15CBPH81 PHARMACEUTICAL ANALYSIS-III

Course Objective

The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like NMR, Mass, GC, HPLC and different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. Also to taught the Rules for regulatory control data and various quality assurance topics like ISO, TQM, ISO 9000, and GLP.

Theory **3-0-0-3**

Unit I Quality assurance **10hrs**

(a) Organization and personnel responsibilities training, hygiene,Concept and philosophy of TQM, ISO 9000

(b) Regulatory control, regulatory drug analysis, interpretation of analytical data,Quality review and documentation

(c) GLP- Responsibilities, good laboratory practices, Routine controls, instruments, protocols, non clinical testing, control on animal house.

Unit II: Validation of Analytical Instrument **10 hrs**

Validation and calibration of various instruments used for drug analysis such as UV-Visible Spectrophotometer, IR Spectrophotometer, Spectrofluorimeter, HPLC, HPTLC and GC.

Unit III: Absorption Spectroscopy **20 hrs**

a) Nuclear Magnetic Resonance Spectroscopy-Theory, Various magnetic sources, Proton NMR, Instrumentation Shielding and Deshielding effect ,NMR spectrum Application .

b) Atomic Absorption Spectroscopy-Principle, Instrumentation, application, drug analysed by absorption spectroscopy

c) Mass Spectroscopy –Theory, Different ionization methods, chemical ionization method magnetic sources, Mass spectrum, Application.

Unit IV Emission spectroscopy **10 hrs**

Flame Photometry-Introduction, Theory, Different types of light source, Instrumentation, working procedure, application

Atomic Emission Spectroscopy- Principle, Instrumentation, Application, drug analysed by absorption spectroscopy

Unit V-Miscellaneous methods **10 hrs**

a) X-ray Diffraction-Theory, production of x-rays, Instrumentation, Application.

b) Radio immunoassay -Principle, Sources of radioisotopes, methods, measurement of radioisotopes Application.

Total **60 hrs**

Course Outcomes

At the end of the course, the student will be able to

CO1: Outline of the Quality Assurance, TQM,GLP,Regulatorycontrol and Organizationandpersonnelresponsibilities.

CO2: Explain the Validation of Analytical Procedure and Instrument like UV-Visible Spectrophotometer, IR Spectrophotometer, Spectrofluorimeter, HPLC, HPTLC and GC

CO3: Explain the Principle, Instrumentation and working procedure of Absorption spectroscopy like NMR, Mass Spectroscopy and Atomic absorption spectroscopy.

CO4: Discuss the Principle, Instrumentation and working procedure of Atomic emission spectroscopy like Flame photometry.

CO5: Study the theoretical and Practical aspects of X-ray Diffraction and Radio immuno assay technique.

Practicals **0-0-3-2**

1. Assay of the official formulations- Frusemide Tablet
2. Assay of the official formulations - Metformin Tablet
3. Assay of the official formulations -Paracetamol Tablet
4. Assay of the official formulations - Chloramphenicol Capsule
5. Analysis of drugs by using HPLC & HPTLC method
6. Quantitative Colorimetric determination of suitable drugs using following reagents : Ninhydrin.
7. IR of samples with different functional groups COOH,NH2,OH.
8. Assays of official compounds by fluorimetry : Quinine sulphate
9. Quantitative estimation of formulations containing Paracetamol and nimesulide in combined form.
10. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.
11. Analysis of drugs by using HPLC
12. Calibration of UV spectrophotometer as per IP.

Course Outcomes

At the end of the course, the student will be able to

CO1: Demonstrate the working procedure of UV -Visible Spectroscopy and explain the study of λmax

CO2: Experiment with UV -Visible Spectroscopy and determine the Percentage purity of Drugs and Formulation.

CO3: Measure the amount and percentage purity of Drug and formulation by using Coloring agent

CO4: Utilize the Flame photometry equipment to determine the concentration of metals

CO5: Discuss the interpretation of Mass spectrum with the support of Mass spectrum

Text Books

1. Principles of instrumental analysis, Douglas A. Skoog, F. James Holler, Timothy A. Nieman. Skoog, Douglas A. 5th ed.Published Philadelphia : Saunders College Pub. ; Orlando, Fla. : Harcourt Brace College Publishers, 1998.
2. Vogel's: Text book of quantitative chemical analysis revised by G. H. Jeffery, J.Bassett, J. Mendham, R. C. Denney, 6th Edition, Pearson Education Publishers –New Delhi, 1989, India.

