# Curriculum Structure & Syllabi

Of

# B. Pharm.

(w.e.f. 2025-26)

Overall

Credit

Structure Curriculum

Syllabus



Offered By

DEPARTMENT OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

MADAN MOHAN MALAVIYA UNIVERSITY OF
TECHNOLOGY (MMMUT) GORAKHPUR-273010, UP, INDIA

JULY 2025

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Overall Credit Structure for B. Pharm. Programme

	Credi	t Courses	
Undergraduate Co	re (UC)	Undergraduate	Electives (UE)
Category	Min. credits	Category	Min. credits
Basic Sciences &Maths (BSM)	2#	Program Electives (PE)	8
Engineering Fundamentals (EF)	17	Open Electives (OE) (Other Departments)	3
Department Core (DC)	170/173\$	Humanities & Social Science Electives (HSSE)	
Management (M)			
Humanities & Social Science Core (HSSC)	3		
Project (P)	12		
Total	202/204#/205 <sup>S</sup>	Total	11
		Grand Total	210/212#/213 <sup>5v</sup> (min.)
	Audi	Courses	
Audit Courses (Other Depart	tments)		12 (min.)
Seminar			3
		Grand Total	16 (min.)

<sup>#</sup> applicable ONLY for the students who have Mathematics/Physics/Chemistry at HSC and appearing for Remedial Biology course

Each student has to register for a set of courses as offered in each semester by paying the stipulated fees, which include tuition fee, examination fee, enrolment fee, development fee, insurance fee, degree fee, alumni fee, internet charges, hostel fee, mess advance, miscellaneous user charges etc. as applicable from time to time.

# First Year, Semester I

S.N.	Category	Paper Code	Subject	L	T	P	Credit
1	DC	BP101T	Human Anatomy and Physiology I	3	1	-	4
2	DC	BP102T	Pharmaceutical Analysis I	3	1	( <del>-</del>	4
3	DC	BP103T	Pharmaceutics I	3	1	-	4
4	DC	BP104T	Pharmaceutical Inorganic Chemistry	3	1	7 5	4
5	HSSC	BP105T	Communication skills - Theory *	2		-	2
6	DC/BMS	BP106RBT BP106RMT	Remedial Biology/ Mathematics – Theory*	2		-	2
7	DC	BP107P	Human Anatomy and Physiology I Practical	-	-	4	2
8	DC	BP108P	Pharmaceutical Analysis I Practical	3	-	4	2
9	DC	BP109P	Pharmaceutics I Practical	-	-	4	2
10	DC	BP110P	Pharmaceutical Inorganic Chemistry – Practical	-	-	4	2
11	HSSC	BP111P	Communication skills - Practical*	=	-	2	1
12	DC	BP112RBP	Remedial Biology# Practical	-	-	2	1
13	ECA 1		Induction Program	_	-	_	0
			Total	16	4	18/20 <sup>S</sup>	295/30

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<sup>\$</sup> applicable ONLY for the students who have studied Physics/Chemistry/Botany/Zoology at HSC and appearing for Remedial Mathematics Crouse

<sup>#</sup>applicable ONLY for the students who have Mathematics/Physics/Chemistry at HSC and appearing for Remedial Biology course

\$ applicable ONLY for the students who have studies Physics/Chemistry/Botany/Zoology at HSC and appearing for Remedial Mathematics Course

# Freshman Year, Semester-II

S.N.	Category	Paper Code	Subject	L	T	P	Credit
1	DC	BP201T	Human Anatomy and Physiology II-Theory	3	1	-	4
2	DC	BP202T	Pathophysiology	3	1	-	4
3	DC	BP203T	Biochemistry-Theory	3	1	-	4
4	DC	BP204T	Pharmaceutical Organic Chemistry I-Theory	3	1	-	4
5	DC	BP205T	Computer Applications in Pharmacy - Theory	3	-	-	3
6	DC	BP206T	Environmental sciences – Theory	3	2	-2	3
7	DC	BP207P	Human Anatomy and Physiology II -Practical	-	-	4	2
8	DC	BP208P	Pharmaceutical Organic Chemistry I-Practical	-	2	4	2
9	DC	BP209P	Biochemistry- Practical	-	-	4	2
10	DC	BP210P	Computer Applications in Pharmacy – Practical	-		2	1
11	ECA-II			.50	-	-	0
		187	Total	18	4	14	29

Sophomore Year, Semester-III

S.N.	Category	Paper Code	Subject	L	T	P	Credit
1	DC	BP301T	Physical Pharmaceutics I- Theory	3	1	-	4
2	DC	BP302T	Pharmaceutical Microbiology-Theory	3	1	-	4
3	DC	BP303T	Pharmaceutical Organic Chemistry II	3	1	-	4
4	DC	BP304T	Pharmaceutical Engineering-Theory	3	1	-	4
5	DC	BP305P	Pharmaceutical Organic Chemistry II – Practical	-	-	4	2
6	DC	BP306P	Physical Pharmaceutics I- Practical	-	-	4	2
7	DC	BP307P	Pharmaceutical Microbiology- Practical		-	4	2
8	DC	BP308P	Pharmaceutical Engineering -Practical	-	-	4	2
9	ECA-III			-	-	-	0
	· · · · · · · · · · · · · · · · · · ·		Total	12	4	16	24

Sophomore Vear, Semester-IV

S.N.	Category	Paper Code	Subject	L	T	P	Credit
1	DC	BP401T	Pharmaceutical Organic Chemistry III-Theory	3	1	-	4
2	DC	BP402T	Medicinal Chemistry I – Theory	3	1	-	4
3	DC	BP403T	Physical Pharmaceutics II- Theory	3	1	-	4
4	DC	BP404T	Pharmacology I- Theory	3	1	-	4
5	DC	BP405T	Pharmacognosy and Phytochemistry-theory	3	1	-	4
6	DC	BP406P	Medicinal Chemistry I – Practical	-	-	4	2
7	DC	BP407P	Physical Pharmaceutics II-Practical	-	-	4	2
8	DC	BP408P	Pharmacology I- Practical	2	27	4	2
9	DC	BP409P	Pharmacognosy and Phytochemistry-practical	-	-	4	2
10	ECA-IV			-	-	-	0
	1		Total	15	5	16	28

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# Junior Year, Semester-V

S.N.	Categor	Paper Code	Subject	L	Т	P	Credit
1	DC	BP501T	Medicinal Chemistry II-Theory	3	1	-	4
2	DC	BP502T	Industrial Pharmacy I-Theory	3	1	-	4
3	DC	BP503T	Pharmacology II-Theory	3	1	1-	4
4	DC	BP504T	Pharmacognosy and Phytochemistry II-Theory	3	1	-	4
5	DC	BP505T	Pharmaceutical Jurisprudence	3	1	-	4
6	DC	BP506P	Industrial Pharmacy I-Practical	-	-	4	2
7	DC	BP507P	Pharmacology II-Practical	-	-	4	2
8	DC	BP508P	Pharmacognosy and Phytochemistry II-Practical	-	-	4	2
9	ECA-V			-	-	-	0
			Total	15	5	12	26

### Junior Year, Semester-VI

S.N.	Category	Paper Code	Subject	L	T	P	Credit
1	DC	BP601T	Medicinal Chemistry III-Theory	3	1	-	4
2	DC	BP602T	Pharmacology III-Theory	3	1	-	4
3	DC	BP603T	Herbal Drug Technology-Theory	3	1	7.	4
4	DC	BP604T	Biopharmaceutics and Pharmacokinetics-Theory	3	1	==	4
5	DC	BP605T	Pharmaceutical Biotechnology-Theory	3	1	-	4
6	DC	BP606T	Quality Assurance-Theory	3	1	-	4
7	DC	BP607P	Medicinal Chemistry III-Practical	-	-	4	2
8	DC	BP608P	Pharmacology III-Practical	-	-	4	2
9	DC	BP609P	Herbal Drug Technology-Practical	-	-	4	2
10	ECA-VI			170	-	-	0
			Total	18	6	12	30

Note: The student is required to complete total 50-65 days industrial training (desirable) in Pharmaceutical Industries/Research Institutes/Hospitals, etc after IV and VI Semester and both training will be evaluated in Semester VII.

# Senior Year, Semester-VII

S.N.	Category	Paper Code	Subject	L	T	P	Credit
1	DC	BP701T	Instrumental Methods of Analysis -Theory	3	1		4
2	DC	BP702T	Industrial Pharmacy-II Theory	3	1		4
3	DC	BP703T	Pharmacy Practice-Theory	3	1		4
4	DC	BP704T	Novel Drug Delivery System-Theory	3	1		4
5	DC	BP705P	Instrumental Methods of Analysis -Practical			4	2
6	P	BP706PS*	Practice School			12	6
7	ECA-VII		11.1	-	1.00	-	0
			Total	12	4	16	24

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

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# Senior Year, Semester-VIII

S.N.	Category	Paper Code	Subject	L	T	P	Credit
1	DC	BP801T	Biostatistics and Research Methodology	3	1		4
2	DC	BP802T	Social and Preventive Pharmacy	3	1		4
3	PE	BP803ET	Pharma Marketing Management	3+3=	1+1=	5	4+4=8
4	PE	BP804ET	Pharmaceutical Regulatory Science	6	2		
5	PE	BP805ET	Pharmacovigilance				
6	PE	BP806ET	Quality Control and Standardization of Herbals				
7	PE	BP807ET	Computer Aided Drug Design				
8	PE	BP808ET	Cell and Molecular Biology				
9	PE	BP809ET	Cosmetic Science				
10	PE	BP810ET	Experimental Pharmacology				
11	PE	BP811ET	Advanced Instrumentation Techniques				
12	PE	BP812ET	Dietary Supplements and Nutraceuticals				
13	PE	BP813ET	Pharmaceutical Product Development				
14	P	BP814PW	Project Work		-	12	6
		1	Total	12	4	12	22

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Course Category	Departmental Core (DC)
Pre-requisite Subject	***
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	<ul> <li>This subject is designed to impart</li> <li>fundamental knowledge on the structure and functions of the various systems of the human body.</li> <li>It also helps in understanding homeostatic mechanisms and their imbalances.</li> <li>The subject provides the basic knowledge required to understand the various disciplines of pharmacy.</li> <li>It provides basic knowledge required to Identify structures in the body and analyze their relationship when other structures.</li> <li>To understand coordinated working pattern of different organs of each system.</li> <li>Scientific reasoning ability and the ability to interpret data through the biochemical parameters.</li> </ul>
Course Outcome	Upon completion of this course the student should be able to  o Explain the gross morphology, structure and functions of various organs of the human body.
	<ul> <li>Describe the various homeostatic mechanisms and their imbalances.</li> <li>Identify the various tissues and organs of different systems of human body.</li> </ul>
	<ul> <li>Perform the various experiments related to special senses and nervous system.</li> <li>Appreciate coordinated working pattern of different organs of each system</li> <li>Critically evaluate health articles and medical journals related to</li> </ul>

# Unit -I: Introduction to human body, Cellular level of organization, Tissue level of organization

Definition and scope of anatomy and physiology, levels of structural, organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine

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Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.

# Unit -II: Integumentary system, Skeletal system, Joints

Structure and functions of skin, Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system, Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction, Structural and functional classification, types of joints movements and its articulation

# Unit - III: Body fluids and blood, Lymphatic system

Body fluids, composition and functions of blood, hemopoeisis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system, Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system

# Unit- IV: Peripheral nervous system, Special senses, Cardiovascular system

Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system, Origin and functions of spinal and cranial nerves, Structure and functions of eye, ear, nose and tongue and their disorders, Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

#### Textbook

- K. Sembulingam, and P. Sembulingam, Essentials of Medical Physiology, Jaypee Brothers Medical Publishers, New Delhi.
- Janet S. Ross, and Kathleen J. W. Wilson, Anatomy and Physiology in Health and Illness, 6<sup>th</sup> Edition, Churchill Livingstone, 1987
- O. P. Tandon, and Y. Tripati, Best and Talyor's Physiological basis of Medical Practice-Best and Tailor, 13<sup>th</sup> Edition, Wolters Kluwer India Pvt. Ltd., 2011.
- Arthur C, Guyton and John. E. Hall, Text book of Medical Physiology, Miamisburg, OH, U.S.A.
- 5. Tortora Grabowski, Principles of Anatomy and Physiology by. Palmetto, GA, U.S.A.

#### Reference Book

- Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
- Textbook of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.

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3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje, Academic Publishers Kolkata

BP107P: HUMAN AN	ATOMY AND PHYSIOLOGY I-Practical
Course Category	Departmental Core (DC)
Pre-requisite Subject	
Contact hours/week	Practical: 4
No of Credits	2
Course Assessment Methods	Continuous assessment through attendance, assignment, daily practical work and practical test.
Course Objectives	This subject is designed to impart  o fundamental knowledge on the structure and functions of the various systems of the human body.  o It provides basic knowledge required to Identify structures in the body and analyze their relationship when other structures.  o To understand coordinated working pattern of different organs of each system.  o Scientific reasoning ability and the ability to interpret data through the biochemical parameters.
Course Outcome	<ul> <li>Upon completion of this course the student should be able to</li> <li>Explain the gross morphology, structure and functions of various organs of the human body.</li> <li>Describe the various homeostatic mechanisms and their imbalances.</li> <li>Identify the various tissues and organs of different systems of human body.</li> </ul>
	<ul> <li>Perform the various experiments related to special senses and nervous system.</li> <li>Appreciate coordinated working pattern of different organs of each system</li> <li>Critically evaluate health articles and medical journals related to Anatomy and Physiology.</li> </ul>

#### Practical's

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

- 1. Study of compound microscope.
- 2. Microscopic study of epithelial and connective tissue
- 3. Microscopic study of muscular and nervous tissue
- 4. Identification of axial bones
- 5. Identification of appendicular bones
- 6. Introduction to hemocytometry.
- 7. Enumeration of white blood cell (WBC) count

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- 8. Enumeration of total red blood corpuscles (RBC) count
- 9. Determination of bleeding time
- 10. Determination of clotting time
- 11. Estimation of hemoglobin content
- 12. Determination of blood group.
- 13. Determination of erythrocyte sedimentation rate (ESR).
- 14. Determination of heart rate and pulse rate.
- 15. Recording of blood pressure.

Course Category	Departmental Core (DC)
Pre-requisite Subject	
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	This course deals with the fundamentals of
Course Outcome	Upon completion of the course student shall be able to understand  the principles of volumetric and electro chemical analysis  carryout various volumetric and electrochemical titrations  develop analytical skills  the basic concepts and principles of titrimetric, gravimetric and electrochemical analyses  concentration, calculation of a solution, its preparation, standardization and its storage conditions  preparation of primary and secondary standard solutions.  standardization of secondary standard solutions

UNIT-I: Pharmaceutical analysis- Definition and scope, Errors, Pharmacopoeia

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Different techniques of analysis, Methods of expressing concentration, Primary and secondary standards, Preparation and standardization of various molar and normal solutions, Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate, Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures, Sources of impurities in medicinal agents, limit tests.

#### UNIT-II: Titrimetric Analysis

Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl. Concepts of oxidation and reduction, Types of redox titrations (Principles and applications) Cerimetry, Iodimetry, Iodometry,

UNIT-III: Precipitation titrations: Complexometric titration Classification Gravimetry
Mohr's method, Volhard's, Modified, Volhard's, Fajans method, estimation of sodium
chloride, metal ion indicators, masking and demasking reagents, estimation of Magnesium
sulphate, and calcium gluconate, Principle and steps involved in gravimetric analysis. Purity of
the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate, Basic
Principles, methods and application of diazotisation titration.

#### UNIT-IV: Redox titrations, Electrochemical methods of analysis

Bromatometry, Dichrometry, Titration with potassium iodate, Conductometry- Introduction, Conductivity cell, Conductometric titrations, applications, Potentiometry - Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications, Polarography - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications

#### Textbook

- A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
- 2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
- 3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
- 4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
- 5. John H. Kennedy, Analytical chemistry principles

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# 6. Indian Pharmacopoeia.

	EUTICAL ANALYSIS – I Practical
Course Category	Departmental Core (DC)
Pre-requisite Subject	
Contact hours/week	Practical:2
No of Credits	2
Course Assessment Methods	Continuous assessment through attendance, assignment, daily practical work and practical test.
Course Objectives	This course deals with the fundamentals of
	<ul> <li>analytical chemistry</li> <li>of volumetric analytical skills.</li> </ul>
	o principles of electrochemical analysis of drugs.
	<ul> <li>techniques of conductometry, potentiometry and polarography and their applications in the analysis of pharmaceuticals</li> <li>sources of errors commonly developed during drug analyses and methods to minimize them</li> <li>Student interpretation skills, which will be improved by the course content in terms of choice of analytical techniques to perform the estimation of different category drugs.</li> </ul>
Course Outcome	Upon completion of the course student shall be able to understand  o the principles of volumetric and electro chemical analysis  o carryout various volumetric and electrochemical titrations
	<ul> <li>develop analytical skills</li> </ul>
	o the basic concepts and principles of titrimetric, gravimetric and electrochemical analyses
	<ul> <li>concentration, calculation of a solution, its preparation, standardization and its storage conditions</li> </ul>
	<ul> <li>preparation of primary and secondary standard solutions.</li> <li>standardization of secondary standard solutions</li> </ul>

# Practical's

# I. Limit Test of the following

- o Chloride
- o Sulphate
- o Iron
- o Arsenic

# II. Preparation and standardization of

- Sodium hydroxide
- Sulphuric acid
- Sodium thiosulfate
- o Potassium permanganate
- o Ceric ammonium sulphate

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# III. Assay of the following compounds along with Standardization of Titrant

- Ammonium chloride by acid base titration
- o Ferrous sulphate by Cerimetry
- o Copper sulphate by Iodometry
- Calcium gluconate by complexometry
- Hydrogen peroxide by Permanganometry
- o Sodium benzoate by non-aqueous titration
- o Sodium Chloride by precipitation titration

# IV. Determination of Normality by electro-analytical methods

- o Conductometric titration of strong acid against strong base
- o Conductometric titration of strong acid and weak acid against strong base
- o Potentiometric titration of strong acid against strong base

BP103T: PHARMACI	
Course Category	Departmental Core (DC)
Pre-requisite Subject	NIL
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms. The primary objectives of this course are to-  O Discuss the basic knowledge on the various formulations. O Help the students to understand prescription and handling of the prescription. O Explain how to calculate the dose for child using various
	formulas.  O Help the students to understand the different weighing and measuring systems followed in the field of pharmacy.  O Equip the students to well verse in the different formulations such as solid, liquid and semisolid formulation.  O Facilitating the students to apply theoretical knowledge into practical outcomes such as incompatibility.
Course Outcome	Upon completion of this course the student should be able to:  o Know the history of profession of pharmacy  o Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical
	calculations o Familiar with the different weighing and measuring system

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followed in the field of pharmacy.

