTICAL ANALYSIS-III

(BPH- 803)

Unit-I

Assay of Pharmaceutical Dosage Form

1. Analytical Method Development: Development of new analytical methods for bulk drugs and dosage forms using titrimetry, UV/visible spectrophotometry and HPLC.
2. Development of analytical methods for combination drug products, derivative spectrophotometric methods.
3. Development of stability indicating assay procedures. Drug analysis in biological fluids like blood plasma and urine.

Unit-II

Validation of Analytical Methods and Instruments

1. Validation of analytical methods: Parameters of validation, Pharmacopoeial requirements of analytical method validation.
2. Validation of analytical instruments: UV/visible spectrophotometer and HPLC as per Indian Pharmacopoeia.

Unit-III

ICH, GMP, cGMP and GLP in Pharmaceuticals

1. ICH guidelines for impurities in drug substances and drug products, Residual solvents.
2. Good Manufacturing Practices, c-GMP, Good Laboratory Practices.

Unit-IV

Quality Control in Pharmaceuticals

1. Quality control testing: Dosage form evaluation as per monograph with special reference to Indian Pharmacopoeia.

Unit-V

Assay of Active Pharmaceutical Ingredients and Water

1. Drug identification test, drug content and assay, content uniformity.
2. Sampling considerations.
3. Water analysis: Validation and qualification of water purification systems. Total organic carbon, pH, and conductivity test. Moisture content analysis in drug and dosage forms.

Suggested Books:

1. Indian Pharmacopoeia, 2007.
2. Current ICH guidelines.
3. Vogel's, Quantitative Inorganic Analysis.

LIST OF PRACTICAL'S

1. Quantitative estimation of at least ten formulations containing single drug or more than one drug, using instrumental techniques.
2. Estimation of Na+, K+, Ca++ ions using flame photometry.
3. IR of samples with different functional groups (-COOH, -COOR. _ CONHR; - NH2, -NHR, -OH, etc.).
4. Workshop to interpret the structure of simple organic compounds using UV, IR. NMR and MS.

Packaging Technology (Elective-I)

BPH-804 (A)

Unit-I

Packaging Material Science

Basic materials used in packaging, their properties, method of manufacturing and applications-Paper, Plastics, Glass, Metal, and Elastomers. Containers and closures: Introduction and applications of Glass containers, Plastic containers, Collapsible tubes, Plastic tubes, Aerosol containers, Closures, Liners, and Rubber stoppers.

Unit-II

Quality Control and Quality Assurance of Packaging Materials

Detection of defects in packaging materials, Quality testing of formed packs, Quality testing of containers and closures, testing of child resistance and temper evidence property of packaging materials. Quality control tests for containers and closures as per Indian Pharmacopoeia.

Unit-III

Tamper Resistant and Child Resistant Packages

Introduction, method of preparation, and applications of Blister and Strip packs, Film Wrappers, Bubble packs, Shrink seals, Sachet and Pouches, Tape seals, Breakable caps, Sealed tubes, Aerosol containers, etc. Introduction and applications of Form-Fill-Seal (FFS) technology.

Unit-IV

Legal and Regulatory Requirements

Requirements of labels and labeling as per Drug & Cosmetics act and rules. Product / patient information literatures. Regulatory aspects of storage, handling and distribution of packaging materials with special emphasis on Cgmp and cGLP requirements.

Unit-V

Packaging as a Marketing Tool

Market Considerations – Importance of Demography & Psychography, Retail Market (POP), Equity & Brand Name; Package Embellishment – Graphic Design Elements – Significance of Shape, Size,

Colour, Font, Texture, Lines, Balance & Unity, Symmetry & Harmony; Shelf Appeal Studies - Recall Questioning, Focus Group, Eye-Tracking, S-scope studies.

Suggested Books:

1. Drug and Cosmetic Act and Rules.
2. Dean, D.A.; Evans, E.R.; and Hall I.H., Pharmaceutical Packaging Technology.
3. Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig, The Theory and Practic of Industrial Pharmacy.

Drug Discovery and Development (Elective –I)

BPH-804 (B)

Unit-I

Drug Discovery

Historical perspective, Drug discovery without a lead like penicillin and Lead discovery, Lead modification approaches, Identification of the active part; Pharmacophore, Functional group modification, Privileged structure and drug like molecules, Structure modification to increase potency and therapeutic index, Structure modification to increase Oral Bioavailability.

Unit-II

Drug Receptor Interactions

Theories of drug-receptor interactions, Membrane and Receptor- Structure, Functions and the mechanism of drug action (Receptor Response), Design of agonist and antagonists, Receptor theories, Models and their types.

Unit-III

Molecular Modeling Software

Introduction to molecular modeling software, brief information on academic freeware and commercial software and their applications in drug discovery.