Reference Books

1. Instrumental Methods of Chemical Analysis – B. K. Sharma –Nirali Prakasan Publisher, 9th Edition.2000
2. The controller of publications; New Delhi.Govt of India, Indian Pharmacopoeia,
3. Volume-1 and 2, 1996.
4. .P. D. Sethi, Quantitative Analysis of Drugs in Pharmaceutical Formulation, 3rd Edition.2008
5. J. W. Munson, Pharmaceutical Analysis – Modern Methods, Part – A & B, 2001.
6. H. Beckett and Stenlake, Practical Pharmaceutical Chemistry, Vol. I and Vol. II, 4th Edition CBS Publishers, 1997, New Delhi.
7. Organic Spectroscopy by William Kemp, 3rd Edition. Mac Publishers 2011.
8. Spectroscopy by Y.R.Sharma IV edition,SS publishers,2008. Indian Pharmacopoeia, 1996 By India Ministry of

Health and Family Welfare, Ministry of Health and Family Welfare, India Published 2000 Controller of Publications

9. The United States Pharmacopeia By United States Pharmacopeial Convention Committee of Revision, United StatesPharmacopeial ConventionPublished 2006 United States Pharmacopeial Convention, Inc.
10. British Pharmacopoeia By General Medical Council (Great Britain), By General MedicalCouncil (Great Britain), General Medical Council (Great Britain, General Council ofMedical Education and Registration, Great Britain Published 2006.The Stationery Office

15CBPH82 PHARMACOGNOSY – VI

Course objective

The syllabus framed with the object of the production and utilization of products from medicinal and aromatic plants and its commercial utility in various industries. This provides a detailed information about the utilization of herbs as colorants ,health foods, allergens and as cosmetics. It aso gives a basic tool for micro propagation of plants and its derived products

Theory **3-0-0-3**

UNIT I **12 hours**

Trade of medicinal plants and its products

World-wide trade in medicinal plants and derived products with special reference to diosgenin (disocorea) taxol (Taxus sps), digitalis, tropane alkaloid containing plants, papain, cinchona, ipecac, liquorice, ginseng, Aloe, Valerian, rauwolfia and plants containing laxatives. Role of medicinal and aromatic plants in national economy.

UNIT II **12 hours**

Production and utilization of herbal products from medicinal and aromatic plants

A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India. Utilization and production of phytoconstituents such as Quinine, Calcium sennosides, podophyllotoxin, diosgenin, solasodine and tropane alkaloids and utilization of aromatic plants and derived products with special reference to sandalwood oil, mentha oil, lemon grass oil, vetiver oil, geranium oil and eucalyptus oil.

UNIT III **12 hours**

Colourants /health food/ herbal cosmetics/ allergens

Natural colouring materials:

Natural allergens and photosensitizing agents and fungal toxins. Herbs as health foods

Herbal cosmetics on commercial scale.

12 hours

UNIT IV

Plant tissue culture

Historical development of plant tissue culture, types of cultures, nutritional requirements, growth and their maintenance. Applications of plant tissue culture in pharmacognosy.

UNIT V **12 hours**

Marine drugs / Chemotaxanomy

Chemotaxomy and serotaxomy of medicinal plants.

Marine pharmacognosy, novel medicinal agents from marine sources.

Total - 60 hours

Course Outcomes

At the end of the course, the student will be able to

CO1: Evaluate the global awakening interest towards safe, effective use of natural drugs and to motivate the policy makers, international and national regulatory bodies to streamline the availability.

CO2: Explain the importance of national and international agencies actively involved in different parts of India to promote awareness, documentation, conservation strategies involved in promoting research and utilization of medicinal plants

CO3: Analyse the symptoms of the causative agents for allergens, photosensitizing agents and to decide the medications. Defend the health benefits of health foods and herbal cosmetics.

CO4: Create a technique for a better source of regular, uniform supply of raw materials regulated under reproducible condition for plant based industries to produce phyto pharmaceuticals and to develop new methods of isolation of phytochemicals.

CO5: Discuss the lead of natural classification supplemented by phytochemical knowledge which acts as an excellent guide for chemical exploration of plants. Develop novel compounds from marine natural products for various biological activities

Practicals **0-0-3-2**

1. Isolation of solosodine from potato
2. Isolation of tropane alkaloid from datura leaf
3. Extraction of eucalyptus oil from leaves
4. Extraction of menthal oil from peppermint leaves
5. Extraction of fennel oil from fennel fruits
6. Extraction of vetiver oil from vetiver roots
7. Paper chromatography of sugar from plant extracts
8. TLC of quinine
9. HPTLC of alkaloids / flavonoids
10. TLC of volatile oils
11. GLC of terpenoids from volatile oil
12. Demonstration of tissue culture technique at laboratory level

Total -45 hours

Course Outcomes

At the end of the course, the student will be able to

CO1: Develop the methods for isolation of active constituents from natural products.

