# **SEMESTER - VIII**

## **PHARMACEUTICS-VII**

(Pharmaceutical Technology III)

### PH. 8.1 THEORY

3 hours / week

#### UNIT -I 1.

### Preformulation studies: Principal areas like

- a. Bulk Characterization: Crystallinity and Polymorphism, hygroscopicity, bulk density, powder flow properties.
- b. Solubility analysis: pKa, pH solubility profile, Common ionic effect, thermal effects, solubilization, partition coefficient and dissolution.

#### UNIT -II

2. Sustained release formulations: Concept, Rationale for Extended – Release Pharmaceuticals, Terminology, Techniques of Extended – Release oral dosage forms, Delayed - Release oral dosage forms, Evaluation of sustained release formulations.

#### UNIT -III

Brief introduction to controlled release dosage forms.
 Design and evaluation of transdermal drug delivery systems.
 Basic concepts of liposomes, nanoparticles, resealed erythrocytes, osmotic pump, implants, IUDs and ocuserts,

#### UNIT -IV

4. Cosmetics: Fundamentals of cosmetic science, Formulation, preparation and packaging of cosmetics like anti-perspirants & deodorants, creams, lotions, shampoos, hair conditioners & dyes, nail polish and lipsticks. Special formulation considerations for baby care products.

# PHARMACEUTICS-VII

#### (Pharmaceutical Technology III)

## PH. 8.2 PRACTICAL 3 hours / week (A minimum of 15 experiments shall be conducted)

- 1. Solubility enhancement by different techniques (at least 2).
- 2. Dissolution testing and data evaluation for oral solid dosage forms.
- 3. Determination of pharmacokinetic parameters from the given plasma drug concentration time and urinary excretion data.
- 4. Preparation (at least 6) and evaluation (at least 2) of cosmetic products.

- 1. The Theory and Practice of Industrial Pharmacy by Lachmann, Libermann and Kanig
- 2. Pharmaceutical Dosage Forms and Drug Delivery Systems by Ansel, Allen and Popovich
- 3. REMINGTON : The Science and Practice of Pharmacy, 20<sup>th</sup> Edition
- 4. Pharmaceutics : The Science of Dosage Form Design by Aulton
- 5. Bently's Textbook of pharmaceutics edited by E.A. Rawlins

# **CLINICAL PHARMACY & THERAPEUTICS**

### PH.8.3 THEORY

#### 3 hours/week

#### UNIT -I

- **1.** Introduction to Clinical Pharmacy
- 2. Basic concepts of Pharmacotherapy:
- **3.** The Basics of Drug Interactions with suitable examples: Pharmacokinetic drug interactions, pharmacodynamic drug interactions, food and drug interactions, alcohol and drug interactions

#### UNIT -II

4. Important disorders of organ systems and their management: Cardiovascular Disorders – Hypertension, Congestive Heart, Failure, Angina, Acute Myocardial infarction, Cardiac arrhythmias, CNS Disorders : Epilepsy Parkinsonism, Schizophrenia, Depression Respiratory Diseases – Asthma Gastrointestinal Disorders – Peptic ulcer, Ulcerative colitis, Hepatitis,

Cirrhosis

Endocrine Disorders - Diabetes mellitus and Thyroid Disorders.

#### UNIT – III

Infectious Diseases – Tuberculosis, Urinary Tract Inflection, Enteric inflections, Upper Respiratory Inflections

Haematopoietic Disorders – Anemias

Joint and Connective Tissue Disorders – Rheumatic Disease, Gout and Hyperuricemia Neoplastic Diseases – Acute Leukemias, Hodgkin's diseases

#### UNIT -IV

- 5. Therapeutic Drug Monitoring.
- 6. Concept of Essential Drugs and Rational Drug use.
- 7. Adverse drug reactions and approaches to minimize them

#### **RECOMMENDED BOOKS:**

- 1. Remington the Science and Practice of Pharmacy
- 2. Clinical Pharmacology by Laurence, Bennett and Brown
- 3. Medical diagnosis and treatment by Tierney, Mc phee and Papadakis

- 4. Clinical Pharmacy & Therapeutics by Roger Walker, Edwards.
- 5. Clinical Pharmacy and Therapeutics by Herfindal, Gourley and Lloyd Hart.
- 6. Physiological basis of Medical Practice by John B. West
- 7. Drug Interactions by Ivan Stockley

### **QUALITY ASSURANCE & GMP**

#### PH. 8.4 THEORY

#### 3 hours/week

#### UNIT -I

1. Good Manufacturing practices: GMP and cGMP and salient features of Drugs & Cosmetics Act & Rules with reference to manufacture of drugs in India.