Unit-IV

Computers Aided Drug Design

Basic concept of Computational chemistry like Quantum Mechanics, Molecular Mechanics, Force fields, Energy minimization, Conformational search, Molecular dynamics, SBDD(Structure Based Drug Design) LBDD (Ligand Based Drug Design), analog approach, pharmacophore mapping, Molecular-modeling and Virtual screening.

Unit-V

Quantitative Structure Activity Relationship

Free Wilson analysis**,** Hansch analysis, Physicochemical properties, Craig Plot, Application of Hansch analysis, Statistical methods in QSAR

Introduction to Bioinformatics and Structural Biology

Knowledge of various databases and bioinformatics tools available at these resources, the major content of the databases like Nucleic acid databases and Protein databases. Current advancements in bioinformatics, introduction to system biology, structural biology, structural bioinformatics. Applications of bioinformatics and system biology in drug discovery.

Suggested Books:

1. Comprehensive Medicinal Chemistry Vol-I (Hansch (1990) Pergamon pres.
2. Principle of Drug action-Goldstein.
3. Introduction to medicinal Chemistry, III Edn. Patrick (2001) Oxford
4. Organic Chemistry of Drug Design and Drug Action. R.B.Silverman (1993)Academic
5. Medicinal Chemistry Vol. I Burger.
6. Molecular Modeling, Principles and applications -Andrew Leach(Longman) 1998.
7. Statistical MethodS in Biology-Norman Bailey(1995) Cambridge.
8. Introduction to Bioinformatics by Aurther M lesk

Food and Nutraceutical Technology (Elective –I)

BPH-804 (C)

UNIT-I

Functional Foods and Nutraceuticals

Sources and role of Tocotrienols, polyunsaturated fatty acids, sphingolipids, lecithin, choline, terpenoids. Vegetables, Cereals, milk and dairy products as Functional foods.

UNIT-II

Nutrition

Nutritive and Non-nutritive food components with potential health effects. Effect of processing on Nutrients. Soy proteins and soy isoflavones in human health; Functional foods from wheat and rice and their health effects. Role of Dietary fibers and nuts in disease prevention. General ideas about role of Probiotics and Prebiotics as nutraceuticals.

UNIT-III

Nutraceuticals

Properties, structure and functions of various Nutraceuticals: Glucosamine, Octacosanol, Lycopene, Carnitine, Melatonin and Ornithine alpha ketoglutarate. Use of proanthocyanidins, grape products, flaxseed oil as Nutraceuticals.

UNIT-IV

Food Processing and Preservation

(i) General principles and techniques of food processing and food preservation, shelf life of food and nutraceutical products. Food stability: methods to enhance stability- freezing, lyophilization, and air drying techniques.

(ii) Methods of food preservation, approved preservatives, Radiation and food preservation: Role of radiation in food preservation. Principles underlying destruction of micro-organisms by irradiation. Effect of irradiation on food constituents. Legal status of food irradiation.

(iii) Contamination and microbial spoilage of food products: Milk and milk products, eggs and poultry, fish, breads and cereals, meat, canned foods, vegetables and fruits. Food borne infections and intoxications.

UNIT-V

Regulatory Affairs

(a) Regulatory aspects of food and nutraceutical products. The prevention of Food Adulteration ct 1954, The Food Safety & Standards Act, 2006.

(b) Regulatory certifications: FPO regulations, Manufacturing guidelines, Manufacturing and

Marketing licenses, AGMARK, Green Label certification, Organic food certifications.

Suggested Books:

1. Nutraceuticals by L. Rapport and B. Lockwood, Pharmaceutical Press.

2. Food packaging principals and practice, Gordon L. Robertson, Marcel and Dekker

3. Essentials of Food and Nutrition by Swaminathan M., Ganesh and Co, 1985

4. Dietary Supplements of Plant Origin, M. Maffei (Ed.), Taylor & Francis, 2003 Handbook of Nutraceuticals and Functional Foods Edited by Robert E.C. Wildman, Routledge Publishers.

Perfumes and Colours (Elective –II)

BPH-805 (A)

UNIT-I

Perfumes

Historical background & present scenario of perfumery industry. Definition of odor, its classification. Definition of perfumes, attars, cologne, deodorants, aromatic waters. Chemical classification of perfumes obtained from plant and animal sources.

UNIT-II

Essential Oils

Introduction, study of various physical and chemical properties of essential oils. Study of various isolation methods of essential oils. Formulation of perfumes, formulation excipients, manufacturing methods of perfumes, deodorants, colognes, and aromatic waters. Regulatory considerations: Analysis & standardization of perfumes. Toxicological aspects of use of perfumes, safety study of perfumes on naked skin including various dermatological tests

UNIT-III

Colours

Definition of colour, lake, dye, pigment. Theory of color formation at molecules level including Hund's Rule of multiplicity volume band approach & molecular orbital approach to colour. Detailed classification of colour obtained from natural sources like plant & animal sources, colours obtained from mineral sources, synthesis colours, dyes & pigments. FDA classification of colours. Various physiochemical properties of dyes & colours.

