SARDAR PATEL UNIVERSITY
Vallabh Vidyanagar, Gujarat
(Reaccredited with 'A' Grade by NAAC (CGPA 3.11)
Syllabus with effect from the Academic Year 2024-2025

PROGRAMME STRUCTURE

Bachelor of Pharmacy (B. Pharm) Semester: VII

To Pass	At least 40% Marks in the aggregate of University and Internal examination in each course.							
Course Type	**Course code**	**Name of the course**	**Credit**	**Contact Hours per Week**	**Exam Duration in Hrs**	**Component of Marks**		
						Internal	**End Semester**	**Total**
Core Course	UP07CBPH01	Instrumental Methods of Analysis – Theory	4	4	3	25/10	75/30	100/40
	UP07CBPH02	Industrial Pharmacy – Theory	4	4	3	25/10	75/30	100/40
	UP07CBPH03	Pharmacy Practice – Theory	4	4	3	25/10	75/30	100/40
	UP07CBPH04	Novel Drug Delivery System – Theory	4	4	3	25/10	75/30	100/40
	UP07CBPH05	Instrumental Methods of Analysis – Practical	2	4	4	15/6	35/14	50/20
Skill Enhancement	UP07SBPH01	Practice School	6	12	5	25/10	125/50	150/60
		Total:	**24**	**-**	**-**	**140**	**460**	**600/240**

Semester VII

Schemes for internal assessments and end semester examinations

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
UP07CBPH01	**Instrumental Methods of Analysis – Theory**	10	15	1 Hr	25	75	3 Hrs	100
UP07CBPH02	**Industrial Pharmacy – Theory**	10	15	1 Hr	25	75	3 Hrs	100
UP07CBPH03	**Pharmacy Practice – Theory**	10	15	1 Hr	25	75	3 Hrs	100
UP07CBPH04	**Novel Drug Delivery System – Theory**	10	15	1 Hr	25	75	3 Hrs	100
UP07CBPH05	**Instrumental Methods of Analysis – Practical**	5	10	4 Hr	15	35	4 Hrs	50
UP07SBPH01	**Practice School**		25	3 Hrs	25	125	5 Hrs	150
	Total	**45**	**95**	**11 Hrs**	**140**	**460**	**21 Hrs**	**600**

Bachelor of Pharmacy
B. Pharm Semester VII

Course Code	UP07CBPH01	Title of the Course	INSTRUMENTAL METHODS OF ANALYSIS - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

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	Description	Hours
I	**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**
II	**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	**10**

	Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications **Nepheloturbidometry**- Principle, instrumentation and applications	
III	**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	**10**
IV	**Gas chromatography -** Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications **High performance liquid chromatography (HPLC)-** Introduction, theory, instrumentation, advantages and applications.	**08**
V	**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	**07**

Suggested References:	
Sr. No	**References**
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

Bachelor of Pharmacy
B. Pharm Semester VII

Course Code	UP07CBPH02	Title of the Course	INDUSTRIAL PHARMACY II - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

Scope	This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market
Objectives:	Upon completion of this course the student should 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

Course Content:

Unit	Description	Hours
I	**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**
II	**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**
III	**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**

IV	**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	**08**
V	**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.	**07**

Suggested References:

Sr. No	References
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.

Bachelor of Pharmacy
B. Pharm Semester VII

Course Code	UP07CBPH03	Title of the Course	PHARMACY PRACTICE - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

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 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

Course Content:

Unit	Description	Hours
I	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.	**10**

	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	
II	**A. 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. **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 Drug Monitoring, 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.	**10**
III	**A. 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. **Information services** Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information. **C. 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**
IV	**A. Budget preparation and implementation** Budget preparation and implementation **B. Clinical Pharmacy** Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and	**08**

	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.	
V	**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** Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee. **C. Interpretation of Clinical Laboratory Tests** Blood chemistry, hematology, and urinalysis	**07**

Suggested References:

Sr. No	References
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

Suggested Journals:

Sr. No	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)

Bachelor of Pharmacy
B. Pharm Semester VII

Course Code	UP07CBPH04	Title of the Course	NOVEL DRUG DELIVERY SYSTEMS - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

Scope	This subject is designed to impart basic knowledge on the area of novel drug delivery systems.
Objectives:	**Upon completion of this course the student should 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	Description	Hours
I	**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**
II	**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**
III	**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**

IV	**Targeted drug Delivery:** Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications	**08**
V	**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	**07**

Suggested References:

Sr. No	References
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

Sr. No	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)

SARDAR PATEL UNIVERSITY

Vallabh Vidyanagar, Gujarat
(Reaccredited with 'A' Grade by NAAC (CGPA 3.11)
Syllabus with effect from the Academic Year 2023-2024

Bachelor of Pharmacy
B. Pharm Semester VI

Course Code	UP07CBPH05	Title of the Course	INSTRUMENTAL METHODS OF ANALYSIS (Practical)
Total Credits of the Course	2	Hours per Week	4

Objectives:	Students would be able to: 1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis. 2. Perform the Chromatographic separation and analysis of drugs. 3. Perform the Qualitative and Quantitative analysis with the help of modern analytical instruments used for the drug analysis.

Course Content	
Sr. No.	**Description**
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

Suggested References:	
Sr. No	**References**

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

Bachelor of Pharmacy
B. Pharm Semester VI

Course Code	UP07SBPH01	Title of the Course	Practice School
Total Credits of the Course	6	Hours per Week	12

Course Content

Description

In the VII semester, 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 for practice school declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 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.

Program committee declares the domains for practice school in particular academic year. A domain head shall be appointed to frame the modules. A coordinator faculty member will be appointed for the practice school. Practice School coordinator facilitates the Guide/Mentor Allocation, time-table announcement, assessment schedule and submission requirements.

Submission:

1. Progress Report (at the end of 50 Hrs and 100 Hrs) along with attendance record
2. Final Report (not more than 25 pages)
3. Learning outcomes (as per the prescribed format)
4. Course completion certificate (as per the prescribed format)
5. Presentation (not more than 15 slides) handouts

Evaluation:

Internal assessment (25 marks):

1. Written tests (10 marks)
2. Progress Reports (10 marks)
3. Attendance (5 marks)

End Semester Assessment (125 marks):

1. Presentation (75 marks) (Mentor – 25, Examiner 1 – 25, Examiner 2 – 25)
2. Final Report (50 marks – Mentor)