#### UNIT -II

2. Pharmaceutical Validation: Validation of Water systems for sterile & Non Sterile products, cleaning validation, process validation, Equipment validation, Analytical method validation.

#### UNIT -III

- 3. Quality Assurance with reference to organization, personnel, Building & facility equipment, Product Control, ware housing, Returned goods & reprocessing, Documentation.
- 4. Introduction to SOP, TQM, ISO and IPR.

#### UNIT -IV

- 5. Drug Regulatory Affairs: Role of Regulatory Affairs Dept, Nomenclature and salient features of regulatory authorities of India, US, Japan and EU.
- 6. Stability testing protocols of drug products as per ICH guidelines.

#### **RECOMMENDED BOOKS:**

- 1. Pharmaceutical Process Validations Ira R.Berry, Robert A.Nash
- 2. GMP P.P.Sharma
- 3. Quality Assurance Manual D.H.Shab Business Hortzons
- 4. Quality Assurance for Pharmaceuticals Vol-I&II-Pharma Book Syndicate
- 5. SOP Guidelines D.H.Shab Business Horizons

# PHARMACEUTICAL MANAGEMENT

#### PH. 8.5 THEORY

#### 3 hours/week

#### UNIT – I

**1. Concept of Management:** Administrative management (Planning, Organizing, Staffing, Directing and Controlling), Entrepreneurship development, Operative Management (Personnel, Materials, Production, Financial, Marketing, Time/space,

Margin/Morale). Principles of Management (Co-ordination, Communication, Motivation, Decision-making, leadership, innovation, creativity, delegation of authority/responsibility and record keeping) Identification of Key points to give maximum thrust for development and perfection.

## UNIT – II

- 2. Accountancy: Principles of accountancy, Ledger posting and book entries, Preparation of trial balance, columns of a cash book, bank reconciliation statement, rectification of errors, profits and loss account, balance sheet, purchase, keeping and pricing of stocks, treatment of checks, bills of exchange, promissory notes and hundies, documentary bills.
- **3.** Economics: Principles of economics with special reference to the laws of demand and supply, demand schedule, demand curves, labour welfare, general principles of insurance, inland and foreign trade, procedure of exporting and importing goods.

### UNIT – III

- **4. Pharmaceutical Marketing:** Function, buying, selling, transportation, storage, finance, feedback, information, channels of distribution, wholesale, retail, departmental store, multiple shop and mail order business.
- **5. Salesmanship:** Principles of sales promotion, advertising, ethics of sales, merchandising, literature & detailing. Recruitment, training, evaluation and compensation to the pharmacist.
- 6. Market research: Prerequisites, Basic information services.

#### UNIT – IV

- 7. Materials management: A brief exposure to the basic principles of materials management, purchase, stores & inventory control and evaluation of materials management.
- 8. Production Management : A brief exposure of the different aspects of production management (Visible & Invisible) inputs, methodology of activities, performance evaluation techniques, process flow, process know how and maintenance management.

#### **RECOMMENDED BOOKS:**

1. M. J. Etazel , B. J. Walker and W. J. Stanton, Marketing, Tata McGraw Hill, 13<sup>th</sup> Edition, 2004.

2. R. Saxena, "Marketing Management" Tata McGraw Hill, second Edition, 2003.

PH. 8.6	ELECTIVE – II
PH. 8.7	ELECTIVE – II PRACTICAL
РН. 8.8	COMPREHENSIVE VIVA-VOCE
РН. 8.9	PROJECT REPORT & VIVA-V0CE

#### **ELECTIVES**

(To be chosen one each against papers PH. 7.7, PH. 7.8, PH. 8.6 and PH. 8.7)

## **COSMETIC TECHNOLOGY**

#### PH. E.1 THEORY

#### 3 hours/week

UNIT –I
1. Fundamentals of cosmetic technology, classification of cosmetics, A brief study of raw materials used for Cosmetic preparations: surfactants, humectants, cream bases, aerosol propellants, perfumes, colours.

#### UNIT -II

- 2. Stability aspects of cosmetics: Shelf-life, effects of environmental factors like light, temperatures etc on product stability.
- 3. Quality control tests of different cosmetic products, Packaging of Cosmetics

#### UNIT -III

- 4. Hair Care Products: Hair structure, Shampoos, Conditioners, Setting lotion, Hair creams, Hair dyes.
- 5. Skin Care Products: Anatomy and physiology of skin, formulation of skin cleaners, moisturizers, sunscreen products, acne products, anti ageing creams.