- Understand the professional way of handling the prescription
- Understand the basic knowledge on the various formulation's aspects.
- Preparation of various conventional dosage forms
- Use of practical knowledge in the field of incompatibility and method to overcome.

# UNIT - I: Historical background and development of profession of pharmacy, Dosage forms, Prescription, Posology

History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia, Introduction to dosage forms, classification and definitions, Definition, Parts of prescription, handling of Prescription and Errors in prescription, Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

# UNIT - II: Pharmaceutical calculations, Powders, Liquid dosage forms

Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight, Definition, classification, advantages and disadvantages, Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions, Advantages and disadvantages of liquid dosage forms, Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques.

# UNIT - III: Monophasic liquids, Biphasic liquids, Suspensions Emulsions

Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions, Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome, Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

#### UNIT - IV: Suppositories, Pharmaceutical incompatibilities, Semisolid dosage forms

Definition, types, advantages and disadvantages, types of bases, methods of preparations, Displacement value & its calculations, evaluation of suppositories, Definition, classification, physical, chemical and therapeutic incompatibilities with examples, Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments,

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pastes, creams and gels, Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms

#### Textbooks

- H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
- Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
- 3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
- 4. Indian pharmacopoeia.
- 5. British pharmacopoeia.
- Lachmann. Theory and Practice of Industrial Pharmacy, Lea & Febiger Publisher, The University of Michigan.
- Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott, Williams, New Delhi.
- 8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
- E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
- Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
- Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
- Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

Course Category	Departmental Core (DC)
Pre-requisite Subject	NIL
Contact hours/week	Practical:4
No of Credits	2
Course Assessment Methods	Continuous assessment through attendance, assignment, daily practical work and practical test.
Course Objectives	This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms. The primary objectives of this course are to-  O Discuss the basic knowledge on the various formulations.

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č	<ul> <li>Help the students to understand prescription and handling of the prescription.</li> <li>Help the students to understand the different weighing and</li> </ul>
	measuring systems followed in the field of pharmacy.
	o Equip the students to well verse in the different formulations
	such as solid, liquid and semisolid formulation.
	o Facilitating the students to apply theoretical knowledge into
	practical outcomes such as incompatibility.
Course Outcome	Upon completion of this course the student should be able to:
	<ul> <li>Know the history of profession of pharmacy</li> </ul>
287	o Understand the basics of different dosage forms,
	pharmaceutical incompatibilities and pharmaceutical calculations
	<ul> <li>Familiar with the different weighing and measuring system followed in the field of pharmacy.</li> </ul>
	<ul> <li>Understand the professional way of handling the prescription</li> </ul>
	<ul> <li>Understand the basic knowledge on the various formulation's aspects.</li> </ul>
	<ul> <li>Preparation of various conventional dosage forms</li> </ul>
	<ul> <li>Use of practical knowledge in the field of incompatibility and method to overcome.</li> </ul>

### Practical's

# 1.Syrups

- Syrup IP'66
- o Compound syrup of Ferrous Phosphate BPC'68

# 2. Elixirs

- o Piperazine citrate elixir
- Paracetamol pediatric elixir

# 3.Linctus

- o Terpin Hydrate Linctus IP'66
- o Iodine Throat Paint (Mandles Paint)

#### 4. Solutions

- o Strong solution of ammonium acetate
- o Cresol with soap solution
- o Lugol's solution

# 5. Suspensions

- Calamine lotion
- o Magnesium Hydroxide mixture

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o Aluminium Hydroxide gel

### 6. Emulsions

- o Turpentine Liniment
- o Liquid paraffin emulsion

### 7. Powders and Granules

- o ORS powder (WHO)
- o Effervescent granules
- Dusting powder
- o Divided powders

# 8. Suppositories

- o Glycero gelatin suppository
- Coca butter suppository
- o c) Zinc Oxide suppository

## 8. Semisolids

- o Sulphur ointment
- o Non staining-iodine ointment with methyl salicylate
- o Carbopal gel

# 9. Gargles and Mouthwashes

- o Iodine gargle
- o Chlorhexidine mouthwash

Course Category	Department Core (DC)
Pre-requisite Subject	
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objective	This subject deals with the monographs of inorganic drugs and pharmaceuticals. The primary objectives of this course are to-  o To provide knowledge about important inorganic pharmaceuticals in pharmacopoeia regarding their preparation, quality standard and pharmaceutical uses.  o To discuss various therapeutic classes of inorganic agents.  o Describe acids, bases, buffers, water and different GIT agents.  o Describe the major intra and extra cellular electrolytes, essential and trace elements, cationic and anionic components of inorganic drugs.  o Familiarize with the principles of limit tests, different classes of inorganic pharmaceuticals and their analysis.

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	<ul> <li>Explain topical agents, antacids, gases and vapours, dental products, pharmaceuticals aid and radio pharmaceuticals.</li> </ul>
Course Outcome	Upon completion of course student shall be able to  know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals  understand the medicinal and pharmaceutical importance of inorganic compounds  Having basic knowledge about various impurities in pharmaceuticals and also principles and methods of limit tests to control common impurities in pharmaceutical substances.  To highlight the domain of radiopharmaceuticals used in the diagnostics and therapy  Explain different pharmaceutical buffers, their preparations and uses in pharmaceutical system  Acquire basic knowledge regarding general methods of preparation of inorganic compounds of pharmaceutical importance  Knowledge identify/confirm the unknown inorganic anions and cations.

# UNIT - I: Impurities in pharmaceutical substances, General methods of preparation

History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate, assay for the compounds superscripted with **asterisk** (\*), properties and medicinal uses of inorganic compounds belonging to the following classes.

# UNIT – II: Acids, Bases and Buffers Major extra and intracellular electrolytes, Dental products

Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity, Functions of major physiological ions, Electrolytes used in the replacement therapy, Sodium chloride\*, Potassium chloride, Calcium gluconate\* and Oral Rehydration Salt (ORS), Physiological acid base balance, Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

### UNIT - III: Gastrointestinal agents, Acidifiers, Antacid, Cathartics, Antimicrobials

Ammonium chloride\* and Dil. HCl, Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate\*, Aluminum hydroxide gel, Magnesium hydroxide mixture, Magnesium

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sulphate, Sodium orthophosphate, Kaolin and Bentonite Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide\*, Chlorinated lime\*, Iodine and its preparations

# UNIT IV: Miscellaneous compounds, Expectorants, Emetics, Haematinics, Poison and Antidote Astringents, Radiopharmaceuticals

Potassium iodide, Ammonium chloride\*, Copper sulphate\*, Sodium potassium tartarate, Ferrous sulphate\*, Ferrous gluconate, Sodium thiosulphate\*, Activated charcoal, Sodium nitrite333, Zinc Sulphate, Potash Alum, Radio activity, Measurement of radioactivity, Properties of a, β, γ radiations, Half-life, radio isotopes and study of radio isotopes – Sodium iodide I131, Storage conditions, precautions & pharmaceutical application of radioactive substances.

#### Textbooks

- A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.
- 2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
- 3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition
- 4. M.L Schroff, Inorganic Pharmaceutical Chemistry
- 5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
- 6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
- 7. Indian Pharmacopoeia

Course Category	Department Core (DC)
Pre-requisite Subject	***
Contact hours/week	Practical:4
No of Credits	2
Course Assessment Methods	Continuous assessment through attendance, assignment, daily practical work and practical test.
Course Objective	This subject deals with the monographs of inorganic drugs and pharmaceuticals. The primary objectives of this course are to- o To provide knowledge about important inorganic pharmaceuticals in pharmacopoeia regarding their preparation, quality standard and pharmaceutical uses. o Describe the major intra and extra cellular electrolytes, essential and trace elements, cationic and anionic components of inorganic drugs. o Familiarize with the principles of limit tests, different classes of inorganic pharmaceuticals and their analysis. o Explain topical agents, antacids, gases and vapours, dental

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	products, pharmaceuticals aid and radio pharmaceuticals.
Course Outcome	Upon completion of course student shall be able to
	<ul> <li>know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals</li> <li>understand the medicinal and pharmaceutical importance of inorganic compounds</li> <li>Having basic knowledge about various impurities in pharmaceuticals and also principles and methods of limit tests to control common impurities in pharmaceutical substances.</li> <li>Explain different pharmaceutical buffers, their preparations and uses in pharmaceutical system</li> <li>Acquire basic knowledge regarding general methods of preparation of inorganic compounds of pharmaceutical importance</li> <li>Knowledge identify/confirm the unknown inorganic anions and cations.</li> </ul>

# Practical's

# I. Limit tests for following ions

- o Limit test for Chlorides and Sulphates
- Modified limit test for Chlorides and Sulphates
- o Limit test for Iron
- o Limit test for Heavy metals
- o Limit test for Lead
- o Limit test for Arsenic

### II Identification test

- o Magnesium hydroxide
- o Ferrous sulphate
- o Sodium bicarbonate
- o Calcium gluconate
- o Copper sulphate

# III Test for purity

- o Swelling power of Bentonite
- o Neutralizing capacity of aluminum hydroxide gel
- o Determination of potassium iodate and iodine in potassium Iodide

# IV Preparation of inorganic pharmaceuticals

- Boric acid
- Potash alum

# o Ferrous sulphate

BP105T: Communicat	ion Skills Theory
Course Category	HSSC
Pre-requisite Subject	****
Contact hours/week	Lecture: 2, Tutorial: 0
No of Credits	2
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	The primary objectives of this course are to  O Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation  O Communicate effectively (Verbal and Non Verbal)  O Effectively manage the team as a team player  O Develop interview skills  O Develop Leadership qualities and essentials
Course Outcome	<ul> <li>Upon completion of the course, the student shall be able to</li> <li>equip students with the ability to communicate effectively in various contexts, both orally and in writing,</li> <li>and to engage in active listening and critical thinking</li> <li>Students should be able to adjust their communication style to different audiences, contexts, and situations. This includes understanding cultural differences and using appropriate language and tone.</li> <li>Students should be able to build and maintain positive relationships with others through effective communication and collaboration. This includes developing teamwork skills and resolving conflicts constructively.</li> </ul>

## Unit-I

Communication Skills: Introduction, Definition, The Importance of Communication, the communication process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context. Barriers to communication: Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers. Perspectives in communication: Introduction, Visual perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment.

#### Unit-II

Elements of communication: Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication. Communication styles: Introduction, The Communication Styles Matrix with example for each Direct communication style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style.

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#### Unit-III

**Basic listening skills**: Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in difficult situations.

Effective written communication: Introduction, When and When Not to Use Written Communication- Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication.

Writing effectively: Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message.

#### Unit-IV

Interview skills: Purpose of an interview, Do's and Don'ts of an interview.

Giving presentations: Dealing with Fears, planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery.

Group discussion: Introduction, Communication skills in group discussion, Do's and Don'ts of group discussion.

# Recommended Books: (Latest Edition)

- Basic communication skills for Technology, Andreja. J. Ruther Ford, 2 nd Edition, Pearson Education, 2011
- 2. Communication skills, Sanjay Kumar, Pushpalata, 1 st Edition, Oxford Press, 2011
- 3. Organizational Behaviour, Stephen .P. Robbins, 1 st Edition, Pearson, 2013
- 4. Brilliant- Communication skills, Gill Hasson, 1 st Edition, Pearson Life, 2011
- The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5thEdition, Pearson, 2013
- 6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
- 7. Communication skills for professionals, Konar nira, 2 nd Edition, New arrivals PHI, 2011
- 8. Personality development and soft skills, Barun K Mitra, 1 st Edition, Oxford Press, 2011
- 9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
- 10. Soft skills and professional communication, Francis Peters SJ, 1 st Edition, Mc Graw Hill Education, 2011
- 11. Effective communication, John Adair, 4th Edition, Pan Mac Millan, 2009
- 12. Bringing out the best in people, Aubrey Daniels, 2 nd Edition, Mc Graw Hill, 1999

<b>BP111P:</b> Communicat	ion Skills Practical
Course Category	HSSC
Pre-requisite Subject	
Contact hours/week	Practical: 2
No of Credits	1
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	The primary objectives of this course are to

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e: 0	<ul> <li>Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation</li> <li>Communicate effectively (Verbal and Non Verbal)</li> <li>Effectively manage the team as a team player</li> <li>Develop interview skills</li> <li>Develop Leadership qualities and essentials</li> </ul>
Course Outcome	Upon completion of the course, the student shall be able to

#### Course content:

The following learning modules are to be conducted using words worth® English language lab software.

# Basic communication covering the following topics

Meeting People. Asking Questions. Making Friends. What did you do? Do's and Don'ts.

# Pronunciations covering the following topics

Pronunciation (Consonant Sounds). Pronunciation and Nouns. Pronunciation (Vowel Sounds).

# Advanced Learning

Listening Comprehension / Direct and Indirect Speech.
Figures of Speech.
Effective Communication.
Writing Skills.
Effective Writing.
Interview Handling Skills.
E-Mail etiquette.
Presentation Skills.

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BP100KB1: KEMEDI	AL BIOLOGY Theory
Course Category	Departmental Core (DC)
Pre-requisite Subject	(max)
Contact hours/week	Lecture: 2, Tutorial: 0
No of Credits	2
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	To learn and understand the components of living world, structure and functional system of plant and animal kingdom. The primary objectives of this course are to  O Know the classification and salient features of five kingdoms of life  O Understand the basic components of anatomy & physiology of plant  O Understand the basic components of anatomy & physiology of animal with special reference to human  O To understand structure of prokaryotic cells  O To Understand cellular, tissue and organ level systems of eukaryotes.  O To understand about secondary metabolites.
Course Outcome	<ul> <li>Upon completion of the course, the student shall be able to</li> <li>know the classification and salient features of five kingdoms of life</li> <li>understand the basic components of anatomy &amp; physiology of plant</li> <li>know understand the basic components of anatomy &amp; physiology animal with</li> <li>special reference to human</li> <li>Recognize about the different cell inclusions, cell wall components and some secondary metabolite</li> <li>Recognize the different cell inclusions, cell wall components and some secondary metabolites</li> <li>To know about the anatomy and physiology of animals in reference to human beings</li> </ul>

# UNIT I: Living world:

Definition and characters of living organisms, Diversity in the living world, Binomial nomenclature, Five kingdoms of life and basis of classification. Salient features of Monera, Potista, Fungi, Animalia and Plantae, Virus, Morphology of Flowering plants, Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed. General Anatomy of Root, stem, leaf of monocotyledons & Dicotylidones.

UNIT II: Body fluids and circulation

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Composition of blood, blood groups, coagulation of blood, Composition and functions of lymph, Human circulatory system, Structure of human heart and blood vessels, Cardiac cycle, cardiac output and ECG, Digestion and Absorption, Human alimentary canal and digestive glands, Role of digestive enzymes, Digestion, absorption and assimilation of digested food Breathing and respiration, Human respiratory system, Mechanism of breathing and its regulation, Exchange of gases, transport of gases and regulation of respiration, Respiratory volumes

# UNIT III: Excretory products and their elimination

Modes of excretion, Human excretory system- structure and function, Urine formation, Rennin angiotensin system, Neural control and coordination, Definition and classification of nervous system, Structure of a neuron, Generation and conduction of nerve impulse, Structure of brain and spinal cord, Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical coordination and regulation, Endocrine glands and their secretions, Functions of hormones secreted by endocrine glands

Human reproduction: Parts of female reproductive system, Parts of male reproductive system, Spermatogenesis and Oogenesis, Menstrual cycle

# UNIT IV: Plants and mineral nutrition:

Essential mineral, macro and micronutrients, Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation, Photosynthesis, Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.

Plant growth and development: Phases and rate of plant growth, Condition of growth, Introduction to plant growth, regulators, Cell - The unit of life structure and functions of cell and cell organelles. Cell division tissues Definition, types of tissues, location and functions.

