

## **Syllabus for Bachelor of Pharmacy (B. Pharm.) Course**

## SEMESTER VII

Course code	Name of the course	No. of hours	Tutorial	Credit points	Evaluation Scheme		
					Internal	External	Total
BP701T	Instrumental Methods of Analysis – Theory	3	1	4	20	80	100
BP702T	Industrial Pharmacy – Theory	3	1	4	20	80	100
BP703T	Pharmacy Practice – Theory	3	1	4	20	80	100
BP704T	Novel Drug Delivery System – Theory	3	1	4	20	80	100
BP705T	Quality Assurance	3	1	4	20	80	100
BP705P	Instrumental Methods of Analysis – Practical	4	-	2	10	40	50
BP706T	Clinical Pharmacy and Therapeutics	3	1	4	20	80	100
<b>Total</b>		<b>22</b>	<b>6</b>	<b>26</b>	<b>130</b>	<b>520</b>	<b>650</b>

## **BP701T: INSTRUMENTAL METHODS OF ANALYSIS (Theory)**

**45 Hours**

**Scope:** This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

**Objectives:** Upon completion of this course the student should be able to:

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

### **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

**Nepheloturbidometry**- 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 (Practical)**

**4 Hours/week**

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
2. Estimation of dextrose by colorimetry
3. Estimation of sulfanilamide by colorimetry
4. Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
5. Assay of paracetamol by UV- Spectrophotometry
6. Estimation of quinine sulfate by fluorimetry
7. Study of quenching of fluorescence
8. Determination of sodium by flame photometry
9. Determination of potassium by flame photometry
10. Determination of chlorides and sulphates by nephelo turbidometry
11. Separation of amino acids by paper chromatography
12. Separation of sugars by thin layer chromatography
13. Separation of plant pigments by column chromatography
14. Demonstration experiment on HPLC
15. Demonstration experiment on Gas Chromatography

### **Recommended Books (Latest Editions)**

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

## **BP702T: INDUSTRIAL PHARMACY (Theory)**

**45 Hours**

**Scope:** This course is designed to impart fundamental knowledge on pharmaceutical product commercialization from laboratory to market.

**Objectives:** Upon completion of the course student shall be able to

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different laws and acts that regulate pharmaceutical industry in India and US
4. Understand the approval process and regulatory requirements for drug products

### **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:** Terminologies, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packing materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TOT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; Technology of Transfer (TOT) related documentation - confidentiality agreements, 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, 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, Common Technical Document (CTD), Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

#### **Recommended Books: (Latest Editions)**

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at [http://en.wikipedia.org/wiki/Regulatory\\_Affairs](http://en.wikipedia.org/wiki/Regulatory_Affairs).
2. International regulatory affairs updates, 2005. available at <http://www.iraup.com/about.php>
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at <http://www.cgmp.com/ra.htm>.

## **BP703T: PHARMACY PRACTICE (Theory)**

**45 Hours**

**Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

**Objectives:** Upon completion of this course the student should be able to:

1. know various drug distribution methods in a hospital
2. appreciate the pharmacy stores management and inventory control
3. monitor drug therapy of patient through medication chart review and clinical review
4. obtain medication history interview and counsel the patients
5. identify an drug related problems
6. detect and assess adverse drug reactions
7. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. know pharmaceutical care services
9. do patient counselling in community pharmacy;
10. appreciate the concept of Rational drug therapy.

### **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 it's 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 labelling, 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 the formulary drug classification, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

### **Drug information services**

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

### **Patient counseling**

Definition of patient counseling; steps involved in patient counseling, 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**

**08 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.

### **Over the counter (OTC) sales**

Introduction and sale of over the counter, and Rational use of common over the counter medications.

## **UNIT-V**

**07 Hours**

### **Drug store management and inventory control**

Organisation 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, hematology, and urinalysis

### **Recommended Books (Latest Editions)**

1. Merchant S.H. and Dr. J.S.Quadry. A textbook of hospital pharmacy, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. Hospital pharmacy, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. Hospital Pharmacy, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. Basic skills in interpreting laboratory data, 4thed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. Health Education and Community Pharmacy, 18th ed. India: CBS Publishers & Distributers; 2008.