#### UNIT -IV

**PH. E.2** 

- 6. Colour Cosmetics: Introduction, lip colour, nail polish, face make-up eye make-up.
- 7. Dental products: Dentifrices, Oral rinses, Tooth powder, Tooth paste.
- 8. Personal Hygiene Products: Shaving creams, after shave products.

## **COSMETIC TECHNOLOGY**

3 hours/week

# (A minimum of 15 experiments shall be conducted)

- 1. Preparation of selected cosmetic preparations representing the following classes:
  - a) Shampoos
  - b) Hair conditioners

PRACTICAL

c) Hair creams

- d) Skin creams
- e) Nail polish
- f) Face powders
- g) Tooth pastes
- h) Tooth powder
- i) Shaving cream
- j) After shave lotion
- 2. Evaluation of any two products mentioned above
- 3. Collection of various packaging materials used for cosmetics and their description (Each student shall collect at least 10 different types of containers.)

- 1. Cosmetics: Formulation, manufacturing, and Quality control by P.P.Sharma
- 2. A Handbook of Cosmetics by B.M. Mithal, R.N. Saha
- 3. The Theory and Practice of Industrial Pharmacy by Lachman L., Liberman, H.A.
- 4. Modern Cosmetics by Thomson, E.G.
- 5. Paucher's Perfumes, cosmetics & soaps by W.A.Paucher.
- 6. Hary's cosmeticology by J.B.Wilkimsson.

# HERBAL DRUG TECHNOLOGY

## PH. E.3 THEORY

#### 3 hours/week

#### UNIT -I

Definition of Herbal drug, Importance of Herbal therapies, Herbal verses conventional drugs, Safety in herbal drugs, Toxicity in Herbals and their interactions.

#### UNIT -II

Herbs used as nutraceuticals and healing agents Herbal cosmetics.

#### UNIT -III

Making and using herbal medicines for common ailments like cold, skin infections and diarrhoea.

Analytical Profiles of selected herbs – Brahmi Aradrographis paniculata, Aegle marmelos and Gymnema sylvestre.

#### UNIT -IV

Quality Control and Quality Assurance of Herbal ingredients as per W.H.O. guidelines – Determination of tannins, Ash value, Extractable matter and Pesticide residues.

# HERBAL DRUG TECHNOLOGY

# PH. E.4 PRACTICAL 3 hours/week (A minimum of 15 experiments shall be conducted)

- 1. Identification of sugar from plant extracts
- 2. Preparation of plant extracts and their standardization by analytical profiles (any five)
- 3. Quality Control tests for raw materials used in Herbal preparation

- 1. Trease and Evan's Pharmacognosy 15<sup>th</sup> edition
- 2. Indian Herbal Pharmacopeia Vol-I and II
- 3. Quality Control methods for medicinal plant material by W.H.O., Geneva.
- 4. Quality Control of Herbal drugs by Dr. Pulak K. Mukherjee
- 5. Botanical safety hand book by Michael Meguffin, Christopher Hobbs published by American Herbal Product Association.
- 6. Herbal drugs by P.Mukherjee

## BIOASSAYS

#### PH. E.5 THEORY

#### 3 hours/week

#### UNIT -I

Definition, principles, and design of Bioassays. Requirements applications, importance advantages and disadvantages of Bioassays

#### UNIT -II

Types of Bioassay (quantal and graded response Bioassys), Bioassay of agonists and antagonists, Biological variation, Biological standardization, Microbiological assay (antibiotics, vitamin B12), Bioassay in Humans

#### UNIT -III

Bioassay of some important drugs like Digitalis, Adrenaline, Noradrenaline, acetylcholine, Histamine, 5-hydroxy tryptamine, d-tubocurarine, Heparin, antibiotics, Vitamin-D,

#### UNIT -IV

Bioassay of Insulin, Oxytocin, Vassopressin, Growth Hormone, FSH, LH, Prolactin, Thyrotrophin, Corticotrophin, Androgen, Progesterone, Estrogen.

## BIOASSAYS

PH. E.6 PRACTICAL 3 hours/week (A minimum of 15 experiments shall be conducted)

- 1. To find out the strength of the given sample of acetylcholine by comparative bioassay using rectus abdominis muscle of frog.
- 2. To find out the strength of the given sample of acetylcholine by interpolation bioassay using rectus abdominis muscle of frog.
- 3. To find out the strength of the given sample of acetylcholine by three-point bioassay using rectus abdominis muscle of frog.
- 4. To find out the strength of the given sample of acetylcholine by four-point bioassay using rectus abdominis muscle of frog.
- 5. To find out the strength of the given sample of d-tubocurarine by graphical bioassay using rectus abdominis muscle of frog.
- 6. To find out the strength of the given sample of acetylcholine by four-point bioassay using guinea pig ileum.
- 7. To find out the strength of the given sample of histamine by four-point bioassay using guinea pig ileum.
- 8. To find out the strength of the given sample of oxytocin by four-point bioassay using rat uterus.
- 9. To find out the strength of the given sample of 5-hydroxy tryptamine by four-point bioassay using rat fundus.
- 10. To find out the strength of the given sample of 5-hydroxy tryptamine by comparative bioassay using rat fundus.