CO2: Estimate the amount of volatile oils obtained by extraction in laboratory scale.

CO3: Test for separation of compounds where the substances are distributed between liquid phases.

CO4: Analyze the separation of compounds from a mixture for purification and identification.

CO5: Design of versatile tool for automated, sophisticated quantification of compounds.

Text books

1. Trease and Evans Pharmacognosy. Fifteenth Edition, William Charles Evans, W. B. Saunders, Edinburg London New York Philadelphia St. Louis Sydney Toronto 2002.
2. Pharmacognosy: V. E. Tyler, L. R. Brady, J. E. Habbers, Lea and Febiger Philadelphia, 9th Edition, 1988.
3. Textbook of Industrial Pharmacognosy by A.N. Kalia.V.K.Jain for CBS Publishers1 st edition 2005
4. Quality control herbal drugs –Pulok K. Mukherjee,Business horizons 1st edition 2002

Reference books

1. Treatise on Indian Medicinal Plants – Asima chatterji , Nirali publication. 1st edition 1980
2. Pharmacognosy and pharmacobiotechnology by Ashutosh Kar New age international (p) limited,2008
3. Pharmacognosy & Phytochemistry Vol 1 by Vinod D Rangari,career publications 1 st edition 2002
4. Textbook of Chemical plant taxonomy – Swain .Academic press 1 st edition 1963
5. Clarke, E. C. G., “Isolation and Identification of Drugs”, The Pharmaceutical Press, London.1960
6. Quality control herbal drugs –Pulok K. Mukherjee.Business Horizons,2008

15CBPH83 Pharmaceutics - IX (Dosage form Design)

Course Objective:

The aim of this course is to provide knowledge of the physicochemical principles of dosage form design and also to enable the successful student to recognize and understand the development process for pharmaceutical delivery systems that are therapeutically effective, bioavailable, safe and elegant. The objective is to study the different phases in the development of a dosage form. The different phases for conventional dosage forms include the stages in which the substance drug is clinically tested, formulated, manufactured and the quality control procedures related to each stage.

Theory **3-0-0-3**

Unit I: Pre-formulation studies **12 hrs**

(a) Study of physical properties of drug like physical form, particle size, shape, density, wetting dielectric constant. Solubility, dissolution and organoleptic property 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 stability of products.

(c) Study of pro-drugs in solving problems related to stability, bioavailability and elegancy of formulations.

Unit II: Design, development and process validation methods **12 hrs**

Design, development and process validation methods for pharmaceutical operations involved in the production of pharmaceutical products with special reference to tablets, suspensions.

Unit III: Stability testing **12 hrs**

Stabilization and stability testing protocol for various pharmaceutical products.

Unit IV: GMP and quality assurance **12 hrs**

GMP and quality assurance, Quality audit. Policy making of manufacturable items, demand and costing, personnel requirements, manufacturing practice, master formula card, production control, manufacturing records.

Unit V: Controlled released formulations **12 hrs**

Design, development, production and evaluation of controlled released formulations

Total **60 hrs**

Course Outcomes

At the end of the course, the student will be able to

CO1: Outline the importance of Preformulation studies and prodrugs related to stability of pharmaceutical preparations

CO2: Develop and design the validation methods for preparation of pharmaceutical products.

CO3: Analyse the stability of pharmaceutical products and test the stability using standard protocol

CO4: Explain and assess the concepts Good manufacturing practice and maintaining the manufacturing records

CO5: Design development production and evaluation of controlled release formulation

Practicals **0-0-3-2**

1. Preformulation studies including drug-excipient compatibility studies, effect of stabilizers, preservatives etc. in dosage form design.
2. Accelerated stability studies and prediction of expiration dates shelf life for tablets, capsules and paranterals.
3. Dissolution testing and data evaluation for oral solid dosage form.

4. Evaluation of Bioequivalence of some marketed products.
5. Preparation and evaluation of controlled release formulations.
6. Preparation aspirin tablets with different excipients and determining the stability.
7. Determination of minimum concentration of preservatives in the preparation of eye drops, ear drops.
8. Accelerated stability studies of some marketed preparations - tablets and suspensions
9. Dissolution testing of diclofenac tablets
10. Powder characteristics in pre-formulation - bulk density, porosity, wettability.
11. Preparation of master formula cards for tablet manufacturing.
12. Maintenance of manufacturing records.

