# Shri Rawatpura Sarkar University, Raipur



# For BACHELOR IN PHARMACY Semester- SEMESTER VII

(Effective from the session: 2019-20)



# **Faculty of Pharmacy** Shri Rawatpura Sarkar University, Raipur

**BACHELOR OF PHARMACY SEMESTER - VII** 

**Examination Scheme** 

(Effective from the session: 2019-20)

			In	ternal a	ssessment	-					End ser	nester e	exams	
Sr.	Subject			Sessional exams Teaching hours per								Total Marks		
No.	Code	Name of the Course with PCI code	TA	СТ	Duration	Total		-		Credit				
							L	T	P		Mar	ks	Duration	
1	BPH701T	Instrumental Methods of Analysis  – Theory	10	15	1 Hr	25	3	1		4	75	25	3 Hrs	100
2	BPH702T	Industrial Pharmacy-II – Theory	10	15	1 Hr	25	3	1		4	75	25	3 Hrs	100
3	BPH703T	Pharmacy Practice – Theory	10	15	1 Hr	25	3	1		4	75	25	3 Hrs	100
4	BPH704T	Novel Drug Delivery System – Theory	10	15	1 Hr	25	3	1		4	75	25	3 Hrs	100
5	BPH701P	Instrumental Methods of Analysis  – Practical	5	10	4 Hr	15			4	2	35	15	4 Hrs	50
6	BPH709PS	Practice School*	25			25			12	6	125	25	5 Hrs	150
			70	70	8 Hrs	140		To	otal	24	460	140	21 Hrs	600

<sup>\*</sup>The subject experts at college level shall conduct examination

# **Board of Studies Members**

Course Title	In	Instrumental Methods of Analysis - Theory							
Course Code	BP	H <b>7</b> 01	T		Total theory periods : 45 Hrs	Total Tutorial periods : 15			
Course	L	Т	P	TC	Total marks in the end semes	ter : 75			
Credits	3	1		4	Minimum of class tests to be c	onducted: 02			
Prerequisites	Bas	sic fu	ndam	ental s	tudied in previous class in B.Ph	arm.			
Course Objectives		<ul> <li>At the end of the course, the student shall be able to</li> <li>Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis</li> <li>Understand the chromatographic separation and analysis of drugs.</li> <li>Perform quantitative &amp; qualitative analysis of drugs using various analytical instruments.</li> </ul>							
Course Contents	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								

# **Board of Studies Members**



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 electrophoresis mobility, Techniques of paper, gel, capillary electrophoresis, applications.

UNIT-IV 8 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



Course Outcomes	<ul> <li>Explain the theoretical principles underpinning the instrumental techniques and their applications.</li> <li>Independently integrate concepts and techniques in instrumental analysis and correlate to relevant applications.</li> </ul>
Text Books	<ol> <li>Instrumental Methods of Chemical Analysis by B.K Sharma.</li> <li>Organic spectroscopy by Y.R Sharma.</li> <li>Text book of Pharmaceutical Analysis by Kenneth A. Connors.</li> <li>Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel.</li> </ol>
Reference Books	<ol> <li>Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi.</li> <li>Spectrophotometric identification of Organic Compounds by Silverstein</li> </ol>



<b>Course Title</b>	Indu	strial	Phar	macy –	- Theory						
Course Code	ВРН	702T			Total theory periods : 45 Hrs	Total Tutorial periods : 15					
Course	L	T	P	TC	Total marks in the end semest	er : 75					
Credits	3	1		4	Minimum of class tests to be co	onducted: 02					
Prerequisites		Basic fundamental concept studied in brief in B.Pharm. I Sem in Physical pharmacy									
Course Objectives	<ul> <li>Upon completion of the course the student shall be able to</li> <li>Know the process of pilot plant and scale up of pharmaceutical dosage forms.</li> <li>Understand the process of technology transfer from lab scale to commercial batch.</li> <li>Know different laws and acts that regulate pharmaceutical industry in India and US.</li> <li>Understand the approval process and regulatory requirements for drug products.</li> </ul>										
	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										
Course Contents	Tech Term R & (API equip Appr proble	D to proved lems (E / SI	gies, 'gies, 'gies, 'gients', quaregula' regula' (case DBI;	Fechnol uction (s, finish alification atory be studies Techno	ent and transfer: WHO guideling logy transfer protocol, Quality rise (Process, packaging and cleaning ed products, packing materials) on and validation, quality controcodies and agencies, Commercialise, TOT agencies in India - APO logy of Transfer (TOT) related de MoUs, legal issues.	k management, Transfer from (s), Granularity of TT Process Documentation, Premises and I, analytical method transfer, zation - practical aspects and CTD, NRDC, TIFAC, BCIL,					