#### **Textbooks**

- 1. Textbook of Biology by S. B. Gokhale
- 2. A Textbook of Biology by Dr. Thulajappa and Dr. Seetaram.
- 3. Textbook of Biology by B.V. Sreenivasa Naidu
- 4. A Textbook of Biology by Naidu and Murthy
- 5. Botany for Degree students By A.C.Dutta.
- 6. Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.
- 7. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

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BP112RBP: REMEDI	AL BIOLOGY -Practical
Course Category	Departmental Core (DC)
Pre-requisite Subject	
Contact hours/week	Practical:2
No of Credits	1
Course Assessment Methods	Continuous assessment through attendance, assignment, daily practical work and practical test.
Course Objectives	To learn and understand the components of living world, structure and functional system of plant and animal kingdom. The primary objectives of this course are to  O Know the classification and salient features of five kingdoms of life  O Understand the basic components of anatomy & physiology of plant  O Understand the basic components of anatomy & physiology of animal with special reference to human  O To understand structure of prokaryotic cells  O To Understand cellular, tissue and organ level systems of eukaryotes.
Course Outcome	Upon completion of the course, the student shall be able to     understand the basic components of anatomy & physiology of plant     know understand the basic components of anatomy & physiology animal with     special reference to human     Recognize about the different cell inclusions, cell wall components and some secondary metabolite     Recognize the different cell inclusions, cell wall components and some secondary metabolites     To know about the anatomy and physiology of animals in reference to human beings

# Practical

- 1. Introduction to experiments in biology
  - Study of Microscope
  - o Section cutting techniques
  - Mounting and staining
  - o Permanent slide preparation
- 2. Study of cell and its inclusions
- 3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
- 4. Detailed study of frog by using computer models
- 5. Microscopic study and identification of tissues pertinent to Stem, Root Leaf, seed, fruit and flower

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- 6. Identification of bones
- 7. Determination of blood group
- 8. Determination of blood pressure
- 9. Determination of tidal volume

#### Reference Books

- 1. Practical human anatomy and physiology. by S. R. Kale and R. R. Kale.
- A Manual of pharmaceutical biology practical by S. B. Gokhale, C. K. Kokate and S. P. Shriwastava.
- Biology practical manual according to National core curriculum. Biology forum of Karnataka. Prof. M. J. H. Shafi

Course Category	Departmental Core (DC)
Pre-requisite Subject	
Contact hours/week	Lecture: 2, Tutorial: 0
No of Credits	2
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	Upon completion of the course the student shall be able to:      Know the theory and their application in Pharmacy     Solve the different types of problems by applying theory     Appreciate the important application of mathematics in Pharmacy
Course Outcome	Upon completion of the course, the student shall be able to O Apply mathematical concepts and principles to perform computations for Pharmaceutical Sciences. O Create, use and analyze mathematical representations and
- *	mathematical relationships  Ocommunicate mathematical knowledge and understanding to help in the field of Clinical Pharmacy  Perform abstract mathematical reasoning

#### Course Content:

UNIT-I

Partial fraction

Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction, Resolving into Partial fraction, Application of Partial Logarithms Fraction in Chemical Kinetics and Pharmacokinetics

Logarithms

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Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

#### Function

Real Valued function, Classification of real valued functions,

#### Limits and continuity

Introduction, Limit of a function, Definition of limit of a function ( $\in$  -  $\delta$  definition),  $\lim_{x \to a} \frac{x^n - a}{x - a} = na^{n-1}, \quad \lim_{\theta \to 0} \frac{\sin \theta}{\theta} = 1,$ 

### UNIT II

#### Matrices and Determinant:

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants, Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix, Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley–Hamilton theorem, Application of Matrices in solving Pharmacokinetic equation.

#### UNIT - III

#### Calculus

Differentiation: Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function, Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions (Quotient formula) – Without Proof, Derivative of  $x^n$  w.r.t. x,where n is any rational number, Derivative of  $e^x$ , Derivative of  $\log_e x$ , Derivative of  $a^x$ , Derivative of trigonometric functions from first principles (without Proof), Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point.

**Differential Equations**: Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations, Application in solving Pharmacokinetic equations

#### UNIT-IV

# Application Analytical Geometry

Introduction: Signs of the Coordinates, Distance formula, Straight Line: Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line Integration: Introduction,

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Definition, Standard formulae, Rules of integration, Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

Laplace Transform: Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, Application in solving Chemical kinetics and Pharmacokinetics equations

Recommended Books (Latest Edition)

- 1. Differential Calculus by Shanthinarayan
- 2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.
- 3. Integral Calculus by Shanthinarayan
- 4. Higher Engineering Mathematics by Dr.B.S.Grewal

#### II SEMESTER

BP201T: HUMAN AN	ATOMY AND PHYSIOLOGY - II, Theory
Course Category	Departmental Core (DC)
Pre-requisite Subject	BPT-11
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. The primary objectives of this course are to  O Learn the various cells and tissues of different systems of human body.  O Understand the gross morphology, structure and functions of bones and various organs of the human body.  O Determining the abnormalities in the ranges of blood and physiological parameters through interpreting the normal values  O Understand the anatomy & Physiology of various systems  O Understand the role of different systems in maintenance of homeostasis  O provide the basic knowledge required to understand the various disciplines of pharmacy
Course Outcome	Upon completion of the course, the student shall be able to  o Explain the gross morphology, structure and functions of various organs of the human body.  o Describe the various homeostatic mechanisms and their imbalances.

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- Identify the various tissues and organs of different systems of human body.
- Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.
- Appreciate coordinated working pattern of different organs of each system and the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.
- Explain the physiology of skeletal muscle contraction

#### Unit I: Nervous system

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters. Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. Structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity).

# Unit II Digestive system, Energetics

Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT, Formation and role of ATP, Creatinine Phosphate and BMR.

#### Unit III: Respiratory system, Urinary system

Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods, Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

#### Unit IV: Endocrine system, Reproductive system, Introduction to genetics

Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders, Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition, Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

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#### Textbooks

- Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
- Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
- Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA
- Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
- 5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
- Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.
- Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
- 8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

#### Reference Books:

- Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
- Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
- 3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje, Academic Publishers Kolkata

BP207P: HUMAN AN	ATOMY AND PHYSIOLOGY – II, Practical
Course Category	Departmental Core (DC)
Pre-requisite Subject	BPT-11
Contact hours/week	Practical:4
No of Credits	2
Course Assessment Methods	Continuous assessment through attendance, assignment, daily practical work and practical test.
Course Objectives	This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. The primary objectives of this course are to  o Learn the various cells and tissues of different systems of human body.  o Understand the gross morphology, structure and functions of

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	bones and various organs of the human body.  Determining the abnormalities in the ranges of blood and physiological parameters through interpreting the normal values  Understand the anatomy & Physiology of various systems  Understand the role of different systems in maintenance of homeostasis  provide the basic knowledge required to understand the various
Course Outcome	disciplines of pharmacy
Course Outcome	<ul> <li>Upon completion of the course, the student shall be able to</li> <li>Explain the gross morphology, structure and functions of various organs of the human body.</li> <li>Describe the various homeostatic mechanisms and their imbalances.</li> <li>Identify the various tissues and organs of different systems of human body.</li> </ul>
	<ul> <li>Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.</li> <li>Appreciate coordinated working pattern of different organs of each system and the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.</li> <li>Explain the physiology of skeletal muscle contraction</li> </ul>

## Practical's

Practical physiology is complimentary to the theoretical discussions in physiology. Practical's allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

- 1. To study the integumentary and special senses using specimen, models, etc.,
- 2. To study the nervous system using specimen, models, etc.,
- 3. To study the endocrine system using specimen, models, etc
- 4. To demonstrate the general neurological examination
- 5. To demonstrate the function of olfactory nerve
- 6. To examine the different types of taste.
- 7. To demonstrate the visual acuity
- 8. To demonstrate the reflex activity
- 9. Recording of body temperature
- 10. To demonstrate positive and negative feedback mechanism.
- 11. Determination of tidal volume and vital capacity.

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- 12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
- 13. Recording of basal mass index .
- 14. Study of family planning devices and pregnancy diagnosis test.
- 15. Demonstration of total blood count by cell analyser
- 16. Permanent slides of vital organs and gonads.

BP202T: PATHOPHY	SIOLOGY
Course Category	Departmental Core (DC)
Pre-requisite Subject	
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course objective	<ul> <li>The primary objectives of this course are to</li> <li>Understand relevant aspects of pathology of various conditions with reference to its pharmacological applications,</li> <li>to understand basic pathophysiological mechanisms.</li> <li>To study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.</li> <li>Understand the role of different systems in maintenance of homeostasis</li> <li>Describe the etiology and pathogenesis of AIDS, Syphilis, Gonorrhea</li> <li>Describe Pathogenesis of chronic inflammation</li> </ul>
Course Outcome	Upon completion of the course, the student shall be able to  Describe the etiology and pathogenesis of the selected disease states;  Describe the principles of Cell Injury and Adaptation  Name the signs and symptoms of the diseases; and  Mention the complications of the diseases  Knowledge of signs and symptoms of the diseases  Identify the complications of the diseases.  Know most commonly encountered pathophysiological state(s) and/or disease mechanism(s), as well as any clinical testing requirements

# Unit I: Basic principles of Cell injury and Adaptation, Basic mechanism involved in the process of inflammation and repair:

Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy,

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Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance, Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation - Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis

# Unit II: Cardiovascular System, Respiratory system, Renal system:

Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis), Asthma, Chronic obstructive airways diseases, Acute and chronic renal failure.

# Unit II: Haematological Diseases, Endocrine system, Nervous system, Gastrointestinal system:

Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia, Diabetes, thyroid diseases, disorders of sex hormones Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease, Peptic Ulcer

# Unit IV: Inflammatory bowel diseases, Disease of bones and joints, Principles of cancer, Diseases of bones and joints, Principles of Cancer Infectious diseases, Sexually transmitted diseases

jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease, Rheumatoid arthritis, osteoporosis and gout, classification, etiology and pathogenesis of cancer, Rheumatoid Arthritis, Osteoporosis, Gout, Classification, etiology and pathogenesis of Cancer, Meningitis, Typhoid, Leprosy, Tuberculosis, Urinary tract infections, AIDS, Syphilis, Gonorrhea

# Textbooks

- 1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins &Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
- 2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
- 3. Laurence B, Bruce C, Bjorn K.; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
- 4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;

5. William and Wilkins, Baltimore; 1991 [1990 printing

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- Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
- Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
- Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey;
   Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
- 9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia;
- 10. WB Saunders Company; 1997.
- 11. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

#### Recommended Journals

- 1. The Journal of Pathology. ISSN: 1096-9896 (Online)
- 2. The American Journal of Pathology. ISSN: 0002-9440
- 3. Pathology. 1465-3931 (Online)
- International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online)
- 5. Indian Journal of Pathology and Microbiology. ISSN-0377-4929.

Course Category	Department Core
Pre-requisite Subject	Biology
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. The primary objectives of this course are to  O Provide the biochemical facts and the principles to the students of pharmacy.  O Understand the catalytic activity of enzymes and importance of enzymes in diagnosis of diseases and therapeutic agents.  O Know the metabolic pathways of biomolecules in health and

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	<ul> <li>illness (metabolic disorders).</li> <li>Understand the genetic organization of mammalian genome, protein synthesis, replication, mutation and repair mechanism.</li> <li>Know the biochemical principles of organ function tests of kidney, liver and endocrine gland do the qualitative analysis and determination of biomolecules in the body fluids and their clinical significance.</li> <li>It is also emphasizing on genetic organization of mammalian genome and hetero &amp; autocatalytic functions of DNA.</li> </ul>
Course Outcome	<ul> <li>Upon completion of course student shall be able to</li> <li>understand the catalytic role of enzymes, importance of enzyme inhibitors in</li> <li>design of new drugs, therapeutic and diagnostic applications of enzymes.</li> <li>understand the metabolism of nutrient molecules in physiological and pathological conditions.</li> <li>understand the genetic organization of mammalian genome and functions of</li> <li>DNA in the synthesis of RNAs and proteins.</li> <li>: Link the biochemical reactions and pathways of several diseases.</li> <li>Critically interpret how the biomolecules acts on the body and its mechanisms.</li> </ul>

# UNIT I: Biomolecules, Bioenergetics

Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins, Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential, Energy rich compounds; classification; biological significances of ATP and cyclic AMP

### UNIT II: Carbohydrate metabolism, Biological oxidation

Glycolysis - Pathway, energetics and significance Citric acid cycle- Pathway, energetics and significance HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency Glycogen metabolism Pathways and glycogen storage diseases (GSD) Gluconeogenesis- Pathway and its significance Hormonal regulation of blood glucose level and Diabetes mellitus Electron transport chain (ETC) and its mechanism, Oxidative phosphorylation & its mechanism and substrate phosphorylation Inhibitors ETC and oxidative phosphorylation/Uncouplers level Pulson Angly Verma salder 20026

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### UNIT III: Lipid metabolism, Amino acid metabolism

B-Oxidation of saturated fatty acid (Palmitic acid), Formation and utilization of ketone bodies; ketoacidosis, De novo synthesis of fatty acids (Palmitic acid), Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity. General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia) Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline Catabolism of heme; hyperbilirubinemia and jaundice

# UNIT IV: Nucleic acid metabolism and genetic information transfer, Enzymes

Biosynthesis of purine and pyrimidine nucleotides Catabolism of purine nucleotides and Hyperuricemia and Gout disease Organization of mammalian genome Structure of DNA and RNA and their functions, DNA replication (semi conservative model) Transcription or RNA synthesis Genetic code, Translation or Protein synthesis and inhibitors, Introduction, properties, nomenclature and IUB classification of enzymes Enzyme kinetics (Michaelis plot, Line Weaver Burke plot), Enzyme inhibitors with examples Regulation of enzymes: enzyme induction and repression, allosteric, enzymes regulation Therapeutic and diagnostic applications of enzymes and isoenzymes, Coenzymes –Structure and biochemical functions

### Textbooks

- 1. Principles of Biochemistry by Lehninger.
- 2. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
- 3. Biochemistry by Stryer.
- 4. Biochemistry by D. Satyanarayan and U.Chakrapani
- 5. Textbook of Biochemistry by Rama Rao.
- 6. Textbook of Biochemistry by Deb.
- 7. Outlines of Biochemistry by Conn and Stumpf
- 8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
- 9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
- 10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.

11. Practical Biochemistry by Harold Varley.

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BP209P: BIOCHEMIS	STRY-Practical
Course Category	Department Core
Pre-requisite Subject	Biology
Contact hours/week	Practical
No of Credits	2
Course Assessment	Continuous assessment through attendance, assignment, daily practical
Methods	work and practical test.
Course Objectives	Biochemistry deals with complete understanding of the molecular
	levels of the chemical process associated with living cells. The scope
	of the subject is providing biochemical facts and the principles to
	understand metabolism of nutrient molecules in physiological and
	pathological conditions. The primary objectives of this course are to
	o Provide the biochemical facts and the principles to the students
	of pharmacy.
	o Understand the catalytic activity of enzymes and importance of
	enzymes in diagnosis of diseases and therapeutic agents.
	o Know the metabolic pathways of biomolecules in health and
	illness (metabolic disorders).
	<ul> <li>Understand the genetic organization of mammalian genome,</li> </ul>
	protein synthesis, replication, mutation and repair mechanism.
	o Know the biochemical principles of organ function tests of
	kidney, liver and endocrine gland do the qualitative analysis
2	and determination of biomolecules in the body fluids and their
	clinical significance.
Course Outcome	Upon completion of course student shall be able to
	o understand the metabolism of nutrient molecules in
	physiological and pathological conditions.
	o understand the genetic organization of mammalian genome and
	functions of
	<ul> <li>DNA in the synthesis of RNAs and proteins.</li> </ul>
	Link the biochemical reactions and pathways of several
	diseases.
	<ul> <li>Critically interpret how the biomolecules acts on the body and</li> </ul>
	its mechanisms.

- Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
- 2. Identification tests for Proteins (albumin and Casein)

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- 3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
- 4. Qualitative analysis of urine for abnormal constituents
- 5. Determination of blood creatinine
- 6. Determination of blood sugar
- 7. Determination of serum total cholesterol
- 8. Preparation of buffer solution and measurement of pH
- 9. Study of enzymatic hydrolysis of starch
- 10. Determination of Salivary amylase activity
- 11. Study the effect of Temperature on Salivary amylase activity.
- 12. Study the effect of substrate concentration on salivary amylase activity.

Course Category	Departmental Core (DC)
Pre-requisite Subject	Basic Chemistry
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objective	This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The primary objectives of this course are to impart a very good knowledge about  O IUPAC/Common systems of nomenclature of simple organic compounds belonging to different classes of organic
	<ul> <li>Some important physical properties of organic compounds</li> <li>Free radical/ nucleophylic [alkyl/ acyl/ aryl] /electrophylic-substitution, free radical/ nucleophylic / electrophylic- addition, elimination, oxidation and reduction reactions with mechanism orientation, order of reactivity, stability of compounds</li> <li>Some named organic reactions with mechanisms</li> <li>Uses of organic compounds in pharmacy.</li> <li>The syllabus also emphasizes on mechanisms and orientation of reactions</li> </ul>

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- write the structure, name and the type of isomerism of the organic compound
- write the reaction, name the reaction and orientation of reactions
- o account for reactivity/stability of compounds,
- o identify/confirm the identification of organic compound
- Various uses of organic compounds in pharmacy
- Know about various reactions with mechanism, orientation, order of reactivity, stability of organic compounds
- Understand Systemic qualitative analysis of some unknown organic compounds

### UNIT-I: Classification, nomenclature and isomerism

Classification of Organic Compounds Common and IUPAC systems of nomenclature of organic compounds (up to 10 Carbons open chain and carbocyclic compounds) Structural isomerisms in organic compounds

# UNIT-II: Alkanes\*, Alkenes\* and Conjugated dienes\*

SP3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins, Stabilities of alkenes, SP2 hybridization in alkenes, E 1 and E 2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E 1 verses E 2 reactions, Factors affecting E1 and E 2 reactions, Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation, Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition, reactions of conjugated dienes, allylic rearrangement

### UNIT-III: Alkyl halides\*, Alcohols\*

SN 1 and SN 2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations, SN 1 versus SN 2 reactions, Factors affecting SN 1 and SN 2 reactions, Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform, Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol

# UNIT-IV: Carbonyl compounds\*(Aldehydes and ketones), Carboxylic acids\*, Aliphatic amines\*

Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde, Acidity of carboxylic acids, effect of

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substituents on acidity, inductive effect and qualitative tests for carboxylic acids, amide and ester Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine

### **Textbooks**

- 1. Organic Chemistry by Morrison and Boyd
- 2. Organic Chemistry by I.L. Finar, Volume-I
- 3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
- 4. Organic Chemistry by P.L.Soni
- 5. Practical Organic Chemistry by Mann and Saunders.
- 6. Vogel's text book of Practical Organic Chemistry
- 7. Advanced Practical organic chemistry by N.K. Vishnoi.
- 8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
- 9. Reaction and reaction mechanism by Ahluwaliah/Chatwal.

