Semester VII

BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

Course Content:

Unit -I **10 Hours**

UV Visible spectroscopy: Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.
Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors-Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.
Applications- Spectrophotometric titrations, Single component and multi component analysis.
Fluorimetry: Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications.

Unit-II **10 Hours**

IR spectroscopy: Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations.
Instrumentation- Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications.
Flame Photometry- Principle, interferences, instrumentation and applications.
Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications.
Nephelo-turbidimetry- Principle, instrumentation and applications.

Unit-III **10 Hours**

Introduction to chromatography:
Adsorption and partition column chromatography- Methodology, advantages, disadvantages and applications.
Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.
Paper chromatography- Introduction, methodology, development techniques, advantages, disadvantages and applications.
Electrophoresis– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications.

Unit-IV **08 Hours**

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications.
High performance liquid chromatography (HPLC)- Introduction, theory, instrumentation, advantages and applications.

Unit-V **07 Hours**

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications.
Gel chromatography- Introduction, theory, instrumentation and applications**.**
Affinity chromatography- Introduction, theory, instrumentation and applications.

BP705P. INSTRUMENTAL METHODS OF ANALYSIS / NDDS (Practical)

4 Hours/Week

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds.
2. Estimation of sulphanilamide by colorimetry.
3. Simultaneous estimation of ibuprofen and Paracetamol by UV spectroscopy.
4. Estimation of quinine sulphate by fluorimetry.
5. Study of quenching of fluorescence.
6. Determination of sodium by flame photometry.
7. Determination of potassium by flame photometry.
8. Determination of chlorides and sulphates by nephelo-turbidimetry.
9. Separation of sugars by thin layer chromatography.
10. Separation of plant pigments by column chromatography.
11. Demonstration experiment on HPLC.
12. Demonstration experiment on Gas Chromatography.
13. To perform in-vitro dissolution profile of CR/SR marketed formulation.
14. To prepare sustained release matrix tablets and evaluate by UV spectroscopy.
15. Formulation of nanoparticles and evaluate by HPLC.
16. Formulation and evaluation of liposomes.
17. To prepare buccal dosage form and evaluate by UV spectroscopy.
18. To prepare Paracetamol transdermal patch and evaluate by UV spectroscopy.

Recommended Books (Latest Editions)

- Instrumental Methods of Chemical Analysis by B.K. Sharma, Krishna Prakashan Media (P) Ltd., Meerut, India.
- Organic Spectroscopy by Y.R Sharma, S. Chand & Company Ltd., New Delhi.
- Pharmaceutical Chemistry Instrumental Technique by Leslie G. Chatten, CBS Publisher and Distributer Pvt. Ltd., New Delhi.
- Textbook of Pharmaceutical Analysis by Kenneth A. Connors, John Wiley & Sons, Inc., New York.
- Vogel's Textbook of Quantitative Chemical Analysis by A.I. Vogel, Addison Wesley Logman, Singapore.
- Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake, CBS Publishers & Distributers Pvt. Ltd., New Delhi.
- Organic Spectroscopy by William Kemp, Palgrave, NY.
- Quantitative Analysis of Drugs by D.C. Garrett, Chapman & Hall Ltd., London.
- Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi, CBS Publishers & Distributers Pvt. Ltd., New Delhi.
- Spectrophotometric Identification of Organic Compounds by Silverstein, John Wiley & Sons, Inc., New York.
- Controlled and Novel Drug Delivery by N.K. Jain, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
- Novel Drug Delivery Systems by Y W. Chien, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York.

BP702T. INDUSTRIAL PHARMACY II (Theory)

45 Hours

Course Content:

Unit-I **10 Hours**

Pilot plant scale up techniques: General considerations- including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology.

Unit-II **10 Hours**

Technology development and transfer: WHO guidelines for Technology Transfer (TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from RD to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipment, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE
/SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues.

Unit-III **10 Hours**

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals.

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

Unit-IV **08 Hours**

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP.

Unit-V **07 Hours**

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

- Regulatory Affairs from Wikipedia, the Free Encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory Affairs.
- International Regulatory Affairs Updates, 2005, available at http://www.iraup.com/about.php.
- Textbook of FDA Regulatory Affairs. A Guide for Prescription Drugs, Medical Devices, and Biologics' by Douglas J Pisano and David S. Mantus.
- Regulatory Affairs brought by Learning Plus, Inc., available at http.//www.cgmp.com/ra.htm.
- Intellectual Property Rights in Pharmaceutical Industry Theory and Practice by Bayya Subba Rao and Appaji.
- How to Practice GLP by P.P. Sharma, Vandana Publications Pvt. Ltd., Delhi.
- Validation of Active Pharmaceuticals Ingredients by Ira R. Bony & Daniel Harpaz., CRC Press.
- Drugs and Pharmaceutical Sciences by Richard A. Guarina, 4th edition, Vol 139.

BP703T. PHARMACY PRACTICE (Theory)

45 Hours

Course Content:

Unit-I **10 Hours**

Hospital and it's organization

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non-clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

Hospital pharmacy and its organization

Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

Unit-II **10 Hours**

Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labeling. Dispensing of drugs to ambulatory patients and dispensing of controlled drugs.

Hospital formulary

Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

Medication adherence

Causes of medication non-adherence, pharmacist role in the medication adherence and monitoring of patient medication adherence.

Patient medication history interview

Need for the patient medication history interview, medication interview forms.

Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

Unit-III **10 Hours**

Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

Drug information services

Drug and Poison information centre, Sources of drug information, Computerized services, and storage and retrieval of information.