	UNIT – III 10 Hour
	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
	<b>Quality management systems:</b> 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.
Course Outcomes	<ul> <li>To correlate the theoretical knowledge with professional and practical need of pharmaceutical industry.</li> <li>Know the professional practice management skills in industry.</li> </ul>
Reference Books	<ul> <li>Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.</li> <li>International Regulatory Affairs Updates, 2005. Available at <a href="http://www.iraup.com/about.php">http://www.iraup.com/about.php</a>.</li> <li>Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs.</li> <li>A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.</li> <li>Regulatory Affairs brought by learning plus, inc. available at <a href="http://www.cgmp.com/ra.htm">http://www.cgmp.com/ra.htm</a>.</li> </ul>



Course Title	Pharmacy Practice – Theory										
Course Code	BP	H403	T		Total theory periods : 45 Hrs	Total Tutorial periods : 15					
Course	L	Т	P	TC	Total marks in the end semester: 75						
Credits	3	1		4	Minimum of class tests to be co	onducted: 02					
Prerequisites	Bas	Basic fundamental studied in previous class in B.Pharm.									
Course	U	• K	now	various d	of the course student shall be abluring distribution methods in a hosp	oital.					
Objectives		• A	pprec	tate the p	pharmacy stores management and	inventory control.					
		<ul> <li>Monitor drug therapy of patient through medication chart review and clinical review.</li> </ul>									
		• D	etect	and asse	ss adverse drug reactions.						
	τ	J <b>NIT</b> -	·I			10 Hours					
	a	) <b>H</b> o	spita	l and its	organization						
	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										
Course Contents	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, idiosyncrasy, allergic drug reactions, genetically determined to toxicity following sudden withdrawal of drugs,										
		Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting 150 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.

UNIT-II 10 Hours

#### a) 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.

#### 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.

UNIT-III 10 Hours

#### 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) Drug information services

Drug and Poison information centre, Sources of drug information, Computerized 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.

UNIT-IV 08 Hours

#### 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.

UNIT-V 07 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.								
	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								
	Students will use knowledge of drug distribution method in hospitals and apply in it the practice of pharmacy.								
Course Outcomes	• Students will engage in innovative activities by making use of the knowledge of clinical trials.								
	Students will effectively apply principles of drug store management and inventory control to medication use.								
	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.								
Text Books	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.								
	1. Therapeutic drug monitoring. ISSN: 0163-4356								
	2. Journal of pharmacy practice. ISSN: 0974-8326								
Journals	3. American journal of health system pharmacy. ISSN: 1535-2900 (online)								
	4. Pharmacy times (Monthly magazine)								



<b>Course Title</b>	No	Novel Drug Delivery Systems (Theory)									
Course Code	BP	H704	T		Total theory periods : 45 Hrs	Total Tutorial periods : 15					
Course	L	Т	P	TC	Total marks in the end semester: 75						
Credits	3	1		4	Minimum of class tests to be co	onducted: 02					
Prerequisites	Bas	Basic fundamental studied in previous class in B.Pharm.									
Course Objectives		<ul> <li>Upon completion of this course the student should be able to</li> <li>To understand various approaches for development of novel drug delivery systems.</li> <li>To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation</li> </ul>									
Course											



#### **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.

#### 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

#### **Targeted drug Delivery:**

Concepts and approaches for targeted drug delivery systems, advantages and disadvantages, introduction to liposomes, noisome, 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.

#### Course Outcomes

- Study various properties for sustained and controlled drug delivery systems.
- Learn mucosal and Transdermal drug delivery.



	Learn about site specific drug delivery.
	Study ocular drug delivery its tissues and challenges, drug selection.
Text Books	<ol> <li>Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.</li> <li>Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.</li> <li>Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim.</li> <li>N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers &amp; Distributors, New Delhi, First edition 1997 (reprint in 2001).</li> <li>S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.</li> </ol>
Journals	<ol> <li>Indian Journal of Pharmaceutical Sciences (IPA).</li> <li>Indian Drugs (IDMA).</li> <li>Journal of Controlled Release (Elsevier Sciences).</li> <li>Drug Development and Industrial Pharmacy (Marcel &amp; Decker).</li> <li>International Journal of Pharmaceutics (Elsevier Sciences).</li> </ol>



Course Title	INS	INSTRUMENTAL METHODS OF ANALYSIS (Practical)							
Course Code	BP	H705	P		Total Practical periods: 04 Hrs / week				
Course	L	T	P	TC	Total marks in the end semester: 35				
Credits			4	2					
Prerequisites		Basic fundamental studied in previous class B.Pharm. in subject of Pharmaceutical analysis							
Course Objectives	•	To give basic knowledge on instrumental methods of analysis and train students to perform practical work on real samples to get acquainted with instrumentation and equipments which is needed in monitoring of environmental pollution.							
Course Contents									
Course Outcomes	•	Cap	abilit	y of trea	ofessional sampling and sample treatment prior to analysis.  tment and evaluation of the result of analysis.  forming measurement on basic analytical instruments.				