Course Category	Departmental Core (DC)
Pre-requisite Subject	Basic Chemistry
Contact hours/week	Practical
No of Credits	2
Course Assessment Methods	Continuous assessment through attendance, assignment, daily practical work and practical test.
Course Objective	The primary objectives of this course are to impart a very good
	knowledge about
	o IUPAC/Common systems of nomenclature of simple organic
*	compounds belonging to different classes of organic compounds
	<ul> <li>Free radical/ nucleophylic [alkyl/ acyl/ aryl] /electrophylic- substitution, free radical/ nucleophylic / electrophylic- addition,</li> </ul>
	elimination, oxidation and reduction reactions with mechanism, orientation, order of reactivity, stability of compounds
	<ul> <li>Some named organic reactions with mechanisms</li> </ul>
	<ul> <li>Uses of organic compounds in pharmacy.</li> </ul>
	<ul> <li>The syllabus also emphasizes on mechanisms and orientation of</li> </ul>

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	reactions
Course Outcome	Upon completion of course student shall be able to  o write the structure, name and the type of isomerism of the organic compound  o write the reaction, name the reaction and orientation of reactions  o account for reactivity/stability of compounds,  o identify/confirm the identification of organic compound  o Various uses of organic compounds in pharmacy  o Know about various reactions with mechanism, orientation, order of reactivity, stability of organic compounds  o Understand Systemic qualitative analysis of some unknown organic compounds

- 1. Systematic qualitative analysis of unknown organic compounds like
  - Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
  - ii. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
  - iii. Solubility test
  - iv. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
  - v. Melting point/Boiling point of organic compounds
  - vi. Identification of the unknown compound from the literature using melting point/ boiling point.
  - vii. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
- 2. Minimum 5 unknown organic compounds to be analysed systematically.
  - Preparation of suitable solid derivatives from organic compounds
  - ii. Construction of molecular models

Course Category	Department Core	
Pre-requisite Subject	Mar.	
Contact hours/week	Lecture: 3	
No of Credits	3	
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.	
Course Objectives	Upon completion of the course the student shall be able to	

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	<ol> <li>know the various types of application of computers in pharmacy</li> <li>know the various types of databases</li> <li>know the various applications of databases in pharmacy</li> </ol>
Course Outcome	<ol> <li>Apply the knowledge of mathematics and computing fundamentals to pharmaceutical applications for any given requirement</li> <li>Design and develop solutions to analyze pharmaceutical problems using computers.</li> </ol>
	<ul><li>3. Integrate and apply efficiently the contemporary IT tools to all Pharmaceutical related activities</li><li>4. Solve and work with a professional context pertaining to ethics, social, cultural and regulations with regard to Pharmacy.</li></ul>

#### Course content:

#### UNIT - I

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction - One's complement ,Two's complement method, binary multiplication, binary division Concept of Information Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project.

### UNIT-II

Web technologies: Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

### UNIT - III

Application of computers in Pharmacy - Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

## UNIT - IV

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery, Computers as data analysis in Preclinical development: Chromatographic dada analysis (CDS), Laboratory Information management System (LIMS) and Text Information Management System (TIMS).

### Recommended books (Latest edition):

1. Computer Application in Pharmacy - William E.Fassett -Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.

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- Computer Application in Pharmaceutical Research and Development –Sean Ekins Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
- 3. Bioinformatics (Concept, Skills and Applications) S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi 110 002(INDIA)
- 4. Microsoft office Access 2003, Application Development Using VBA, SQL Server, DAP and Infopath Cary N.Prague Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi 110002

<b>BP210P: COMPUTE</b>	R APPLICATION IN PHARMACY-Theory
Course Category	Department Core
Pre-requisite Subject	
Contact hours/week	Preatical: 2
No of Credits	1
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	Upon completion of the course the student shall be able to 1. know the various types of application of computers in pharmacy 2. know the various types of databases 3. know the various applications of databases in pharmacy
Course Outcome	<ol> <li>Apply the knowledge of mathematics and computing fundamentals to pharmaceutical applications for any given requirement</li> <li>Design and develop solutions to analyze pharmaceutical problems using computers.</li> <li>Integrate and apply efficiently the contemporary IT tools to all Pharmaceutical related activities</li> <li>Solve and work with a professional context pertaining to ethics, social, cultural and regulations with regard to Pharmacy.</li> </ol>

- 1. Design a questionnaire using a word processing package to gather information about a particular disease.
- 2. Create a HTML web page to show personal information.
- 3 Retrieve the information of a drug and its adverse effects using online tools
- 4 Creating mailing labels Using Label Wizard, generating label in MS WORD
- 5 Create a database in MS Access to store the patient information with the required fields Using access
- 6. Design a form in MS Access to view, add, delete and modify the patient record in the database
- 7. Generating report and printing the report from patient database
- 8. Creating invoice table using MS Access
- 9. Drug information storage and retrieval using MS Access

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- 10. Creating and working with queries in MS Access
- 11. Exporting Tables, Queries, Forms and Reports to web pages
- 12. Exporting Tables, Queries, Forms and Reports to XML pages

Course Category	Department Core	
Pre-requisite Subject	<u></u>	
Contact hours/week	Lecture: 3	
No of Credits	3	
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.	
Course Objectives	practical test.  Upon completion of the course the student shall be able to  1. Create the awareness about environmental problems among learners.  2. Impart basic knowledge about the environment and its allied problems.  3. Develop an attitude of concern for the environment.  4. Motivate learner to participate in environment protection and environment improvement.  5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.  6. Strive to attain harmony with Nature.	
Course Outcome	This program shall create an awareness about environmental problems, develop an attitude towards of concern for the environment.	

#### Course content:

### Unit-I

The Multidisciplinary nature of environmental studies

Natural Resources Renewable and non-renewable resources

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

# Unit-II

# **Ecosystems**

- · Concept of an ecosystem.
- · Structure and function of an ecosystem.
- · Concept of an ecosystem.
- Introduction, types, characteristic features, structure and function of Ecosystems the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

Unit- III

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Environmental Pollution: Air pollution; Water pollution; Soil pollution

# III SEMESTER

BP301T: PHYSICAL	PHARMACEUTICS-I-Theory
Course Category	Departmental Core (DC)
Pre-requisite Subject	Physics
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	The primary objective of the course are-  The course deals with the various physical and physicochemical properties, and principles involved in dosage forms/formulations.  Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development.  Stability studies of pharmaceutical dosage forms.  To understand behaviour of surface-active agents  To understand effect of physical properties of product development and its stability.  To understand thermodynamic reason of instability for heterogeneous dosage forms.
Course Outcome	Upon completion of the course student shall be able to understand
	<ul> <li>Understand the pharmaceutical applications of various physical properties</li> <li>Analyze the chemical stability tests of various drug products</li> </ul>

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## UNIT-I: Solubility of drugs:

Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications

# UNIT-II: States of Matter and properties of matter:

State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols - inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism.

Physicochemical properties of drug molecules: Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations and applications

# UNIT-III: Surface and interfacial phenomenon:

Liquid interface, surface & interfacial tensions, surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface.

### **UNIT-IV:** Complexation and protein binding:

Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants.

pH, buffers and Isotonic solutions: Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.

### Recommended Books (latest Edition)

- 1. Tutorial Pharmacy by Cooper and Gunn.
- 2. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
- Physical Pharmaceutics by Ramasamy C and ManavalanR.
- 4. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee

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- 5. Physical Pharmaceutics by C.V.S. Subramanyam
- 6. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar
- 1. Physical Pharmacy by Alfred Martin
- 2. Stocklosam J. Pharmaceutical Calculations, Lea & Febiger, Philadelphia.
- 3. Experimental Pharmaceutics by Eugene, Parott.
- 4. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.

	PHARMACEUTICS-I-Practical
Course Category	Departmental Core (DC)
Pre-requisite Subject	Physics
Contact hours/week	Practical:4
No of Credits	2
Course Assessment	Continuous assessment through attendance, assignment, daily practical
Methods	work and practical test.
Course Objectives	The primary objective of the course are-
	o The course deals with the various physical and
	physicochemical properties, and principles involved in dosage
	forms/formulations.
	<ul> <li>Theory and practical components of the subject help the student</li> </ul>
	to get a better insight into various areas of formulation research
	and development.
	Stability studies of pharmaceutical dosage forms.
	<ul> <li>To understand behaviour of surface-active agents</li> </ul>
	<ul> <li>To understand effect of physical properties of product</li> </ul>
	development and its stability.
	o To understand thermodynamic reason of instability for
	heterogeneous dosage forms.
Course Outcome	Upon completion of the course student shall be able to understand
Course Outcome	o various physicochemical properties of drug molecules in the
. 8	designing the dosage forms
	o To know the principles of chemical kinetics & to use them for
	stability testing and determination of expiry date of
	formulations
	o Demonstrate use of physicochemical properties in the
	formulation development and evaluation of dosage forms
	o State the physicochemical properties of drug molecules, pH,
	and solubility
	o Explain the role of surfactants, interfacial phenomenon and
	thermodynamics
	o Describe the flow behavior of fluids and concept of
	complexation
	<ul> <li>Understand the pharmaceutical applications of various physical</li> </ul>

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	properties
0	Analyze the chemical stability tests of various drug products

- 1. Determination the solubility of drug at room temperature
- 2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
- 3. Determination of Partition co- efficient of benzoic acid in benzene and water
- 4. Determination of Partition co- efficient of Iodine in CCl4 and water
- Determination of % composition of NaCl in a solution using phenol-water system by CST method
- Determination of surface tension of given liquids by drop count and drop weight method
- 7. Determination of HLB number of a surfactant by saponification method
- 8. Determination of Freundlich and Langmuir constants using activated char coal
- 9. Determination of critical micellar concentration of surfactants
- Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
- Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Course Category	Departmental Core (DC)
Pre-requisite Subject	Biology
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	Study of all categories of microorganisims especially for the production of alchol antibiotics, vaccines, vitamins enzymes etc. The objectives of this course are to:  o know the anatomy, identification, growth factors and sterilization of microorganisms  know the mode of transmission of disease-causing microorganism, symptoms of disease, and treatment aspect  appreciate the behavior of motility and behavioral characteristics of microorganisms  estimate RNA and DNA and there by identifying the source  do cultivation and identification of the microorganisms in the laboratory  identify the diseases by performing the diagnostic tests
Course Outcome	Upon completion of this course the student should be able to:

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- Understand methods of identification, cultivation and preservation of various microorganisms
- o To understand the importance and implementation of sterlization in pharmaceutical processing and industry
- Learn sterility testing of pharmaceutical products.
- Carried out microbiological standardization of Pharmaceuticals.
- Understand the cell culture technology and its applications in pharmaceutical industries
- o recognize the importance of sterilization and disinfectants process and aseptic conditions
- importance industrially Appreciate the of important microorganism.
- o Demonstrate use of physical, chemical and biological methods of controlling microorganism

UNIT - I: Introduction, history of microbiology, its branches, scope and its importance. Introduction to Prokaryotes and Eukaryotes Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count). Identification of bacteria using staining techniques (simple, Gram's & Acid fast staining) and biochemical tests (IMViC). Study of different types of phase constrast microscopy, dark field microscopy and electron microscopy.

UNIT - II: Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous, radiation and mechanical method of sterilization. Evaluation of the efficiency of sterilization methods. Equipments employed in large scale sterilization. Sterility indicators.

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses. Classification and mode of action of disinfectants Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions Evaluation of bactericidal & Bacteriostatic.

UNIT - III: Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification. Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic. Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

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UNIT – IV: Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage. Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations. Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures. Application of cell cultures in pharmaceutical industry and research.

### Recommended Books (latest Edition)

- 1. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
- 2. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
- 3. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
- 4. Peppler: Microbial Technology.
- 5. I.P., B.P., U.S.P.- latest editions.
- 6. Ananthnarayan: Text Book of Microbiology, Orient-Longman, Chennai
- 7. Edward: Fundamentals of Microbiology.
- 8. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
- W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
- 10. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
- 11. Rose: Industrial Microbiology.
- Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.
- Prescott and Dunn., Industrial Microbiology, 4 th edition, CBS Publishers & Distributors, Delhi.

Course Category	Departmental Core (DC)
Pre-requisite Subject	Biology
Contact hours/week	Practical:4
No of Credits	2
Course Assessment Methods	Continuous assessment through attendance, assignment, daily practical work and practical test.
Course Objectives	Study of all categories of microorganisims especially for the production of alchol antibiotics, vaccines, vitamins enzymes etc. The objectives of this course are to:  o know the anatomy, identification, growth factors and sterilization of microorganisms o know the mode of transmission of disease-causing

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	microorganism, symptoms of disease, and treatment aspect o appreciate the behavior of motility and behavioral characteristics of microorganisms o estimate RNA and DNA and there by identifying the source o do cultivation and identification of the microorganisms in the laboratory o identify the diseases by performing the diagnostic tests
Course Outcome	Upon completion of this course the student should be able to:  Understand methods of identification, cultivation and preservation of various microorganisms  To understand the importance and implementation of sterlization in pharmaceutical processing and industry  Learn sterility testing of pharmaceutical products.  Carried out microbiological standardization of Pharmaceuticals.  Understand the cell culture technology and its applications in pharmaceutical industries  recognize the importance of sterilization and disinfectants process and aseptic conditions  Appreciate the importance of industrially important microorganism.  Demonstrate use of physical, chemical and biological methods of controlling microorganism

- Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
- 2. Sterilization of glassware, preparation and sterilization of media.
- 3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
- Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
- Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
- 6. Microbiological assay of antibiotics by cup plate method and other methods
- 7. Motility determination by Hanging drop method.
- 8. Sterility testing of pharmaceuticals.
- 9. Bacteriological analysis of water
- 10. Biochemical test.

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Course Category	Departmental Core (DC)
Pre-requisite Subject	Basic Chemistry
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment	Continuous assessment through tutorials, attendance, home
Methods	assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	The objectives of this course are -:      This subject deals with general methods of preparation and reactions of some organic compounds.      Reactivity of organic compounds is also studied here.      The syllabus emphasizes on mechanisms and orientation or reactions.      Chemistry of fats and oils are also included in the syllabus.      Various reactions with mechanism such as Free radical nucleophylic/ electrophylicsubstitution, free radical nucleophylic / electrophylic- addition, elimination, oxidation and reduction and synthesis of organic compounds      Some named organic reactions with mechanisms and synthesis.      Uses of organic compounds in pharmacy
Course Outcome	<ul> <li>Upon completion of this course the student should be able to</li> <li>Write the structure, name and the type of isomerism of the organic compound</li> <li>Write the reaction, name the reaction and orientation of reactions</li> <li>Account for reactivity/stability of compounds,</li> <li>Prepare organic compounds</li> <li>Determination of some important physical properties like m.pt b.pt, solubility etc</li> <li>Synthesis of organic compounds with named reactions and study about mechanisms.</li> <li>Systemic qualitative analysis of some unknown organic compounds</li> </ul>

### Unit -I: Benzene and its derivatives

- A. Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule
- B. Reactions of benzene nitration, sulphonation, halogenationreactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.
- C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction
- D. Structure and uses of DDT, Saccharin, BHC and Chloramine

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#### Unit -II:

- Phenols Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols
- Aromatic Amines Basicity of amines, effect of substituents on basicity, and synthetic uses
  of aryl diazonium salts
- Aromatic Acids –Acidity, effect of substituents on acidity and important reactions of benzoic acid.