- 1. Sharma, H.L.; Sharma, K.K. General Pharmacology Basic Concepts
- 2. Barar, F.S.K. Essentials of Pharmacotherapeutics
- 3. Rang, H.P.; Dale, M.M.; Ritter, J.M.; Moore, P.K. Pharmacology
- 4. Satoshkar, R.S.; Bhandarkar, S.D.; Ainapure, S.S. Pharmacology and Pharmacotherapeutics
- 5. Sharma, V.N. Essentials of Pharmacology
- 6. Derasari and Gandhi's Elements of Pharmacology
- 7. Remington's Pharmaceutical Sciences
- 8. Indian Pharmacopeia
- 9. Pillai, K.K. Experimental Pharmacology
- 10. Kulkarni, S.K. Hand Book of Experimental Pharmacology

# HOSPITAL PHARMACY ADMINISTRATION

## PH. E.7 THEORY

#### UNIT -I

- **1.** The role of hospital pharmacy department and its relationship to other hospital departments and staff.
- 2. Hospital drug policy Drug Committee, formulary and guidelines, other hospital committees such as infection control committee and research & ethics committee.

## UNIT -II

**3.** Hospital Pharmacy management – Staff (Professional and non-professional), Materials (drugs, non-drugs consumables), Financial (drug budget, cost centers,

## 3 hours/week

Planning infrastructure requirements (building, furniture and fitting, specialized Eq1uipment, maintenance and repairs), Work load statistics, Hospital formulary.

4. Organization of Hospital Pharmacy Services,

## UNIT -III

**5.** Drug Distribution: Purchasing, warehousing (Storage conditions, expiry date control, recycling of drugs, stock-taking, drug recalls), Drug distribution methods (ward stock, individual patient dispensing, unit doses), specific requirements for inpatients, causality / emergency theatre, ICU/ICCU, Drugs of dependence.

## UNIT -IV

**6.** Manufacturing: Sterile and non sterile production, including total parenteral nutrition, IV additive service, Pre-Packing and labeling Quality control.

# HOSPITAL PHARMACY ADMINISTRATION

# PH. E.8PRACTICAL3 hours/week(A minimum of 15 experiments shall be conducted)

- 1. Experiments based on sterilization of various types of materials used in Hospitals.
- 2. Practicals designed on the use of computers in Drug information Centre,.
- 3. Prescription filling documentation of information of drug interaction.
- 4. Manufacture of LVP used in hospitals.
- 5. Observing Drug distribution pattern in a local hospital and writing report.
- 6. Any other experiments to Substantiate theory.

## **RECOMMENDED BOOKS:**

- 1. Hospital Pharmacy-Hassan WE, Lec and Febiger Publication ., 1999.
- 2. Text book of Hospital Pharmacy-Allowood MC and Blackwell, 1980, 1<sup>st</sup> ed.
- 3. Avery's Drug Treatment, 4<sup>th</sup> edition, Adis international limited
- 4. Managing Drug Supplt-2<sup>nd</sup> Edition, Management Sciences for health, Kumarian press, 1997.

# ADVANCED PHARMACEUTICAL ANALYSIS

#### PH. E.9 UNIT -I

- 1. Theory, instrumentation and applications of the following Instrumental Methods of Analysis.
  - (i) X-ray fluorescence spectrometry
  - (ii) X-ray diffraction

THEORY

- (iii) Electron spin resonance spectroscopy (ESR)
- (iv) Advanced chromatographic techniques like super critical fluid chromatography, size exclusion chromatography.