Patient counselling

Definition of patient counselling; steps involved in patient counselling, and Special cases that require the pharmacist

Education and training program in the hospital

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

Prescribed medication order and communication skills

Prescribed medication order- interpretation and legal requirements, and Communication skills-communication with prescribers and patients.

Unit-IV **8 Hours**

Budget preparation and implementation: Budget preparation and implementation. **Clinical Pharmacy:** Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring- medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

Over the counter (OTC) sales: Introduction and sale of over the counter and rational use of common over the counter medications.

Unit-V **7 Hours**

Drug store management and inventory control

Organization of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure.

Investigational use of drugs

Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

Interpretation of Clinical Laboratory Tests Blood chemistry, haematology and urine analysis.

Recommended Books (Latest Edition):

- A Textbook of Hospital Pharmacy by Merchant S.H. and Dr. J.S. Quadry, 4th ed. Ahmadabad: B.S. Shah Prakashan.
- A Textbook of Clinical Pharmacy Practice- Essential Concepts and Skills by Parthasarathi G., Karin Nyfort-Hansen, Milap C. Nahata, 1st ed. Chennai: Orient Longman Private Limited.
- Hospital Pharmacy by William E. Hassan, 5th ed. Philadelphia: Lea & Febiger; 1986.
- Hospital Pharmacy by Tipnis Bajaj, 1st ed. Maharashtra: Career Publications.
- Basic Skills in Interpreting Laboratory Data by Scott L.T., 4thed. American Society of Health System Pharmacists Inc.
- Health Education and Community Pharmacy by Parmar N.S. 18th ed. India: CBS Publishers & Distributers.

Journals:

- Therapeutic Drug Monitoring. ISSN: 0163-4356
- Journal of Pharmacy Practice. ISSN: 0974-8326
- American Journal of Health System Pharmacy. ISSN: 1535-2900 (Online)
- Pharmacy Times (Monthly Magazine)

BP704T. NOVEL DRUG DELIVERY SYSTEMS (NDDS) (Theory)

45 Hours

Course content:

Unit-I **10 Hours**

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design-controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations.

Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

Unit-II **10 Hours**

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications.

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion/mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems.

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump.

Unit-III **10 Hours**

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches.

Gastro-retentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS– Floating, high density systems, inflatable and gastro-adhesive systems and their applications.

Naso-pulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers.

Unit-IV **08 Hours**

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications.

Unit-V **07 Hours**

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome– Preliminary study, ocular formulations and ocuserts.

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications.

Recommended Books: (Latest Editions)

- Novel Drug Delivery Systems by Y W. Chien, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
- Controlled Drug Delivery Systems by Robinson, J. R., Lee V. H. L, Marcel Dekker, Inc., New York, 1992.
- Encyclopaedia of Controlled Drug Delivery by Edith Mathiowitz, Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim.
- Controlled and Novel Drug Delivery by N.K. Jain, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
- Controlled Drug Delivery-Concepts and Advances by S.P. Vyas and R.K. Khar, Vallabh Prakashan, New Delhi, First edition 2002.
- Modern Pharmaceutics by Gilbert S. Banker; Christopher T. Rhodes, 4th edition; (vol-121), Marcel Dekker, Inc., NY.
- Handbook of Pharmaceutical Controlled Release Technology by Donald L. Wise**,** Marcel & Dekker Inc., NY.
- Dermatological and Transdermal Formulations by Kenneth A. Walters**,** Mercell & Dekker Inc., NY.
- Drug Delivery System by Vasant V. Ranaday, Manffred A. Hollinger**,** CRC Press, NY.
- Design of Controlled Release Drug Delivery System by Xialing Li, Bhaskara R. Jasti**,** Mc-Graw Hill.

Journals

- Indian Journal of Pharmaceutical Sciences (IPA)
- Indian Drugs (IDMA)
- Journal of Controlled Release (Elsevier Sciences)
- Drug Development and Industrial Pharmacy (Marcel & Decker)
- International Journal of Pharmaceutics (Elsevier Sciences)

BP706PS. PRACTICE SCHOOL

150 Hours

Course content:

Every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains. Every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages).

Domains (anyone to be opted):

- Phytomedicine
- Formulation development
- Quality control and quality assurance
- Drug design and process chemistry
- Pharmaceutical software
- Artificial intelligence
- 3D printing
- Nutraceuticals
- Cosmeceuticals
- Alternative medicine

Recommended Books (Latest Editions)

- Trease and Evans Pharmacognosy by W. C. Evans, 16th edition, W.B. Sounders & Co., London.
- Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals by Mukherjee, P. W., Business Horizons Publishers, New Delhi, India, 2002.
- Current Concepts in Drug Design by T. Durai and Ananda Kumar, BSP Books.
- An Introduction to Medicinal Chemistry by Patrick Graham, L., Oxford University Press.
- Introduction to the Principles of Drug Design by Smith H.J., Williams H, Wright Boston.
- Industrial Microbiology by Prescott and Dunn, 4th edition, CBS Publishers & Distributors, Delhi.
- Molecular Biotechnology: Principles and Applications of Recombinant DNA by B.R. Glick and J.J. Pasternak: ASM Press Washington, D.C.
- Harry's Cosmetology by Wilkinson, Moore, Seventh Edition.
- Poucher's Perfumes, Cosmetic and Soaps by Poucher W.A., Butler, H., Springer India Pvt. Ltd, New Delhi.

BP707P. HOSPITAL TRAINING-II

Training of students at a hospital establishment for a minimum duration of 45 days. The hospital training shall include: First aid (wound dressing, artificial respiration etc.), different routes of injection, study of patient observation charts, prescriptions and dispensing, simple diagnostic reports etc.

May be performed at the end of the 6th semester.