### **Journals**

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)

## **BP704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)**

**Scope:** This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

**Objectives:** Upon completion of course student shall be able to

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

### **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

**Gastroretentive drug delivery systems:** Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications

**Nasopulmonary 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**

**Nanotechnology and its Concepts:** Concepts and approaches for targeted drug delivery systems, 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)**

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

#### **Journals**

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)

## **BP705T: PHARMACEUTICAL QUALITY ASSURANCE (Theory)**

**45 Hours**

**Scope:** This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

**Objectives:** Upon completion of course student shall be able to

1. understand the cGMP aspects in a pharmaceutical industry
2. appreciate the importance of documentation
3. understand the scope of quality certifications applicable to pharmaceutical industries
4. understand the responsibilities of QA & QC departments

### **Course Content**

#### **UNIT-I**

**10 Hours**

**Quality Assurance and Quality Management concepts:** Definition and concept of Quality control, Quality assurance and GMP

**Total Quality Management (TQM):** Definition, elements, philosophies

**ICH Guidelines:** purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

**Quality by design (QbD):** Definition, overview, elements of QbD program, tools

**ISO 9000 & ISO14000:** Overview, Benefits, Elements, steps for registration

**NABL accreditation:** Principles and procedure

#### **UNIT-II**

**10 Hours**

**Organization and personnel:** Personnel responsibilities, training, hygiene and personal records.

**Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

**Equipments and raw materials:** Equipments selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

**UNIT-III****10 Hours**

**Quality Control:** Quality control test for containers, rubber closures and secondary packing materials.

**Good Laboratory Practices:** General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

**UNIT-IV****08 Hours**

**Complaints:** Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

**Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

**UNIT-V****07 Hours**

**Calibration and Validation:** Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

**Warehousing:** Good warehousing practice, materials management

**Recommended Books (Latest Editions)**

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines.

## **BP706T: CLINICAL PHARMACY AND THERAPEUTICS**

**45 Hours**

**Scope:** This course deals with the various aspects of clinical pharmacy and pharmacotherapeutics. It covers the important aspects like clinical trials, monitoring and reporting of ADR and specific drug therapies.

**Objectives:** Upon completion of course student shall be able to

1. understand the clinical trials
2. appreciate the importance of ADRs
3. understand the scope of drug therapy monitoring
4. understand the responsibilities of clinical pharmacists

### **Course Content**

#### **UNIT-I**

**10 Hours**

General Principles, preparation, maintenance, analysis of observational records in clinical Pharmacy. Clinical trials, type and phases of clinical trials, placebo, ethical and regulatory issues including Good clinical practice in clinical trials.

#### **UNIT-II**

**10 Hours**

Therapeutic drug monitoring, adverse drug reaction (ADR), types of ADR, Mechanism of ADR. Drug interaction, Monitoring and reporting of ADR and its significance. Drug information services, Drug interactions. Drug interaction in pediatric and geriatric patients, drug treatment during pregnancy, lactation and menstruation. Pharmacovigilance, Therapeutic drug monitoring.

#### **UNIT-III**

**10 Hours**

Neutraceuticals, essential drugs and rational drug usage. Age related drug therapy: concept of posology, drug therapy for neonates, pediatrics and geriatrics. Drugs used in pregnancy and lactation. Drug therapy in gastrointestinal, hepatic, renal, cardiovascular and respiratory Disorders.



**UNIT-IV****08 Hours**

Drug therapy for neurological and psychological disorders. Drug therapy in infections of respiratory system, urinary system, infectivemeningitis, TB, HIV, malaria and filaria.

**UNIT-V****07 Hours**

Drug therapy for thyroid and parathyroid disorders, diabetes mellitus, menstrual cycle disorders, menopause and male sexual dysfunction. Drug therapy for malignant disorders like leukemia, lymphoma and solid tumors. Drug therapy for rheumatic, eye and skin disorders.

**Recommended Books (Latest Editions)**

1. Alain L. I. Non Prescription Drugs Blackwell Scientific Publishers
2. Carter S. J. Dispensing For Pharmaceutical CBS Publishers Student
3. Collet D. M. & Aulton M. E. Pharmaceutical Practice Churchill Livingston
4. Mulholland B. V. Drug Calculations Mosby
5. Stone P. & Curtis S. J. Pharmacy Practice SAGE