3 hours/week

(v) Differential scanning calorimetry, Differential thermal analysis and Thermal gravimetric analysis,

### UNIT - II

- **2.** Theory and procedure involved in the qualitative and quantitative analysis of pharmaceutical properties and dosage forms containing the following drugs: (Biological and microbiological method excluded).
  - NSAID Analgesics and antipyretics (Diclofenac sodium, Ketoprofen, Oxyphenebutazone, Paracetamol, Allopurinol, Aspirin + Caffeine)
  - Barbiturates (Phenobarbitone sodium)
  - Steroids (Nandrolone, Cortisone acetate, Fludrocortisone acetate, Prednisolone, Dexamethasone)
  - Antihistaminics (Mepyramine maleate, Chlorpheniramine maleate, promethazine hydrochloride, Cyclazine hydrochloride, Astemizole)
  - Alkaloids (Codeine, Opium, Vincristine, Ergotamine and Ergometrine)

#### UNIT -III

- 3. Theory and procedure involved in the qualitative and quantitative analysis of pharmaceutical properties and dosage forms containing the following drugs: (Biological and microbiological method excluded).
  - Antibiotics (Cycloserine, Chloramphenicol, Ampicillin, Rifampicin, Cefotaxim sodium)
  - Vitamins (Riboflavin, Nicotinamide, Pyridoxine hydrochloride, Folic acid, Cyanocobalamine)
  - Cardiovascular agents (Digoxin, Isosorbide dinitrate, nifedipine, Verapamil hydrochloride, Propranolol hydrochloride, Timolol maleate, Atenolol)
  - Hypoglycaemic agents (Insulin and its different forms, Chlorpropamide, glibenclamide, Metformine)
  - Sulphonamides (Sulphadiazine, Sulphamethoxazole, Sulphacetamide)

## UNIT - IV

- **4.** Theory and procedure involved in the qualitative and quantitative analysis of pharmaceutical preparations and dosage forms using the following reagents / reactions.
  - (i) Diazotisation followed by coupling.
  - (ii) Oxidation followed by complexation.

(iii) Condensation reactions using the reagents Para Dimethyl Amino Benzaldehyde (PDAB), Folin's reagent, Gibb's reagent and para Dimethyl Amino Cinnamaldelyde (PDAC) reagent.

#### ADVANCED PHARMACEUTICAL ANALYSIS

# P.H. E.10 PRACTICAL 31 (A minimum of 15 experiments shall be conducted)

3 hours/week

1. Estimation of following classes of drugs using different analytical methods.

NSAID - Analgesics and Antipyretics. Barbiturates. Sulphonamides. Antibiotics. Steroidal hormones Vitamins Alkaloids Cardiovascular drugs Hypoglycaemic agents Antihistaminics

2. Estimation of different classes of drugs using the following reagents.

- (i) Feric chloride.
- (ii) Perchloric acid.
- (iii)2-6 Dichlorophenol indophenol.

Instrumental methods of analysis by Scoog and West. Chemical Analysis – Modern Instrumentation methods and techniques by Wiley.

Instrumental methods of analysis by Willard Den & Merrit.

Hand book of Instrumental techniques for analytical chemistry edited by Frank Settle by Prentice Hall Inc.

A text book of Pharmaceutical analysis by K.A.Conners (John Wiley) Spectrometric identification of organic compounds by silverstein (7<sup>th</sup> Edition) 1981. IP.BP.USP.

# PHARMACY PRACTICE

#### PH. E.11 THEORY

#### 3 hours/week

#### UNIT-I

Rational use of drugs: Problems of irrational drug use, prescribing indicators, patient care indicators, health facility indicators, role of pharmacist in promotion of rational use of drugs.

Essential drugs concept, selection, quantification, procurement and distribution of essential drugs, WHO model list of essential drugs, Pharmaceutical policy

#### UNIT-II

Pharmacoepidemiology, Pharmacoeconomics: types of health economic evaluations Therapeutics in practice – decision making in drug therapy

#### UNIT-III

Drug Information system:Introduction to drug information resources, Drugs and poisons information, design of literature searches, development of a drug and poison information database, emergency treatment of poisoning.

#### UNIT-IV

Public health policy and Health care system.

#### **RECOMMENDED BOOKS:**

- 1. Role of Pharmacist in the Health care system, WHO/ PHARM/94.569
- 2. Remington's sciences and practice of Pharmacy; 20<sup>th</sup> edition Lippin cott. Williams and Welkens.
- 3. Medicare scenario in India; Perceptions and Perspectives Delhi society for promotion of rational use of drugs.
- 4. WHO publications on essential drugs and medicines.
- 5. Relevant review articles from recent medical and pharmaceutical journals

# PHARMACY PRACTICE

## PH. E.12 PRACTICAL 3 hours/week (A minimum of 15 experiments shall be conducted)

- 1. Patient medication history, interview, answering drug information questions, patient medication counseling, participation in ward rounds. Case studies related to laboratory investigations covering the topics dealt in theory classes.
- 2. The students are required to be posted in various clinical wards for their exposure with therapeutic management and other clinical aspects. There will be tutorial and case presentation in various clinical conditions.