### Unit - III: Fats and Oils

Fatty acids – reactions. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

# Unit- IV: Polynuclear hydrocarbons

- a. Synthesis, reactions
- b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane,
   Triphenylmethane and their derivatives

### Cyclo alkanes

Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only

### Recommended Books (latest editions)

- 1. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
- 2. Vogel's text book of Practical Organic Chemistry
- 3. Advanced Practical organic chemistry by N.K. Vishnoi.
- 4. Organic Chemistry by Morrison and Boyd
- 5. Organic Chemistry by I.L. Finar, Volume-I
- 6. Organic Chemistry by P.L.Soni
- 7. Practical Organic Chemistry by Mann and Saunders.
- 8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

BP305P: PHARMACEUTICAL ORGANIC CHEMISTRY –II-Practical
Course Category Departmental Core (DC)

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Pre-requisite Subject	Basic Chemistry
Contact hours/week	Practical:4
No of Credits	2
Course Assessment Methods	Continuous assessment through attendance, assignment, daily practical work and practical test.
Course Objectives	The objectives of this course are -:      This subject deals with general methods of preparation and reactions of some organic compounds.      Reactivity of organic compounds is also studied here.      The syllabus emphasizes on mechanisms and orientation of reactions.      Chemistry of fats and oils are also included in the syllabus.      Various reactions with mechanism such as Free radical/ nucleophylic/ electrophylicsubstitution, free radical/ nucleophylic / electrophylic- addition, elimination, oxidation and reduction and synthesis of organic compounds
	<ul><li>Some named organic reactions with mechanisms and synthesis.</li><li>Uses of organic compounds in pharmacy</li></ul>
Course Outcome	Upon completion of this course the student should be able to  O Write the structure, name and the type of isomerism of the organic compound  O Write the reaction, name the reaction and orientation of reactions  O Account for reactivity/stability of compounds,  O Prepare organic compounds  O Determination of some important physical properties like m.pt, b.pt, solubility etc  O Synthesis of organic compounds with named reactions and study about mechanisms.  O Systemic qualitative analysis of some unknown organic compounds

# I Experiments involving laboratory techniques

- Recrystallization
- Steam distillation

# II Determination of following oil values (including standardization of reagents)

- Acid value
- · Saponification value
- Iodine value

# III Preparation of compounds

• Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation

reaction

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- 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
- · Acetanilide by halogenation (Bromination) reaction
- 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
- · Benzoic acid from Benzyl chloride by oxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-napthol from Aniline by diazotization and coupling reactions.
- · Benzil from Benzoin by oxidation reaction.
- · Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
- · Cinnammic acid from Benzaldehyde by Perkin reaction
- 11. P-Iodo benzoic acid from P-amino benzoic acid

	UTICAL ENGINEERING
Course Category	Department Core (DC)
Pre-requisite Subject	
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objective	This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry Explain the theoretical principles involved in unit operations Describe the basic concepts involved in pharmaceutical operations Explain the process of heat exchangers, filters, centrifuges, dryers, refrigeration systems etc. required for the manufacturing of various pharmaceutical formulations Interpret results of the experiments conducted Illustrate the material and energy requirements for optimizing the pharmaceutical unit processes.
Course Outcome	Upon completion of course student shall be able to  To know various unit operations used in Pharmaceutical industries.  To understand the material handling techniques.  To perform various processes involved in pharmaceutical manufacturing process.  To carry out various test to prevent environmental pollution.  To appreciate and comprehend significance of plant lay out design for optimum use of resources.  To appreciate the various preventive methods used for

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- corrosion control in Pharmaceutical industries.
- o Recommend the coordinated functioning of several unit operations for completion of any unit process

### UNIT - I

- Flow of fluids: Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer.
- · Size Reduction: Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.
- · Size Separation: Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.

#### UNIT - II:

- Heat Transfer: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat inter changers & heat exchangers.
- Evaporation: Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator& Economy of multiple effect evaporator.
- Distillation: Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

### UNIT - III:

Objectives, applications & mechanism of drying process, measurements & Drying: applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer. • Mixing: Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

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- Filtration: Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.
- Centrifugation: Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi-continuous centrifuge & super centrifuge.

# UNIT IV: Materials of pharmaceutical plant construction, Corrosion and its prevention:

Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. Ferrous and nonferrous metals, inorganic and organic non metals, basic of material handling systems.

# Recommended Books (latest Edition)

- Pharmaceutical engineering principles and practices C.V.S Subrahmanyam et al., Latest edition.
- 2. Remington practice of pharmacy- Martin, Latest edition.
- 3. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
- 4. Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
- 5. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition
- Introduction to chemical engineering Walter L Badger & Julius Banchero, Latest edition.
- Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson-Latest edition.
- 8. Unit operation of chemical engineering Mcabe Smith, Latest edition.

Course Category	Department Core (DC)
Pre-requisite Subject	
Contact hours/week	Practical: 4
No of Credits	2
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objective	This course is designed to impart a fundamental knowledge on  o the art and science of various unit operations used in pharmaceutical industry  o Explain the theoretical principles involved in unit operations  o Describe the basic concepts involved in pharmaceutical

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	operations  Explain the process of heat exchangers, filters, centrifuges, dryers, refrigeration systems etc. required for the manufacturing of various pharmaceutical formulations  Interpret results of the experiments conducted  Illustrate the material and energy requirements for optimizing the pharmaceutical unit processes.
Course Outcome	Upon completion of course student shall be able to  To know various unit operations used in Pharmaceutical industries.  To understand the material handling techniques.  To perform various processes involved in pharmaceutical manufacturing process.  To carry out various test to prevent environmental pollution.  To appreciate and comprehend significance of plant lay out design for optimum use of resources.  To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.  Recommend the coordinated functioning of several unit operations for completion of any unit process

- 1. Determination of radiation constant of brass, iron, unpainted and painted glass.
- 2. Steam distillation To calculate the efficiency of steam distillation.
- 3. To determine the overall heat transfer coefficient by heat exchanger.
- 4. Construction of drying curves (for calcium carbonate and starch).
- 5. Determination of moisture content and loss on drying.
- 6. Determination of humidity of air i) From wet and dry bulb temperatures -use of Dew point method.
- 7. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
  - 8. Size analysis by sieving To evaluate size distribution of tablet granulations -Construction of various size frequency curves including arithmetic andlogarithmic probability plots.
  - 9. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
  - 10. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such othermajor equipment. Anju Verma Page 57 of 155

- Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
- 12. To study the effect of time on the Rate of Crystallization.
- 13. To calculate the uniformity Index for given sample by using Double Cone Blender.

### IV SEMESTER

<b>BP401T: PHARMACE</b>	UTICAL ORGANIC CHEMISTRY -III
Course Category	Departmental Core (DC)
Pre-requisite Subject	Basic Chemistry
Contact hours/week	Lecture: 3, Tutorial: 1, Practical: 0
No of Credits	4
Course Assessment	Continuous assessment through tutorials, attendance, home
Methods	assignments, quizzes and one minor test, one major theory and
	practical test.
Course Objectives	This subject imparts knowledge on
53	o stereo-chemical aspects of organic compounds and organic
	reactions, important named reactions,
	<ul> <li>chemistry of important hetero cyclic compounds.</li> </ul>
	o It also emphasizes on medicinal and other uses of organic
	compounds.
2	o IUPAC nomenclature
	Systemic synthetic pathways
	<ul> <li>Ability to demonstrate and co-related with biological receptors</li> </ul>
Course Outcome	Upon completion of the course, the student shall be able to
	o Understand the methods of preparation and properties of
	organic compounds
	<ul> <li>Explain the stereo chemical aspects of organic compounds and</li> </ul>
	stereo chemical reactions
Λ	o know the medicinal uses and other applications of organic
	compounds
	Understand methods of qualitative and quantitative analysis
	Applications of some substances as medicinal agents
#-	Understand configuration of compounds.

# UNIT I: Stereo isomerism

Optical isomerism – Optical activity, enantiomerism, diastereoisomerism, meso compounds Elements of symmetry, chiral and achiral molecules DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers Reactions of chiral molecules Racemic modification and resolution of racemic mixture.

Asymmetric synthesis: partial and absolute

UNIT II: Geometrical isomerism

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Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems) Methods of determination of configuration of geometrical isomers. Conformational isomerism in Ethane, n-Butane and Cyclohexane. Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity. Stereospecific and stereoselective reactions

## UNIT III: Heterocyclic compounds:

Nomenclature and classification Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrrole, Furan, and Thiophene Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene.

Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrazole, Imidazole, Oxazole and Thiazole. Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives.

### UNIT IV Reactions of synthetic importance

Metal hydride reduction (NaBH4 and LiAlH4), Clemmensen reduction, Birch reduction, Wolff Kishner reduction, Oppenauer-oxidation and Dakin reaction, Beckmanns rearrangement and Schmidt rearrangement, Claisen-Schmidt condensation.

## Recommended Books (latest Edition)

- 1. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
- 2. Vogel's text book of Practical Organic Chemistry
- 3. Advanced Practical organic chemistry by N.K.Vishnoi.
- 4. Organic chemistry by I.L. Finar, Volume-I & II.
- 5. Heterocyclic Chemistry by Raj K. Bansal.
- 6. Organic Chemistry by Morrison and Boyd.
- 7. Heterocyclic Chemistry by T.L. Gilchrist.

<b>BP402T: MEDICINAL</b>	CHEMISTRY - I, Theory
Course Category	Departmental Core (DC)
Pre-requisite Subject	Organic Chemistry
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	This subject is designed to impart fundamental knowledge o on the structure, chemistry and therapeutic value of drugs.  The subject emphasizes on structure activity relationships of

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	drugs, importance of physicochemical properties and metabolism of drugs.  The syllabus also emphasizes on chemical synthesis of important drugs under each class.  Understand the chemistry of drugs with respect to their pharmacological activity  Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs  Know the Structural Activity Relationship (SAR) of different class of drugs
Course Outcome	Upon completion of the course, the student shall be able to  O Understand the chemistry of drugs with respect to their pharmacological activity  O Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs  Now the Structural Activity Relationship (SAR) of different class of drugs  Write the chemical synthesis of some drugs.  Helps in correlating between pharmacology of a disease and its mitigation or cure  Knowledge about the mechanism pathways of different class of medicinal compounds.

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (\*)

Unit I: Introduction to Medicinal Chemistry History and development of medicinal chemistry Physicochemical properties in relation to biological action Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism. Drug metabolism Drug metabolism principles- Phase I and Phase II. Factors affecting drug metabolism including stereo chemical aspects.

# Unit II Drugs acting on Autonomic Nervous System Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine. Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic agents Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine\*, Dopamine, Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol\*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

- Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
- Agents with mixed mechanism: Ephedrine, Metaraminol.

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Adrenergic Antagonists: Alpha adrenergic blockers: Tolazoline\*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

**Beta adrenergic blockers**: SAR of beta blockers, Propranolol\*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

**Unit III:** Biosynthesis and catabolism of acetylcholine. Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

**Direct acting agents:** Acetylcholine, Carbachol\*, Bethanechol, Methacholine, Pilocarpine. Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible): Physostigmine, Neostigmine\*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide, Parathione, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents Solanaceous

**Alkaloids and analogues:** Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide\*.

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride\*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride\*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

# Unit IV: Drugs acting on Central Nervous System

- A. Sedatives and Hypnotics: Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam\*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem
- B. Barbiturtes: SAR of barbiturates, Barbital\*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital
- C. Miscelleneous: Amides & imides: Glutethmide. Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol. Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.
- D. Antipsychotics Phenothiazeines: SAR of Phenothiazeines Promazine hydrochloride, Chlorpromazine hydrochloride\*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.
- E. Ring Analogues of Phenothiazeines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine. Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

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- F. Beta amino ketones: Molindone hydrochloride. Benzamides: Sulpieride.
- G. Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action
- H. Barbiturates: Phenobarbitone, Methabarbital. Hydantoins: Phenytoin\*, Mephenytoin, Ethotoin Oxazolidine diones: Trimethadione, Paramethadione
- I. Succinimides: Phensuximide, Methsuximide, Ethosuximide\* Urea and monoacylureas: Phenacemide, Carbamazepine\* Benzodiazepines: Clonazepam Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate.
- J. General anesthetics: Inhalation anesthetics: Halothane\*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane. Ultra short acting barbitutrates: Methohexital sodium\*, Thiamylal sodium, Thiopental sodium. Dissociative anesthetics: Ketamine hydrochloride.\*
- K. Narcotic and non-narcotic analgesics Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anilerdine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate\*, Methadone hydrochloride\*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate. Narcotic antagonists: Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.
- L. Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid\*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepriac, Diclofenac, Ketorolac, Ibuprofen\*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

### Recommended Books (Latest Edition)

- Burger's Medicinal Chemistry, Vol I to IV.
- K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
- 3. S.N. Pandey, Text book of Medicinal Chemistry, Volume I and II
- 4. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
- 5. Foye's Principles of Medicinal Chemistry.
- 6. Introduction to principles of drug design- Smith and Williams.
- 7. Remington's Pharmaceutical Sciences.
- 8. Martindale's extra pharmacopoeia.
- 9. Organic Chemistry by I.L. Finar, Vol. II.
- 10. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
- 11. Indian Pharmacopoeia.
- 12. Text book of practical organic chemistry- A.I. Vogel.

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BP406P: MEDICINAL	CHEMISTRY - I, Practical
Course Category	Departmental Core (DC)
Pre-requisite Subject	Organic Chemistry
Contact hours/week	Practical:4
No of Credits	2
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	This subject is designed to impart fundamental knowledge     on the structure, chemistry and therapeutic value of drugs.     The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs.     The syllabus also emphasizes on chemical synthesis of important drugs under each class.     Understand the chemistry of drugs with respect to their pharmacological activity     Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs     Know the Structural Activity Relationship (SAR) of different class of drugs
Course Outcome	Upon completion of the course, the student shall be able to  Understand the chemistry of drugs with respect to their pharmacological activity  Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs  know the Structural Activity Relationship (SAR) of different class of drugs  Write the chemical synthesis of some drugs.  Helps in correlating between pharmacology of a disease and its mitigation or cure  Knowledge about the mechanism pathways of different class of medicinal compounds.

# I Preparation of drugs/ intermediates

- a. 1,3-pyrazole
- b. 1,3-oxazole 3
- c. Benzimidazole
- d. Benztriazole
- e. 2,3- diphenyl quinoxaline
- f. Benzocaine
- g. Phenytoin

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- h. Phenothiazine
- i. Barbiturate

# II Assay of drugs

- j. Chlorpromazine
- k. Phenobarbitone
- 1. Atropine
- m. Ibuprofen
- n. Aspirin
- o. Furosemide

# III Determination of Partition coefficient for any two drugs

<b>BP403T: PHYSICAL P</b>	PHARMACEUTICS-II-Theory
Course Category	Departmental Core (DC)
Pre-requisite Subject	Physics
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course objective	This course is designed to impart a fundamental knowledge on the various physical and physicochemical properties. on principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms. Describe the factors leading to instability of dispersion systems Outline the principles of chemical kinetics in stability testing Apply the principles of micromeritics, rheology, chemical kinetics,
	stability and course dispersion in the formulation development and evaluation of dosage forms
Course Outcome	Upon completion of the course, the student shall be able to  Understand various physicochemical properties of drug molecules in the designing the dosage forms  Know the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations  Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms  Estimate various flow properties of powders.  Determine the particle size using various methods.

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- Understand the effect of suspending agents on sedimentation volume.
- o Determine various order of reactions

### Unit I: Colloidal dispersions:

Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids &comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization& protective action.

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers

Deformation of solids: Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus

### Unit II Coarse dispersion:

Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of flocculated and deflocculated suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formulation by HLB method.

#### Unit II: Micromeretics:

Particle size and distribution, mean particle size, number and weight distribution, particle number, methods for determining particle size by different methods, counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.

### Unit IV Drug stability:

Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

Recommended Books (Latest Edition)

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- 1. Physical Pharmacy by Alfred Martin, Sixth edition
- 2. Experimental pharmaceutics by Eugene, Parott.
- 3. Tutorial pharmacy by Cooper and Gunn.
- 4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
- 5. Physical Pharmaceutics by Ramasamy C, and Manavalan R.
- Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
- Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2,
   Marcel Dekkar Inc.

BP407P: PHYSICAL P	PHARMACEUTICS-II-Practical
Course Category	Departmental Core (DC)
Pre-requisite Subject	Physics
Contact hours/week	Practical:4
No of Credits	2
Course Assessment Methods	Continuous assessment through attendance, assignment, daily practical work and practical test.
Course objective	This course is designed to impart a fundamental knowledge on the various physical and physicochemical properties. on principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms. Describe the factors leading to instability of dispersion systems Outline the principles of chemical kinetics in stability testing Apply the principles of micromeritics, rheology, chemical kinetics, stability and course dispersion in the formulation development and evaluation of dosage forms
Course Outcome	<ul> <li>Upon completion of the course, the student shall be able to</li> <li>Understand various physicochemical properties of drug molecules in the designing the dosage forms</li> <li>Know the principles of chemical kinetics &amp; to use them for stability testing and determination of expiry date of formulations</li> <li>Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms</li> <li>Estimate various flow properties of powders.</li> <li>Determine the particle size using various methods.</li> <li>Understand the effect of suspending agents on sedimentation volume.</li> <li>Determine various order of reactions</li> </ul>

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- 1. Determination of particle size, particle size distribution using sieving method
- 2. Determination of particle size, particle size distribution using Microscopic method
- 3. Determination of bulk density, true density and porosity
- 4. Determine the angle of repose and influence of lubricant on angle of repose
- 5. Determination of viscosity of liquid using Ostwald's viscometer
- 6. Determination sedimentation volume with effect of different suspending agent
- 7. Determination sedimentation volume with effect of different concentration of single suspending agent
- 8. Determination of viscosity of semisolid by using Brookfield viscometer
- 9. Determination of reaction rate constant first order.
- 10. Determination of reaction rate constant second order
- 11. Accelerated stability studies

Course Category	Department Core
Pre-requisite Subject	Biology
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment	Continuous assessment through tutorials, attendance, home
Methods	assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	The main purpose of the subject is to o understand what drugs do to the living organisms and how their effects can be applied to therapeutics.
	<ul> <li>Learn the drugs acting on various physiological systems in the human body</li> <li>Appreciate the importance of pharmacology subject as a basis of therapeutics</li> <li>Know to correlate and apply the pharmacological knowledge therapeutically</li> <li>Classify the drugs based on the mechanism of action and indications</li> <li>The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.</li> </ul>

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Course Outcome	Upon completion of course student shall be able to  Understand the pharmacological actions of different categories of drugs  Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.  Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.  Observe the effect of drugs on animals by simulated experiments  Appreciate correlation of pharmacology with other bio medical sciences
	medical sciences  o Apply the pharmacological knowledge in therapeutic aspects

### UNIT I: General Pharmacology

**Introduction to Pharmacology-** Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists( competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.

**Pharmacokinetics**- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein—coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action. Adverse drug reactions.

Drug interactions (pharmacokinetic and pharmacodynamic)

**Drug discovery and clinical evaluation of new drugs** -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

### UNIT II: Pharmacology of drugs acting on peripheral nervous system

Organization and function of ANS. Neurohumoral transmission, co-transmission and classification of neurotransmitters. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral). e. Local anesthetic agents.