Total **45 hrs**

Course Outcomes

At the end of the course, the student will be able to

CO1: Compare the bioequivalence of some marketed products, Compare the different binding agent used in the preparation tablet. Demonstrate the Powder characteristics in pre-formulation

CO2: Identify the minimum concentration of preservatives in the preparation of eye drops, ear drops.

CO3: Test for accelerated stability studies and prediction of expiration dates shelf life for tablets, capsules and parenteral.
Analyse the accelerated stability studies of some marketed preparations - tablets and suspensions

CO4: Importance of preparation of master formula cards for tablet manufacturing and Maintenance of manufacturing records.

CO5: Formulate Develop and evaluate the controlled release formulations.

Text Books

1. Pharmaceutics: The Science of Dosage Form Design - M.E. Aulton, 2nd edition, 2002, ELBS/Churchill Livingstone, New York (Elsevier Limited).
2. Lachman L, Lieberman HA, Kanig JL.” The Theory & Practice of Industrial Pharmacy”, 3rd edition, 1991, Varghese Publishing House, Bombay.

Reference Books

1. E.A. Rawlin’s, Bentley’s Text Book of Pharmaceutics, 8th edition, 2012, BSP Books Pvt.Ltd- Hyderabad.
2. Remington: The Science & Practice of Pharmacy. Vol. I & II. Lippincott, williams & Wilkins Philadelphia, 21st

Revised edition (1 May 2005) Mack Publishing Co. Easton.

3. Banker GS, Rhode CT. “Modern Pharmaceutics”, 4th edition, Informa Healthcare, New York.
4. Lieberman HA, Lachman L, Sachwartz JB.” Pharmaceutical Dosage Forms: Tablets”, 2nd edition, 2005, Vol 1- 3 Marcel Dekker, N.Y.
5. Jain NK. “Controlled and novel drug delivery”, 3rd edition, 2004, CBS Publishers & Distributors, New Delhi.

15CBPH84 Pharmaceutical Industrial Management

Course Objective:
To provide an opportunity to learn basic management concepts essential for business -Pharmaceutical Marketing, Salesmanship, Market Research, Materials Management & Production Management; and also to make understand the process involved in the pharmaceutical industries and its management.

Theory **2-0-0-2**

Unit I: Introduction **9 hrs**

Concept of Management Administrative Management Planning, Organizing, Staffing, Directing and Management (Personnel, Materials Production, Financial, Marketing, Time/Space, Margin/ Morale). Principles of Management Co-ordination, Communication, Motivation Decision-making, leadership, Innovation, Creativity, Identification of key points to give maximum thrust for development and perfection.

Unit II: Accountancy & Economics **9 hrs**
Principles of Accountancy, Ledger posting and book entries, preparation of trial balance, columns of cash book, Bank reconciliation statement, rectification of errors, Profits and loss account, balance sheet, cheques, bills of exchange, promissory notes and hundies documentary bills.
Principles of economics with special reference to the laws of demand and supply, demand schedule, demand curves, labor welfare, general principles of insurance and inland and foreign trade, procedure of exporting and importing goods.

Unit III: Pharmaceutical Marketing & Salesmanship **9 hrs**
Functions buying, selling, transportation, storage, finance, feedback, information, channels of distribution, wholesale, retail, departmental store, multiple shop and mail order business.
Principles of sales promotion, advertising, ethics of sales, merchandising, literature, detailing. Recruitment, training, evaluation, compensation to the pharmacist.

Unit IV: Market Research **9 hrs**
Recruitment, training, evaluation, compensation to the pharmacist prerequisition: Basic information services.

Unit V: Materials Management & Production Management **9 hrs**
A brief exposure of the basic principles of Materials Management Purchase, stores and inventory control Eligibility, Efficiency Evaluation, Recruitment Methodology, Service Conditions, Termination, Performance Evaluation, etc.
A brief exposure of the different aspects of Production Management - Visible and Invisible inputs: Methodology of Activities, Performance Evaluation Technique, Process-Flow, Process Know-how, Maintenance Management.

Total **45 hrs**

Course Outcomes
At the end of the course, the student will be able to

CO1: Explain the concept of administrative management Illustrate the principles of management Show the communication skills and study motivation, decision making, leadership and innovation and creativity for pharmacists.

CO2: Apply the principles of accountancy and economics and make use in preparation of ledgers, cheques, promissory notes, bills Plan the procedure for exporting and importing goods.
Utilize the principles of insurance and plan for different policies.

