GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy

Subject Code: BP701TP

SEMESTER: VII

Subject Name: Instrumental Methods of Analysis

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 the course the student shall 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.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	6	80	20	80	20

Sr No	Topics	% weightage
1.	**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	10
2.	**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	10
3.	**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	10

	Electrophoresis– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications	
4.	**Gas chromatography -** Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications **High performance liquid chromatography (HPLC)-**Introduction, theory, instrumentation, advantages and applications	8
5.	**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	7

Practical

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 byWilliam 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

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP702TT
SEMESTER: VII
Subject Name: Industrial Pharmacy II

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market.

Objectives: Upon completion of the course the 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
4. Understand the approval process and regulatory requirements for drug products.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**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	10
2.	**Technology development and transfer:** WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging 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), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues	10
3.	**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.	10
4.	**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	8
5.	**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.	7

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.
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.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP703TT
SEMESTER: VII
Subject Name: Pharmacy Practice

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 the course the student shall 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 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 counseling in community pharmacy;
10. appreciate the concept of Rational drug therapy

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**a) 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. **b) Hospital pharmacy and its organization** Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists. **c) 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. **d) 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.	10
2.	**a) Drug distribution system in a hospital**	10

	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. **b) 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. **c) Therapeutic drug monitoring** Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic DrugMonitoring, and Indian scenario for Therapeutic Drug Monitoring. **d) Medication adherence** Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence. **e) Patient medication history interview** Need for the patient medication history interview, medication interview forms. **f) Community pharmacy management** Financial, materials, staff, and infrastructure requirements.	
3.	**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. **b) Drug information services** Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information. **c) Patient counseling** Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist **d) 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. **e) Prescribed medication order and communication skills** Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.	10
4.	**a) Budget preparation and implementation** Budget preparation and implementation **b) 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. **c) Over the counter (OTC) sales** Introduction and sale of over the counter, and Rational use of common over the counter medications.	8
5.	**a) 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 **b) Investigational use of drugs**	7

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

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy

Subject Code: BP704TT

SEMESTER: VII

Subject Name: NOVEL DRUG DELIVERY SYSTEMS

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

Objectives: Upon completion of the course the 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.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	0	80	20	0	0

Sr No	Topics	% weightage
1.	**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.	10
2.	**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 implantsand osmotic pump	10
3.	**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	10
4.	**Targeted drug Delivery:** Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications	8
5.	**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	7

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)

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP705PP
SEMESTER: VII
Subject Name: Practice School

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
0	0	12	6	0	0	0	100

Guidelines:

In the VII semester, every candidate shall undergo practice school for a period of 150 hours during the semester. The student shall opt any one of the following activity for practice school:

- [+]Hospital training (Hospital having minimum 10 bed facilities)
- [+]Training in Drug store/ CHC/ PHC
- [+]Training in a R & D organization/ CRO/ Manufacturing organization/ QA & QC Laboratory/ Public testing laboratory/ Drug regulatory body
- [+]Successfully pass MOOCS course equivalent to 6 credits through SWAYAM Platform
- Detailed literature review on any technical topic (At least 50 references should be included in the report to be submitted)

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (about 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.

The students can opt for Practice School and can perform the activities for Practice school after completion of Semester IV onwards (during the vacation/ official Holidays). Those who are doing Practice school during this period must complete the prescribed days or hours for practice School as per the guidelines. Institute should maintain documentation regarding Practice school for each student with requisite evidence.

[+] Certificate of training should be incorporated in the report.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP706TT
SEMESTER: VII
Subject Name: Quality Assurance

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

Objectives: Upon completion of the course the 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.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**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 procedures	10
2.	**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:** Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.	10
3.	**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	10
4.	**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	8
5.	**Calibration and Validation:** Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation,	7

	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, SandyWeinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol IWHO Publications.
4. A guide to Total QualityManagement- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total QualityManagement – 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