Drugs used in myasthenia gravis and glaucoma

UNIT III: . Pharmacology of drugs acting on central nervous system

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- a. Neurohumoral transmission in the C.N.S.special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.
- b. General anesthetics and pre-anesthetics.
- c. Sedatives, hypnotics and centrally acting muscle relaxants.
- d. Anti-epileptics e. Alcohols and disulfiram

# UNIT IV: . Pharmacology of drugs acting on central nervous system

- a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
- b. Drugs used in Parkinsons disease and Alzheimer's disease.
- c. CNS stimulants and nootropics.
- d. Opioid analgesics and antagonists
- e. Drug addiction, drug abuse, tolerance and dependence.

### Recommended Books (latest Edition)

- Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
- 2. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
- Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
   100
- K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers
   (P) Ltd, New Delhi.
- 5. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
- 6. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
- 7. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan.
- 8. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert.
- Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
- 10. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier

BP408P: PHARMACO	LOGY-I-Practical
Course Category	Department Core
Pre-requisite Subject	Biology
Contact hours/week	Practical:4
No of Credits	2
Course Assessment	Continuous assessment through attendance, assignment, daily practical

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Methods	work and practical test.
Course Objectives	The main purpose of the subject is to  understand what drugs do to the living organisms and how their effects can be applied to therapeutics.  Learn the drugs acting on various physiological systems in the human body  Appreciate the importance of pharmacology subject as a basis of therapeutics  Know to correlate and apply the pharmacological knowledge therapeutically  Classify the drugs based on the mechanism of action and indications  The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different
Course Outcome	classes of drugs.  Upon completion of course student shall be able to  Understand the pharmacological actions of different categories of drugs  Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.  Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.  Observe the effect of drugs on animals by simulated experiments  Appreciate correlation of pharmacology with other bio medical sciences  Apply the pharmacological knowledge in therapeutic aspects

- 1. Introduction to experimental pharmacology.
- 2. Commonly used instruments in experimental pharmacology.
- 3. Study of common laboratory animals.
- 4. Maintenance of laboratory animals as per CPCSEA guidelines.
- Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
- 6. Study of different routes of drugs administration in mice/rats.
- 7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.

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- 8. Effect of drugs on ciliary motility of frog oesophagus
- 9. Effect of drugs on rabbit eye.
- 10. Effects of skeletal muscle relaxants using rota-rod apparatus.
- 11. Effect of drugs on locomotor activity using actophotometer.
- 12. Anticonvulsant effect of drugs by MES and PTZ method.
- 13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
- 14. Study of anxiolytic activity of drugs using rats/mice.
- 15. Study of local anesthetics by different methods

**Note:** All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Course Category	Departmental Core (DC)
Pre-requisite Subject	Biology
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objective	The subject involves the fundamentals of Pharmacognosy like  o scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal
	properties.  The primary objectives of this course are to  Discuss the fundamentals of Pharmacognosy and phytopharmaceuticals  Understand the macroscopical, microscopical and powdered
(80)	<ul> <li>characteristics of drugs of natural origin.</li> <li>Help students to understand the chemical tests to be carried out for the identification of drugs.</li> <li>Understand the different evaluation methods for the identification of adulterants and also to know the purity of the drugs.</li> </ul>
Course Outcome	Upon completion of course student shall be able to  To know the techniques in the cultivation and production of crude drugs  To know the crude drugs, their uses and chemical nature  know the evaluation techniques for the herbal drugs  To carry out the microscopic and morphological evaluation of crude drugs  Carry out the transverse section of plant parts to understand the

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arrangement of cells and tissues
 Carry out the chemical tests to determine the purity of drugs and to understand the nature of chemical constituents present
 Know the different evaluation methods for the drugs

## **UNIT-I: Introduction to Pharmacognosy:**

- (a) Definition, history, scope and development of Pharmacognosy
- (b) Sources of Drugs Plants, Animals, Marine & Tissue culture
- (c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs: Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs

Quality control of Drugs of Natural Origin: Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties. Quantitative microscopy of crude drugs including lycopodium spore method, leafconstants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

## UNIT-II: Cultivation, Collection, Processing and storage of drugs of natural origin:

Cultivation and Collection of drugs of natural origin Factors influencing cultivation of medicinal plants. Plant hormones and their applications. Polyploidy, mutation and hybridization with reference to medicinal plants. Conservation of medicinal plants.

**Plant tissue culture:** Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance. Applications of plant tissue culture in pharmacognosy. Edible vaccines

# UNIT-III: Pharmacognosy in various systems of medicine:

Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine.

Introduction to secondary metabolites: Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

## UNIT-IV:

Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs

Plant Products: Fibers - Cotton, Jute, Hemp Hallucinogens, Teratogens, Natural allergens
Primary metabolites: General introduction, detailed study with respect to chemistry, sources,
preparation, evaluation, preservation, storage, therapeutic used and commercial utility as
Pharmaceutical Aids and/or Medicines for the following

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Primary metabolites: Carbohydrates: Acacia, Agar, Tragacanth, Honey

Proteins and Enzymes: Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin). Lipids(Waxes, fats, fixed oils): Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax

Marine Drugs: Novel medicinal agents from marine sources

# Recommended Books (Latest Edition)

- 1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
- 2. Text Book of Pharmacognosy by T.E. Wallis
- 3. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
- 4. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
- 5. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
- 6. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
- 7. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
- 8. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
- 9. Anatomy of Crude Drugs by M.A. Iyengar

Course Category	Departmental Core (DC)
Pre-requisite Subject	Biology
Contact hours/week	Practical:4
No of Credits	2
Course Assessment Methods	Continuous assessment through attendance, assignment, daily practical work and practical test.
Course Objective	The subject involves the fundamentals of Pharmacognosy like  o scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.  o The primary objectives of this course are to  o Discuss the fundamentals of Pharmacognosy and phytopharmaceuticals  o Understand the macroscopical, microscopical and powdered characteristics of drugs of natural origin.  o Help students to understand the chemical tests to be carried out

	for the identification of drugs.  O Understand the different evaluation methods for the identification of adulterants and also to know the purity of the drugs.
Course Outcome	Upon completion of course student shall be able to  To know the techniques in the cultivation and production of crude drugs  To know the crude drugs, their uses and chemical nature  know the evaluation techniques for the herbal drugs  To carry out the microscopic and morphological evaluation of crude drugs  Carry out the transverse section of plant parts to understand the arrangement of cells and tissues  Carry out the chemical tests to determine the purity of drugs and to understand the nature of chemical constituents present  Know the different evaluation methods for the drugs

### Practical's

- 3. Analysis of crude drugs by chemical tests: (i)Tragaccanth (ii) Acacia (iii)Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
- 4. Determination of stomatal number and index
- 5. Determination of vein islet number, vein islet termination and paliside ratio.
- 6. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
- 7. Determination of Fiber length and width
- 8. Determination of number of starch grains by Lycopodium spore method
- 9. Determination of Ash value
- 10. Determination of Extractive values of crude drugs
- 11. Determination of moisture content of crude drugs
- 12. Determination of swelling index and foaming

#### SEMESTER V

<b>BP501T: MEDICINAL</b>	CHEMISTRY – II	
Course Category	Departmental Core (DC)	
Pre-requisite Subject	Organic Chemistry, Pharmacology	
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0	
No of Credits	4	
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.	
Course Objectives	This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. Upon completion	

	of the course the student shall be able to  Understand structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs.  chemical synthesis of important drugs under each class.  Understand the chemistry of drugs with respect to their pharmacological activity  Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs  Know the Structural Activity Relationship (SAR) of different class of drugs  Write the chemical synthesis of some drugs
Course Outcome	<ul> <li>Upon completion of the course the student shall be able to</li> <li>Understand the chemistry of drugs with respect to their pharmacological activity.</li> <li>Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs.</li> <li>Know the Structural Activity Relationship of different class of drugs.</li> <li>Well acquainted with the synthesis of some important class of drugs.</li> <li>Study the chemical synthesis of selected drugs</li> <li>Knowledge about the mechanism pathways of different class of medicinal compounds.</li> </ul>

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (\*)

### Unit -I:

Antihistaminic agents: Histamine, receptors and their distribution in the human body.

H1-antagonist: Diphenhydramine hydrochloride\*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Triphelenamine hydrochloride, hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorcyclizine Chlorpheniramine maleate, Triprolidine hydrochloride\*, Phenidamine tartrate, Promethazine hydrochloride\*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrizine Cromolyn sodium.

H2-antagonists: Cimetidine\*, Famotidine, Ranitidine.

Gastric proton-pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole.

Anti-neoplastic agents: Alkylating agents: Meclorethamine\*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa. Antimetabolites: Mercaptopurine\*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate\*, Azathioprine. Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin.

Plant products: Etoposide, Vinblastine sulphate, Vincristine sulphate.

Miscellaneous: Cisplatin, Mitotane.

#### Unit-II

Anti-anginal: Vasodilators: Amyl Nitrite, Nitroglycerin\*, Pentaerythritol tetranitrate, Isosorbide dinitrite\*, Dipyridamole. Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

**Diuretics:** Carbonic Anhydrase Inhibitors: Acetazolamide\*, Methazolamide, Dichlorphenamide. Thiazides: Chlorthiazide\*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide, Loop Diuretics: Furosemide\*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride. Osmotic Diuretics: Mannitol. Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril Hydrochloride, Methyldopate Hydrochloride\* Clonidine hydrochloride, Guanethidine Monosulphate, Guanabenz Acetate, Sodium Nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

Anti-arrhythmic Drugs: Quinidine Sulphate, Procainamide Hydrochloride, Disopyramide Phosphate\*, Phenytoin Sodium, Lidocaine Hydrochloride, Tocainide Hydrochloride, Mexiletine Hydrochloride, Lorcainide Hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholestyramine and Colestipol

#### Unit-III

Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin\*, Anisindione, Clopidogrel.

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

**Drugs acting on Endocrine system:** Nomenclature, Stereochemistry and metabolism of steroids.

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**Sex hormones:** Testosterone, Andralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl Stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrel

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone.

Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

#### Unit-IV

Antidiabetic agents: Insulin and its preparations. Sulfonylureas: Tolbutamide\*, Chlorpropamide, Glipizide, Glimepiride. Biguanides: Metformin. Thiazolidinediones: Pioglitazone, Rosiglitazone, Meglitinides, Repaglinide, Nateglinide. Glucosidase inhibitors: Acarbose, Voglibose.

Local Anesthetics: SAR of Local anesthetics. Benzoic acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine. Amino Benzoic acid derivatives: Benzocaine\*, Butamben, Procaine\*, Butacaine, Propoxycaine, Tetracaine, Benoxinate. Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine. Miscellaneous: Phenacaine, Diperodon, Dibucaine.

## Recommended Books (Latest Editions)

- Wilson and Gisvold's Organic Medicinal and Pharmaceutical Chemistry by Block J.H. and Beale J.M., Lippincott Williams and Wilkins, NY.
- Foye's Principles of Medicinal Chemistry by Lemke T.L., Williams D.A., Roche V.F. and Zito S.W., Lippincott Williams and Wilkins.
- Burger's Medicinal Chemistry and Drug Discovery by Abraham D.J., Volume I to IV, John Wiley and Sons Inc., New York.
- 4. Synthesis of Essential Drugs by Vardanyan R.S. and Hruby V.J., Elsevier.
- 5. Introduction to Medicinal Chemistry by Alex Gringauz, Wiley VCH.
- An Introduction to Medicinal Chemistry by Patrick Graham L., Oxford University Press.
- Medicinal Chemistry: A Biochemical Approach by Nogrady T., Oxford University Press, New York.
- 8. The Organic Chemistry of Drug Design and Drug Action by Silverman R.B., Elsevier.
- 9. Introduction to Principles of Drug Design by Smith and Williams, CRC Press, US.
- 10. Medicinal and Pharmaceutical Chemistry by Singh H. and Kapoor V.K., Vallabh Prakashan, Delhi.

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- 11. Textbook of Drug Design and Discovery by Larsen P.K., Liljefors T. and Madsen U., Taylor and Francis Inc.
- 12. Martindale's Extra Pharmacopoeia

BP502T: INDUSTRIAL	PHARMACY I-Theory
Course Category	Departmental Core (DC)
Pre-requisite Subject	General Pharmacy, Physical Pharmacy
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	Course enables the student to understand and appreciate  the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.  Formulate and prepare tablets, capsules and liquid orals using established procedures and technology.  Evaluation the pharmaceutical dosage forms for quality and stability and compare with standards prescribed in the pharmacopoeia.  the facilities and standards necessary for the industrial production of sterile dosage forms.  preformulation studies to evaluate physicochemical properties of drugs
C 0.4	Perform quality control tests of dosage forms
Course Outcome	Upon completion of the course the student shall be able to  o Know the various pharmaceutical dosage forms and their manufacturing techniques.  o Know various considerations in development of pharmaceutical dosage forms  o Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality  o Describe legal and official requirements for containers  o Elaborate on formulation considerations for ophthalmic dosage forms
	<ul> <li>Produce pharmaceutical formulations from known reference sources in a quality that is suitable for patient use.</li> <li>Develop cosmetics and with desired Safety, stability, and efficacy.</li> </ul>

UNIT -I:

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Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances. a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs & its significant Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms. Tablets: Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling. b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating. c. Quality control tests: In process and finished product tests.

### UNIT-II

Liquid orals: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia. Capsules: a. Hard gelatin capsules: Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules. b. Soft gelatin capsules: Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications. Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

### UNIT III

Parenteral Products: a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity b. Production procedure, production facilities and controls, aseptic processing c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products. d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products. Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

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Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens. Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies. Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

## Recommended Books: (Latest Editions)

- Pharmaceutical dosage forms Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman & J.B. Schwartz
- Pharmaceutical dosage form Parenteral medication vol- 1&2 by Liberman & Lachman.
- 3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman.
- 4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition.
- Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS).
- 6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman.
- Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition.
- 8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5thedition, 2005.
- Drug stability Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

BP506P: INDUSTRIAL	PHARMACY I-Practical
Course Category	Departmental Core (DC)
Pre-requisite Subject	General Pharmacy, Physical Pharmacy
Contact hours/week	Practical:4
No of Credits	2
Course Assessment Methods	Continuous assessment, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	Course enables the student to understand and appreciate  o the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.  o Formulate and prepare tablets, capsules and liquid orals using

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	established procedures and technology.  Evaluation the pharmaceutical dosage forms for quality and stability and compare with standards prescribed in the pharmacopoeia.  the facilities and standards necessary for the industrial production of sterile dosage forms.  preformulation studies to evaluate physicochemical properties of drugs  Perform quality control tests of dosage forms
Course Outcome	Upon completion of the course the student shall be able to  Know the various pharmaceutical dosage forms and their manufacturing techniques.  Know various considerations in development of pharmaceutical dosage forms  Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality  Describe legal and official requirements for containers  Elaborate on formulation considerations for ophthalmic dosage forms  Produce pharmaceutical formulations from known reference sources in a quality that is suitable for patient use.  Develop cosmetics and with desired Safety, stability, and efficacy.

## Practicals

- 1. Preformulation studies of Paracetamol/Aspirin/or any other drug.
- 2. Preparation and evaluation of Paracetamol tablets.
- 3. Preparation and evaluation of Aspirin tablets.
- 4. Coating of tablets- film coating of tables/granules.
- 5. Preparation and evaluation of Tetracycline capsules.
- 6. Preparation of Calcium Gluconate injection.
- 7. Preparation of Ascorbic Acid injection.
- 8. Quality control test of (as per IP) marketed tablets and capsules.
- 9. Preparation of Eye drops/ and Eye ointments.
- 10. Preparation of Creams (cold / vanishing cream).
- 11. Evaluation of glass containers (as per IP).

BP503T: PHARMA	COLOGY II-Theory
Course Category	Departmental Core (DC)
Pre-requisite Subject	Biology, HAP
Contact hours/week	Lecture: 3, Tutorial:1

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No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	This subject is intended to impart the fundamental knowledge on various aspects of-
Course Outcome	<ul> <li>Upon completion of this course the student should be able to</li> <li>Understand the mechanism of drug action and its relevance in the treatment of different diseases.</li> <li>Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments.</li> <li>Demonstrate the various receptor actions using isolated tissue preparation.</li> <li>Appreciate correlation of pharmacology with related medical sciences</li> <li>Explain the pharmacokinetics and mechanism of drug action at organ system/ sub cellular/macromolecular levels</li> <li>Explain the pharmacology of drugs acting on systems</li> <li>Recognize adverse drug reactions and drug interactions</li> <li>Discuss drug mechanisms and their relevance in the treatment of diseases</li> </ul>

# UNIT-I

# Pharmacology of drugs acting on cardio vascular system

- a. Introduction to hemodynamic and electrophysiology of heart.
- b. Drugs used in congestive heart failure
- c. Anti-hypertensive drugs.
- d. Anti-anginal drugs.
- e. Anti-arrhythmic drugs.
- f. Anti-hyperlipidemic drugs.
- g. Drug used in the therapy of shock.
- h. Hematinics, coagulants and anticoagulants.
- i. Fibrinolytics and anti-platelet drugs

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j. Plasma volume expanders.

#### UNIT II

## Pharmacology of drugs acting on urinary system

- a. Diuretics
- b. Anti-diuretics.

## Autocoids and related drugs

- a. Introduction to autacoids and classification
- b. Histamine, 5-HT and their antagonists.
- c. Prostaglandins, Thromboxanes and Leukotrienes.
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatory agents
- f. Anti-gout drugs
- g. Antirheumatic drugs

#### UNIT III

# Pharmacology of drugs acting on endocrine system

- a. Basic concepts in endocrine pharmacology.
- b. Anterior Pituitary hormones- analogues and their inhibitors.
- c. Thyroid hormones- analogues and their inhibitors.
- d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
- e. Insulin, Oral Hypoglycemic agents and glucagon.
- f. ACTH and corticosteroids.