CO3: Analyze the functions involved in buying, selling storage
Categorize the channels of distribution and take part in training given to pharmacist

CO4: Assess the different methods of recruitment and training given to personnels. Evaluate the compensation given to pharmacist

CO5: Discuss about the procedure for purchase and elaborate the inventory control methods. Predict the performance evaluation technique and process flow methods.

Text Books

1. Vidyasagar, G., "Pharmaceutical Industrial Management", 3rd Edition, Varghese Publications, 2001.
2. Subramaniam, C.V.S., "Textbook of Pharmaceutical Production Management", Vallabh Prakashan, 2000.
3. Herald Knottz and Heinz Weihrich, 'Essentials of Management', Tata McGraw Hill Education Pvt. Ltd., 2010.

Reference Books

1. Lachman, L. and Liberman, H.A., "The Theory and Practice of Industrial Pharmacy", 3rd Edition, Varghese Publications, 1986.
2. Evans, J., Sweeny, A. and Wiliams, H "Applied Production and Operations Management", 3rd Edition, West Publishing Company Ltd., 1992.
3. Drucker, P.F., "Management (Task, Responsibility and Practices)", Allied Publication, 1993.
4. Mohan S, Jai D." Drug Store and Business Management ", 1st edition, 1995, S.V Kar & Co, Jalandhar.
5. Singh S, Singh P." Drug Store and Business Management", 1st edition, 1995, S.Dinesh & Co.Circular Road Jalandhar.
6. Koontz & O'Donnel Principles of Management Tata Mc Graw Hill, Delhi.
7. G. Vidya Sagar, Pharamceutical Industrial Management, 2nd edition, 2005, Pharma Book Syndicate.

15CBPH85 PHARMACEUTICS - X (HOSPITAL PHARMACY)

Theory **2-0-0-2**

Unit I: Organization and structure **09 hrs**

Organization of a hospital and hospital pharmacy, Responsibilities of a hospital pharmacist, pharmacy and therapeutic committee, Budget preparation and Implementation, Hospital formulary: Contents, preparation and revision of hospital formulary.

Unit II: Drug store management and inventory control **09 hrs**

Organization of drug store, types of materials stocked, storage conditions, Purchase and inventory control - principles – purchase procedures purchase order - Procurement and stocking

Unit III: Drug distribution systems in hospitals **09 hrs**

Out-patient dispensing - methods adopted, Dispensing of drugs to in-patients, Types of drug distribution systems. Charging policy, labeling, Dispensing of drugs to ambulatory patients, Dispensing of controlled drugs.

Unit IV: Central Sterile Supply Unit and their management **09 hrs**

Types of materials for sterilization, packing of materials prior to sterilization, sterilization equipments, supply of sterile materials.

Blood products and plasma substitutes: Collection, processing and storage of; whole human blood, concentrated human RBCs, dried human plasma, human fibrinogen, human thrombin, human normal immunolglobulin, human fibrin, foam plasma substitutes ideal requirements, PVP, dextran etc. for control of blood pressure as per I.P.

Unit V: Surgical products and Drug Information Services **09 hrs**

Definition, primary wound dressing, absorbents, surgical cotton, surgical gauzes etc., bandages, adhesive tape, protective cellulosic hemostastics, official dressing, absorbable and nonabsorbable sutures, ligatures and catguts. Medical prosthetics and organ replacement materials. Sources of Information on drugs disease, treatment schedules, procurement of information, computerized services (e.g. MEDLIN E), Retrieval of information, Medication error.

Total **45 hrs**

Course Outcomes

At the end of the course, the student will be able to

CO1: Explain the concept of administrative management Illustrate the principles of management Show the communication skills and study motivation, decision making, leadership and innovation and creativity for pharmacists.

CO2: Apply the principles of accountancy and economics and make use in preparation of ledgers, cheques, promissory notes, bills Plan the procedure for exporting and importing goods.
Utilize the principles of insurance and plan for different policies.

CO3: Analyze the functions involved in buying, selling storage
Categorize the channels of distribution and take part in training given to pharmacist

CO4: Assess the different methods of recruitment and training given to personnels. Evaluate the compensation given to pharmacist

CO5: Discuss about the procedure for purchase and elaborate the inventory control methods. Predict the performance evaluation technique and process flow methods.

Text books:

1. Hospital pharmacy by William .E. Hassan, 5th Revised edition. Lippincott Williams and Wilkins Publishers, 1986.
2. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh. B. S. Shah Prakashan Publishers, 2014.

Reference Books:

1. WHO consultative group report.
2. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
3. Hospital pharmacy by Stephens, M. 2nd edition. London :Pharmaceutical Press, 2011
4. Hospital and Clinical Pharmacy by K Sampath, 3rd edition.