UNIT-IV

Manufacturing of Colors

Manufacturing methods of colours, dyes, lakes, and pigments. Regulatory aspects of use of colours in drug and cosmetics as per schedule Q of Drug and Cosmetic Act. Analysis of colours using instrumental methods & chromatographic methods.

UNIT-V

Application of Perfumes

Applications of perfumes and colours in various cosmetics like skin, nail, and hair cosmetics, toiletries etc.

Suggested Books:

1. Sagarine, Cosmetic Science and Technology, Vol. 1-4.

2. Harry's Cosmetology.

3. The Chemistry and Manufacture & Cosmetics, Vol. IV - Mainson G. De. Nawarre.

4. Colour and Cosmetic colour material - New Cosmetic Science - Mitsui.

5. The Cosmetic Industry - edited by Norman Scientific & Regulatory foundation - F.Estrin.

Clinical Research (Elective –II)

BPH-805 (B)

UNIT-I

Introduction

Clinical pharmacy, duties and activities of a clinical pharmacist in hospital, monitoring of pharmacotherapy (patient chart review, medication counseling, clinical out put review), ward round participation, patient relevant history (dieses and medication), prescriptions,

drug prescribing guidelines, therapeutic drug monitoring.

UNIT-II

Patient data analysis

Introduction to common medical terminologies and abbreviation used in clinical pharmacy. Patient case history & case history formats, use of case history in evaluation of drug therapy.

UNIT-III

Clinical Laboratory Tests

Interpretation of laboratory tests used in evaluation of disease state. Tests for hormones, body organ function, blood, urine, microbial culture, etc.

UNIT-IV

Drug and Poison Information

Introduction to information resources and institutes, systemic approach in answering drug information queries, preparation of reports. Detection and assessment of adverse drug reactions and their documentation.

Clinical Pharmacokinetic

Individualization of drug therapy, introduction to clinical pharmacokinetics models, determination of drug clearance and volume of distribution, renal and

non-renal clearance, hepatic clearance.

UNIT-V

Clinical Trial

Designs of clinical trials, Good clinical practices (ICH & GCP guideline for safety and efficacy), Institutional Ethical Committee and its function. Various phases of clinical trials, introduction to monitoring and auditing of clinical trials. Basic concepts of biostatistics.

Clinical Research Organization

Organizational structure, present status and future prospects of clinical research organizations in India.

Suggested Books

1 Hefindal, E. T., Clinical Pharmacy & Therapeutics-. Williams & Wilkins.

2 Katzung, B., Basic and Clinical Pharmacology, Lange Medical Publication, California

3 Laurence D.R. and Bennet, P.N., Clinical Pharmacology, Churchill Livingstone

4 Walker, R. & Edwards, C., Clinical Pharmacy & Therapeutics, Churchill Livingston

5 DiPiro, J.T. et.al., Pharmacotherapy a pathophysiological approach, McGraw-Hill companies, Inc.

6 Green and Harris, Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Chapman and Hall Publications.

Herbal Drug Technology (Elective –II)

BPH-805 (C)

UNIT-I

Introduction

Definition, source of herbal raw materials, identification, authentication, Collection and processing of herbal drugs. Seasonal & geographical variations, natural & artificial drying methods. Packaging & labeling of herbal drugs prior to extraction.

UNIT-II

Standardization Techniques

WHO guidelines for assessing quality of herbal medicine. Analysis of raw herbal extracts and their formulation using TLC, HPTLC, GC, HPLC, UV& IR techniques.

UNIT-III

Regulatory Requirements for Herbal Medicine Industries

Infrastructure, Quality control, safety and stability, import and export of herbal products. Analytical Pharmacognosy – drug adulteration and detection.

UNIT-IV

Plant Tissue Culture Techniques & its Application in Pharmacy

Introduction, techniques of initiation and maintenance of various types of cultures for industrial level production of phyto- constituents. Immobilized cell techniques & biotransformation studies including recent evelopments in production of biological active constituents in static, suspension and hairy root cultures. Brief account of plant based industries of India and world involved in R & D work on medicinal and aromatic plants and manufacturing herbal medicine.

UNIT-V

Herbal Formulations

Principles of Ayurveda, Ayurvedic dosage forms and their evaluation as per Ayurvedic pharmacopoeia. Formulation considerations of herbal infusion, decoction, lotion, washers, insect repellents, tincture, syrups, compresses, poultice, plasters, ointments, oils and salves, tablets and capsules.

Suggested Books:

1. Herbal Drug Technology by S.S. Agrawal & M. Paridhavi.

2. Modern Methods of Plant Analysis by Peach & Tracey

3. Biotechnology by S.S. Purohit.

4. Pharmacognosy by C.K. Kokate, A.P. Purohit and S.B. Gokhale

5. The Ayurvedic Pharmacopoeia of India