#### UNIT IV

# Pharmacology of drugs acting on endocrine system

- a. Androgens and Anabolic steroids.
- b. Estrogens, progesterone and oral contraceptives.
- c. Drugs acting on the uterus.

### Bioassay

- a. Principles and applications of bioassay.
- b. Types of bioassay
- c. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT.

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- 1. Recommended Books (Latest Editions)
- Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
- Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
- 4. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
- Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
- Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
- K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
- 8. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
- 9. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert.
- Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
- 11. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

Course Category	Departmental Core (DC)
Pre-requisite Subject	Biology, HAP
Contact hours/week	Practical:4
No of Credits	2
Course Assessment Methods	Continuous assessment through attendance, home assignments, quizzes and practical test.
Course Objectives	This subject is intended to impart the fundamental knowledge on various aspects of-
Course Outcome	<ul> <li>Upon completion of this course the student should be able to</li> <li>Understand the mechanism of drug action and its relevance in the treatment of different diseases.</li> <li>Demonstrate isolation of different organs/tissues from the</li> </ul>

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laboratory animals by simulated experiments.  o Demonstrate the various receptor actions using isolated tissue preparation.  o Appreciate correlation of pharmacology with related medical sciences
<ul> <li>Explain the pharmacokinetics and mechanism of drug action at organ system/ sub cellular/macromolecular levels</li> </ul>
<ul> <li>Explain the pharmacology of drugs acting on systems</li> </ul>
<ul> <li>Recognize adverse drug reactions and drug interactions</li> </ul>
<ul> <li>Discuss drug mechanisms and their relevance in the treatment of diseases</li> </ul>

#### Practicals

- 1. Introduction to in-vitro pharmacology and physiological salt solutions.
- 2. Effect of drugs on isolated frog heart.
- 3. Effect of drugs on blood pressure and heart rate of dog.
- 4. Study of diuretic activity of drugs using rats/mice.
- 5. DRC of acetylcholine using frog rectus abdominis muscle.
- Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
- 7. Bioassay of histamine using guinea pig ileum by matching method.
- 8. Bioassay of oxytocin using rat uterine horn by interpolation method.
- 9. Bioassay of serotonin using rat fundus strip by three point bioassay.
- 10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay
- Determination of PA2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
- 12. Determination of PD2 value using guinea pig ileum.
- 13. Effect of spasmogens and spasmolytics using rabbit jejunum.
- 14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
- 15. Analgesic activity of drug using central and peripheral methods.

**Note:** All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos.

<b>BP504T: PHARMAC</b>	OGNOSY AND PHYTOCHEMISTRY - II-Theory	
Course Category	Departmental Core (DC)	
Pre-requisite Subject	Biology, Chemistry	
Contact hours/week	Lecture: 3, Tutorial:1	
No of Credits	4	

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Course Assessment	Continuous assessment through tutorials, attendance, home
Methods	assignments, quizzes and one minor test, one major theory and
	practical test.
Course Objectives	The main purpose of subject is to impart the students the knowledge of-
	<ul> <li>how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially.</li> </ul>
	<ul> <li>this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions.</li> </ul>
	o basic principles of traditional system of medicine.
	<ul> <li>chemical tests to identify unorganized crude drugs</li> </ul>
	<ul> <li>Evaluation of quality and purity of crude drugs</li> </ul>
	<ul> <li>linear measurements for crude drug identification</li> </ul>
Course Outcome	Upon completion of the course student shall be able to understand
	<ul> <li>Describe the scope and evolution of Pharmacognosy</li> </ul>
	o to know the modern extraction techniques, characterization and
	identification of the herbal drugs and phytoconstituents.
1	o to understand the preparation and development of herbal
	formulation.
=	<ul> <li>to understand the herbal drug interactions.</li> </ul>
	<ul> <li>to carryout isolation and identification of phytoconstituents</li> </ul>
	o to explain the chemical nature, uses and evaluation of crude
	drugs
	<ul> <li>to explain the cultivation, collection and processing of drugs of natural origin</li> </ul>

## UNIT I

Metabolic pathways in higher plants and their determination

a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway. b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

## **UNIT II**

General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,

Tannins: Catechu, Pterocarpus

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Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

Glycosides: Senna, Aloes, Bitter Almond

Iridoids, Other terpenoids & Naphthaguinones: Gentian, Artemisia, taxus, carotenoids.

#### UNIT III

Isolation, Identification and Analysis of Phytoconstituents

- a) Terpenoids: Menthol, Citral, Artemisin
- b) Glycosides: Glycyrhetinic acid & Rutin
- c) Alkaloids: Atropine, Quinine, Reserpine, Caffeine
- d) Resins: Podophyllotoxin, Curcumin,

Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine.

#### UNIT IV

Basics of Phytochemistry Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.

- 1. Recommended Books: (Latest Editions)
- 2. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
- 3. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
- 4. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
- 5. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
- 6. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
- 7. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
- 8. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
- 9. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
- 10. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
- 11. The formulation and preparation of cosmetic, fragrances and flavours.
- 12. Remington's Pharmaceutical sciences.
- 13. Text Book of Biotechnology by Vyas and Dixit.

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# 14. Text Book of Biotechnology by R.C. Dubey

BP508P: PHARMACO	OGNOSY AND PHYTOCHEMISTRY – II-Practical
Course Category	Departmental Core (DC)
Pre-requisite Subject	Biology, Chemistry
Contact hours/week	Practical:4
No of Credits	2
Course Assessment Methods	Continuous assessment through attendance, home assignments, quizzes and practical test.
Course Objectives	The main purpose of subject is to impart the students the knowledge of-  o how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially.  o this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions.  o basic principles of traditional system of medicine.  o chemical tests to identify unorganized crude drugs  o Evaluation of quality and purity of crude drugs  o linear measurements for crude drug identification
Course Outcome	Upon completion of the course student shall be able to understand  Describe the scope and evolution of Pharmacognosy  to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents.  to understand the preparation and development of herbal formulation.  to understand the herbal drug interactions.  to carryout isolation and identification of phytoconstituents  to explain the chemical nature, uses and evaluation of crude drugs  to explain the cultivation, collection and processing of drugs of natural origin

### **Practicals**

- Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
- 2. Exercise involving isolation & detection of active principles
- a. Caffeine from tea dust.
- b. Diosgenin from Dioscorea
- c. Atropine from Belladonna
- d. Sennosides from Senna
- 3. Separation of sugars by Paper chromatography
- 4. TLC of herbal extract

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- 5. Distillation of volatile oils and detection of phytoconstitutents by TLC
- 6. Analysis of crude drugs by chemical tests:
- (i) Asafoetida
- (ii) Benzoin
- (iii) Colophony
- (iv) Aloes
- (v) Myrrh

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BP505: PHARMACEU	UTICAL JURISPRUDENCE (Theory)
Course Category	Departmental Core (DC)
Pre-requisite Subject	
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India. The primary objectives of this course are to  O Discuss the various concept of the pharmaceutical legislation in India  Help the students to understand the parameters involved in the Drugs and Cosmetics Act and rules  Discuss and understand the professional ethics  Familiarize the concept of Drug Policy, Drug Price Control Order, Patent and Design Act, Drugs and Magic Remedies Act  Help the students to understand the concepts of Narcotics and Psychotropic substances Act, Pharmacy Act and Excise duties Act  Equip the students to prepare label and packaging for any given drug using the guidelines under Drug and Cosmetics Act.
Course Outcome	Upon completion of the course student shall be able to understand  o The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.  o Various Indian pharmaceutical Acts and Laws.
	<ul> <li>The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.</li> <li>The code of ethics during the pharmaceutical practice</li> <li>Define the concepts of Drug Policy, Drug Price Control Order, Patent and Design Act, Drugs and Magic Remedies Act</li> <li>Apply the basic concepts of labeling and packaging of drugs</li> </ul>

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Drugs and Cosmetics Act, 1940 and its rules 1945: Objectives, Definitions, Legal definitions of schedules to the Act and Rules.

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license. Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA).

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties.

### UNIT II

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors.

Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties.

Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.

### UNIT III

Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic &Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties.

Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.

Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of

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Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.

### **UNIT IV**

National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)- 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM), Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee, Code of Pharmaceutical ethics D efinition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath, Medical Termination of Pregnancy Act, Right to Information Act, Introduction to Intellectual Property Rights (IPR).

### Recommended books: (Latest Edition)

- 1. Forensic Pharmacy by B. Suresh.
- 2. 2. Text book of Forensic Pharmacy by B.M. Mithal.
- 3. Hand book of drug law-by M.L. Mehra.
- 4. A text book of Forensic Pharmacy by N.K. Jain.
- 5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
- 6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
- 7. Narcotic drugs and psychotropic substances act by Govt. of India publications.
- 8. Drugs and Magic Remedies act by Govt. of India publication.
- 9. Bare Acts of the said laws published by Government. Reference books (Theory)

### SEMESTER VI

BP601T: MEDIC	CINAL CHEMISTRY - III (Theory)
Course Category	Departmental Core (DC)
Pre-requisite Subject	Pharmacology, Biology, Organic Chemistry
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	This subject is designed to impart fundamental knowledge o on the structure, chemistry and therapeutic value of drugs.

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	<ul> <li>The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR)</li> </ul>
	<ul> <li>Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD).</li> </ul>
	<ul> <li>The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects,</li> </ul>
	<ul> <li>Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.</li> </ul>
Course Outcome	Upon completion of the course student shall be able to understand
	<ul> <li>Understand the importance of drug design and different techniques of drug design.</li> </ul>
	<ul> <li>Understand the chemistry of drugs with respect to their biological activity.</li> </ul>
	<ul> <li>Know the metabolism, adverse effects and therapeutic value of drugs.</li> </ul>
	Know the importance of SAR of drugs.
	Understand synthetic pathways of medicinal agents
	<ul> <li>Understand metabolic pathways of medicinal substances</li> </ul>

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (\*)

### UNIT I

**Antibiotics**: Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

**β-Lactam antibiotics**: Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams **Aminoglycosides**: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline.

## UNIT II

Antibiotics Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes-

Macrolide: Erythromycin Clarithromycin, Azithromycin. Miscellaneous: Chloramphenicol\*, Clindamycin. Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

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Quinolines: SAR, Quinine sulphate, Chloroquine\*, Amodiaquine, Primaquine phosphate, Pamaquine\*, Quinacrine hydrochloride, Mefloquine. Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil. Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone.

Anti-tubercular Agents & Synthetic anti tubercular agents: Isoniozid\*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.\* Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.

Urinary tract anti-infective agents Quinolones: SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin\*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin. Miscellaneous: Furazolidine, Nitrofurantoin\*, Methanamine.

### UNIT III

Antiviral agents: Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir\*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir. Antifungal agents: Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin. Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconozole, Miconazole\*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate\*. Anti-protozoal Agents: Metronidazole\*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaguone, Eflornithine. Anthelmintics: Diethylcarbamazine citrate\*, Thiabendazole, Mebendazole\*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

### UNIT IV

Sulphonamides and Sulfones' Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide\*, Sulphapyridine, Sulfamethoxaole\*, Sulphadiazine, Mefenide acetate, Sulfasalazine. Folate reductase inhibitors: Trimethoprim\*, Cotrimoxazole. Sulfones: Dapsone\*.Introduction to Drug Design Various approaches used in drug design. Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis. Pharmacophore modeling and docking techniques. Combinatorial Chemistry: Concept and applications chemistry: solid phase and solution phase synthesis.

Recommended Books (Latest Editions)

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- 1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
- 2. Foye's Principles of Medicinal Chemistry.
- 3. Burger's Medicinal Chemistry, Vol I to IV.
- 4. Introduction to principles of drug design- Smith and Williams.
- 5. Remington's Pharmaceutical Sciences.
- 6. Martindale's extra pharmacopoeia.
- 7. Organic Chemistry by I.L. Finar, Vol. II.
- 8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
- 9. Indian Pharmacopoeia.
- 10. Text book of practical organic chemistry- A.I.Vogel.

BP607P: MEDIC	INAL CHEMISTRY – III (Practical)
Course Category	Departmental Core (DC)
Pre-requisite Subject	Pharmacology, Biology, Organic Chemistry
Contact hours/week	Practical: 4
No of Credits	2
Course Assessment Methods	Continuous assessment through, attendance, home assignments, quizzes and practical test.
Course Objectives	This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR) Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.
Course Outcome	<ul> <li>Upon completion of the course student shall be able to understand</li> <li>Understand the importance of drug design and different techniques of drug design.</li> <li>Understand the chemistry of drugs with respect to their biological activity.</li> <li>Know the metabolism, adverse effects and therapeutic value of drugs.</li> <li>Know the importance of SAR of drugs.</li> <li>Understand synthetic pathways of medicinal agents</li> <li>Understand metabolic pathways of medicinal substances</li> </ul>

### Practicals

I Preparation of drugs and intermediates;

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- 1. Sulphanilamide
- 2. 7-Hydroxy, 4-methyl coumarin
- 3. Chlorobutanol
- 4. Triphenyl imidazole
- 5. Tolbutamide
- 6. Hexamine

## II Assay of drugs

- 1. Isonicotinic acid hydrazide
- 2. Chloroquine
- 3. Metronidazole
- 4. Dapsone
- 5. Chlorpheniramine maleate
- 6. Benzyl penicillin

III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV Drawing structures and reactions using chem draw®

V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5).

Course Category	Departmental Core (DC)
Pre-requisite Subject	Biology, HAP
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	<ul> <li>This subject is intended to impart</li> <li>the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition,</li> <li>knowledge principles of toxicology and chronopharmacology.</li> <li>Know the pathophysiology of selected disease states and the rationale for drug therapy</li> <li>Design &amp; execution of animal experiments to identify the pharmacological properties.</li> </ul>

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	<ul> <li>Know the therapeutic approach to management of these diseases</li> </ul>
Course Outcome	Upon completion of this course the student should be able to:  o understand the mechanism of drug action and its relevance in the treatment of different infectious diseases.  o comprehend the principles of toxicology and treatment of various poisonings  o appreciate correlation of pharmacology with related medical sciences  o Design and execute a bioassay to determine the potency of experimental drugs.  o Calculate the dose and decide the route of administration of drugs  o Identify the commonly used laboratory animals and apparatus in pharmacology

## UNIT I

# Pharmacology of drugs acting on Respiratory system

- a. Anti -asthmatic drugs
- b. Drugs used in the management of COPD
- c. Expectorants and antitussives
- d. Nasal decongestants
- e. Respiratory stimulants.

# Pharmacology of drugs acting on the Gastrointestinal Tract

- a. Antiulcer agents.
- b. Drugs for constipation and diarrhoea.
- c. Appetite stimulants and suppressants.
- d. Digestants and carminatives.
- e. Emetics and anti-emetics.

## UNIT II

### Chemotherapy

- a. General principles of chemotherapy.
- b. Sulfonamides and cotrimoxazole.
- c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides.
- d. Antitubercular agents

- e. Antileprotic agents,
- f. Antifungal agents
- g. Antiviral drugs
- h. Anthelmintics
- i. Antimalarial drugs
- j. Antiamoebic.

#### UNIT III

Urinary tract infections and sexually transmitted diseases. Chemotherapy of malignancy. Immunopharmacology – Immunostimulants, Immunosuppressant Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

#### UNIT IV

## Principles of toxicology

Definition and basic knowledge of acute, subacute and chronic toxicity. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity. General principles of treatment of poisoning. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning. Chronopharmacology- Definition of rhythm and cycles. Biological clock and their significance leading to chronotherapy.

### Recommended Books (Latest Editions)

- Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
- Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
- 3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
- Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
- Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
- K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
- Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,

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- 8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
- 9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
- 10. N. Udupa and P.D. Gupta, Concepts in Chronopharmacology.

BP608P: PHARMACO	OLOGY – III-Practical
Course Category	Departmental Core (DC)
Pre-requisite Subject	Biology, HAP
Contact hours/week	Practical:4
No of Credits	2
Course Assessment	Continuous assessment through attendance, home assignments, quizzes
Methods	and practical work and test.
Course Objectives	<ul> <li>This subject is intended to impart</li> </ul>
	o the fundamental knowledge on various aspects (classification,
9	mechanism of action, therapeutic effects, clinical uses, side
	effects and contraindications) of drugs acting on respiratory and
	gastrointestinal system, infectious diseases,
St.	immuno-pharmacology and in addition,
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	o knowledge principles of toxicology and chronopharmacology.
	o Know the pathophysiology of selected disease states and the
	rationale for drug therapy
	o Design & execution of animal experiments to identify the
	pharmacological properties.
	o Know the therapeutic approach to management of these
	diseases
Course Outcome	Upon completion of this course the student should be able to:
	o understand the mechanism of drug action and its relevance in
	the treatment of different infectious diseases.
	o comprehend the principles of toxicology and treatment of
	various poisonings
	o appreciate correlation of pharmacology with related medical
	sciences
	Design and execute a bioassay to determine the potency of
	experimental drugs.
100	Calculate the dose and decide the route of administration of
	drugs
	o Identify the commonly used laboratory animals and apparatus
	in pharmacology

# **Practicals**

- 1. Dose calculation in pharmacological experiments.
- 2. Antiallergic activity by mast cell stabilization assay.

- 3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
- 4. Study of effect of drugs on gastrointestinal motility.
- 5. Effect of agonist and antagonists on guinea pig ileum.
- 6. Estimation of serum biochemical parameters by using semi- autoanalyzer
- 7. Effect of saline purgative on frog intestine
- 8. Insulin hypoglycemic effect in rabbit.
- 9. Test for pyrogens (rabbit method).
- 10. Determination of acute oral toxicity (LD50) of a drug from a given data
- 11. Determination of acute skin irritation / corrosion of a test substance.
- 12. Determination of acute eye irritation / corrosion of a test substance.
- 13. Calculation of pharmacokinetic parameters from a given data.
- 14. Biostatistics methods in experimental pharmacology ( student's t test, ANOVA).
- 15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

NOTE- \*Experiments are demonstrated by simulated experiments/videos

Course Category	Departmental Core (DC)
Pre-requisite Subject	Pharmacognosy, Pharmaceutical Technology
Contact hours/week	Lecture: 3, Tutorial:1
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	This subject gives the student the knowledge of  o basic understanding of herbal drug industry, the quality of raw
	material, o guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs. Integration of phytoconstituents in advanced drug delivery systems Standardization of herbal formulations
Course Outcome	Upon completion of this course the student should be able to:  o understand raw material as source of herbal drugs from cultivation to herbal drug product  o know the WHO and ICH guidelines for evaluation of herbal drugs

- know the herbal cosmetics, natural sweeteners,
   to know about nutraceuticals
- o appreciate patenting of herbal drugs, GMP
- Explain the basics of molecular biology.

### UNIT I

Herbs as raw materials- Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs Selection, identification and authentication of herbal materials Processing of herbal raw material.

**Biodynamic Agriculture-** Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

Indian Systems of Medicine a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

#### **UNIT II**

**Nutraceuticals**- General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases. Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification. Study of following drugs and their possible side effects.

Herbal Cosmetics- Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

### UNIT III

**Herbal Excipients** – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

**Herbal formulations**: Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes.

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**Evaluation of Drugs-** WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products: a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

#### UNIT IV

**Regulatory Issues** - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

General Introduction to Herbal Industry- Present scope and future prospects. A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine Components of GMP (Schedule – T) and its objectives Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

### Recommended Books: (Latest Editions)

- 1. Textbook of Pharmacognosy by Trease & Evans.
- 2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
- 3. Pharmacognosy by Kokate, Purohit and Gokhale
- 4. Essential of Pharmacognosy by Dr.S.H.Ansari
- 5. Pharmacognosy & Phytochemistry by V.D.Rangari
- 6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
- 7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

Course Category	Departmental Core (DC)
Pre-requisite Subject	Pharmacognosy, Pharmaceutical Technology
Contact hours/week	Practical:4
No of Credits	2
Course Assessment Methods	Continuous assessment through attendance, home assignments, quizzes and practical work and practical test.
Course Objectives	This subject gives the student the knowledge of  o basic understanding of herbal drug industry, the quality of raw material,

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	<ul> <li>guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc.</li> <li>The subject also emphasizes on Good Manufacturing Practices (GMP),</li> <li>patenting and regulatory issues of herbal drugs.</li> <li>Integration of phytoconstituents in advanced drug delivery systems</li> <li>Standardization of herbal formulations</li> </ul>
Course Outcome	Upon completion of this course the student should be able to:  o understand raw material as source of herbal drugs from cultivation to herbal drug product  o know the WHO and ICH guidelines for evaluation of herbal drugs  o know the herbal cosmetics, natural sweeteners,  to know about nutraceuticals  appreciate patenting of herbal drugs, GMP  Explain the basics of molecular biology.

### **Practicals**

- 1. To perform preliminary phytochemical screening of crude drugs.
- 2. Determination of the alcohol content of Asava and Arista
- 3. Evaluation of excipients of natural origin
- Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
- Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
- 6. Monograph analysis of herbal drugs from recent Pharmacopoeias
- 7. Determination of Aldehyde content
- 8. Determination of Phenol content
- 9. Determination of total alkaloids

	CEUTICS AND PHARMACOKINETICS
Course Category	Departmental Core (DC)
Pre-requisite Subject	Physical Pharmacy, Pharmacology
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	This subject is designed to impart knowledge and skills of  O Biopharmaceutics and pharmacokinetics O their applications in pharmaceutical development,

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	<ul> <li>design of dose and dosage regimen and in solving the problems arised therein.</li> <li>Area under the curve</li> <li>Compartment and non-compartment for determination of pharmacokinetic parameters</li> <li>Multi-compartment kinetics for determination of pharmacokinetic parameters</li> <li>Enable the students to apply the theoretical knowledge into clinical practice</li> </ul>	
Course Outcome		

### UNIT I

Introduction Biopharmaceutics to **Absorption**; Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution**- Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding,

## UNIT II

**Elimination**: Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs.

Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

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#### UNIT III

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - KE, t1/2,Vd,AUC,Ka, Clt and CLR- definitions methods of eliminations, understanding of their significance and application.

#### UNIT IV

Multicompartment models: Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and mainetnance doses and their significance in clinical settins.

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.

## Recommended Books: (Latest Editions)

- 1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
- 2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- 3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall Inernational edition. USA
- 4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- 5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
- 6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- 7. Biopharmaceutics; By Swarbrick
- 8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
- 9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- 10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- 11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
- 12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

	EUTICAL BIOTECHNOLOGY
Course Category	Departmental Core (DC)
Pre-requisite Subject	Biology, Human Anatomy and Physiology
Contact hours/week	Lecture: 3, Tutorial: 1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	Biotechnology has a long promise to revolutionize the biological sciences and technology. This subject is designed to impart knowledge and skills of-  O Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting.  O to new biological revolutions in diagnosis, prevention and cure of diseases,  O discovery of new and cheaper pharmaceutical drugs.  O producing transgenic crops and animals and the future promises
	lot more.  O Hybrodoma techniques  O Concept of immunization and vaccine
Course Outcome	Upon completion of this course the student should be able to:  O Understanding the importance of Immobilized enzymes in Pharmaceutical Industries.  O Genetic engineering applications in relation to production of pharmaceuticals  O Understand recombinant DNA techniques  O Understand MHC complexes, for recognition  O Importance of Monoclonal antibodies in Industries  O Appreciate the use of microorganisms in fermentation technology

### UNIT I

Brief introduction to Biotechnology with reference to Pharmaceutical Sciences. Enzyme Biotechnology- Methods of enzyme immobilization and applications. Biosensors- Working and applications of biosensors in Pharmaceutical Industries. Brief introduction to Protein Engineering. Use of microbes in industry. Production of Enzymes- General consideration -

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Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase. Basic principles of genetic engineering.

### UNIT II

Study of cloning vectors, restriction endonucleases and DNA ligase. Recombinant DNA technology. Application of genetic engineering in medicine. Application of rDNA technology and genetic engineering in the production of: i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin. d) Brief introduction to PCR. Types of immunity- humoral immunity, cellular immunity, Structure of Immunoglobulins, Structure and Function of MHC. Hypersensitivity reactions, Immune stimulation and Immune suppressions. General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.

#### UNIT III

Storage conditions and stability of official vaccines, Hybridoma technology- Production, Purification and Applications, Blood products and Plasma Substituties. Immuno blotting techniques- ELISA, Western blotting, Southern blotting. Genetic organization of Eukaryotes and Prokaryotes, Microbial genetics including transformation, transduction, conjugation, plasmids and transposons. Introduction to Microbial biotransformation and applications. Mutation: Types of mutation/mutants.

#### UNIT IV

Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring. Large scale production fermenter design and its various controls. Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin, Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substituties.

### Recommended Books (Latest edition):

- B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
- 2. RA Goldshy et. al., : Kuby Immunology.
- 3. J.W. Goding: Monoclonal Antibodies.

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- 4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
- 5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
- 6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
- 7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

BP606T: PHARMAC	EUTICAL QUALITY ASSURANCE -	
Course Category	Departmental Core (DC)	
Pre-requisite Subject	Pharmaceutical Analysis	
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0	
No of Credits	4	
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.	
Course Objectives	This course deals with the various aspects of	
Course Outcome	Upon completion of this course the student should be able to:  o understand the cGMP aspects in a pharmaceutical industry.  O Understand GLP in pharmaceutical laboratories  o appreciate the importance of documentation  o understand the scope of quality certifications applicable to pharmaceutical industries  o understand the responsibilities of QA & QC departments	
3-	<ul> <li>Identify appropriate instrumental techniques for the analysis of drugs in bulk or in various dosage forms.</li> </ul>	

# UNIT I

Quality Assurance and Quality Management concepts: Definition and concept of Qualitycontrol, 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

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ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration NABL accreditation: Principles and procedures.

### UNIT II

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

# **UNIT III**

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, Complaints: Complaints and evaluation of complaints, Handling of return good, recalling andwaste 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 IV

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validationmaster 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 Edition)

- 1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
- 2. Good Laboratory Practice Regulations, 2 nd Edition, Sandy Weinberg Vol. 69.
- 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

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- 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

# SEMESTER VII

Course Category	Departmental Core (DC)	
Pre-requisite Subject	Pharmaceutical Analysis	
Contact hours/week	Lecture: 3, Tutorial:1	
No of Credits	4	
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.	
Course Objectives	<ul> <li>To impart fundamental knowledge on the Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis.</li> <li>To understand the chromatographic separation and analysis of drugs.</li> <li>To perform quantitative &amp; qualitative analysis of drugs using various analytical instruments.</li> <li>Explain the different types of instrumental analytical techniques available for quality control of APIs &amp; formulations.</li> <li>To perform various sampling techniques employed in analysis of solid, semisolid and liquid dosage forms while working in industry</li> </ul>	
	<ul> <li>Explain the principles, instrumentation and applications of UV-VIS, Flourimetry, Atomic absorption, atomic emission spectroscopies, Flame photometry, Phosphorimetry and Nepheloturbidimetry</li> </ul>	
Course Outcome	<ul> <li>Upon completion of this course the student should be able to</li> <li>The principle and application of instrumental methods in qualitative and quantitative analysis of drugs.</li> <li>Carryout instrumentation of spectroscopic and others MAT (Modern analytical tools).</li> <li>Develop fundamental knowledge on the principles of chromatographic technique.</li> <li>Emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.</li> </ul>	

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- instruments for the assay of various APIs and formulations as per Pharmacopeial standards.
- To independently process, interpret the data obtained through experimentation and report the results as per regulatory requirements.
- Know the appropriate safety measures while handling instruments, chemicals and apparatus

#### Unit -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.

### Unit-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.

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications Nepheloturbidometry- Principle, instrumentation and applications.

### Unit-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.

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### Unit-IV

**Gas chromatography-** Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications.

**High performance liquid chromatography (HPLC)-** Introduction, theory, instrumentation, advantages and applications.

**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.

# 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.
- N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
- Y W. Chien, Novel Drug Delivery Systems, 2<sup>nd</sup> edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

Course Category	Departmental Core (DC)
Pre-requisite Subject	Pharmaceutical Analysis
Contact hours/week	Practical: 4
No of Credits	2

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Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.	
Course Objectives	<ul> <li>To impart fundamental knowledge on the Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis.</li> <li>To understand the chromatographic separation and analysis of drugs.</li> <li>To perform quantitative &amp; qualitative analysis of drugs using various analytical instruments.</li> <li>Explain the different types of instrumental analytical techniques available for quality control of APIs &amp; formulations.</li> <li>To perform various sampling techniques employed in analysis of solid, semisolid and liquid dosage forms while working in industry</li> <li>Explain the principles, instrumentation and applications of UV-VIS, Flourimetry, Atomic absorption, atomic emission spectroscopies, Flame photometry, Phosphorimetry and Nepheloturbidimetry</li> </ul>	
Course Outcome	Upon completion of this course the student should be able to	
	<ul> <li>The principle and application of instrumental methods in qualitative and quantitative analysis of drugs.</li> <li>Carryout instrumentation of spectroscopic and others MAT (Modern analytical tools).</li> <li>Develop fundamental knowledge on the principles of chromatographic technique.</li> <li>Emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.</li> <li>To independently operate, calibrate various analytical instruments for the assay of various APIs and formulations as per Pharmacopeial standards.</li> <li>To independently process, interpret the data obtained through experimentation and report the results as per regulatory requirements.</li> <li>Know the appropriate safety measures while handling</li> </ul>	
	instruments, chemicals and apparatus	

# Practical's

- Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds.
- 2. Estimation of sulphanilamide by colorimetry.
- 3. Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy.

4. Estimation of quinine sulphate by fluorimetry.

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- 5. Study of quenching of fluorescence.
- 6. Determination of sodium by flame photometry.
- 7. Determination of potassium by flame photometry.
- 8. Determination of chlorides and sulphates by nephelo-turbidimetry.
- 9. Separation of sugars by thin layer chromatography.
- 10. Separation of plant pigments by column chromatography.
- 11. Demonstration experiment on HPLC.
- 12. Demonstration experiment on Gas Chromatography.
- 13. To perform in-vitro dissolution profile of CR/SR marketed formulation.
- 14. To prepare sustained release matrix tablets and evaluate by UV spectroscopy.
- 15. Formulation of nanoparticles and evaluate by HPLC.
- 16. Formulation and evaluation of liposomes.
- 17. To prepare buccal dosage form and evaluate by UV spectroscopy.
- 18. To prepare paracetamol transdermal patch and evaluate by UV spectroscopy.

BP702T: INDUSTRIA	L PHARMACY II	
Course Category	Departmental Core (DC)	
Pre-requisite Subject	Pharmaceutical Technology	
Contact hours/week	Lecture: 3, Tutorial:1	
No of Credits	4	
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.	
Course Objectives	<ul> <li>The objective of course is-</li> <li>To impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market.</li> <li>To the development, production and characterization of dosage forms, as well as the disposition and action of drugs in the body.</li> <li>Works towards promoting a multidisciplinary, team-based approach to drug delivery, embracing a variety of activities in the broad area of drug formulation and delivery.</li> <li>Emphasis physical and applied pharmaceutics, drug disposition and dynamics, and drug delivery.</li> </ul>	

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	<ul> <li>optimization &amp; characterization of solid, liquid and semi-solid dosage forms.</li> <li>o To work with Novel Drug Delivery Systems including Buccal, Osmotic, Gastro Retentive, Vaginal, Colon Targeted, Microsphere, Immediate Release Formulations, Nanotechnology, Medicated Chewing Gum, Multi-Unit Pellet Systems, Ocular Delivery, Novel formulations for surgical site, Transdermal Delivery etc</li> </ul>	
Course Outcome	Upon completion of this course the student should be able to:	
	<ul> <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.</li> <li>Understand the approval process and regulatory requirements for drug products.</li> <li>The subject has played a diverse role in the discovery, characterization, production and standardization of crude drugs</li> <li>Pharmaceutics deals with the formulation of a pure drug substance into a dosage form. Branches of pharmaceutics include: Pharmacokinetics, Pharmacodynamics, Pharmacoepidemiology, Pharmacogenomics, Pharmacoepidemiology, Pharmacogenomics, Pharmacoepidemiology, Pharmacogenomics, Pharmacoutics is the science of dosage form design. There are many chemicals with known pharmacological properties but a raw chemical is of no use to a patient.</li> </ul>	

# Unit-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.

# Unit-II

**Technology development and transfer:** WHO guidelines for Technology Transfer (TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from RD to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipment, qualification and validation, quality control, analytical method transfer,

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Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE /SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues.

#### Unit-III

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

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.

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

# Recommended Books: (Latest Editions)

- 1. Regulatory Affairs from Wikipedia, the free encyclopaedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory\_ Affairs.
- 2. International Regulatory Affairs 2005. Updates, 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.

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- 4. Regulatory Affairs brought learning plus, Inc., available at by http://www.cgmp.com/ra.htm.
- 5. Intellectual Property Rights in Pharmaceutical Industry Theory and practice by Bayya Subba Rao and Appaji.

BP703T: PHARMACY	Y PRACTICE-Theory	
Course Category	Departmental Core (DC)	
Pre-requisite Subject		
Contact hours/week	Lecture: 3, Tutorial:1, Practical: -0	
No of Credits	4	
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.	
Course Objectives	<ul> <li>To provide medications and other health care products and services and to help people and society to make the best use of them</li> <li>To impart fundamental knowledge in the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy.</li> <li>To learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care.</li> <li>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.</li> <li>To blend knowledge in pharmacy and research to relate the concepts of Pharmaceutical Sciences towards serving the betterment of the society.</li> <li>Explain and demonstrate technical procedures for preparing and dispensing drugs in an institutional setting under the supervision of a registered pharmacist</li> <li>Explain and demonstrate technical procedures for preparing and dispensing drugs in an ambulatory care setting under the supervision of a registered pharmacist</li> </ul>	

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Course Outcome	Upon completion of this course the student should be able to:
	Know various drug distribution methods in a hospital.
	o Appreciate the pharmacy stores management and
	inventory control.
	<ul> <li>Monitor drug therapy of patient through medication</li> </ul>
	chart review and clinical review.
	<ul> <li>Obtain medication history interview and counsel the</li> </ul>
	patients.
	<ul> <li>Identify drug related problems.</li> </ul>
	<ul> <li>Detect and assess adverse drug reactions.</li> </ul>
	o interpret selected laboratory results (as monitoring
	parameters in therapeutics) of specific disease states.
	<ul> <li>Know pharmaceutical care services.</li> </ul>
	<ul> <li>Do patient counselling in community pharmacy.</li> </ul>
	<ul> <li>Appreciate the concept of rational drug therapy.</li> </ul>

### Unit-I

# Hospital and it's organization

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

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

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

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

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### Unit-II

**Drug distribution system in a hospital-**Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labeling. Dispensing of drugs to ambulatory patients and dispensing of controlled drugs.

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

**Therapeutic drug monitoring-** Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring. **Medication adherence-** Causes of medication non-adherence, pharmacist role in the medication adherence and monitoring of patient medication adherence.

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

Community pharmacy management, Financial, materials, staff, and infrastructure requirements.

### Unit-III

# Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation. Drug information services- Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information. Patient counselling- Definition of patient counselling; steps involved in patient counselling, and Special cases that require the pharmacist, Education and training program in the hospital. Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education. Prescribed medication order and communication skills. Prescribed medication order-interpretation and legal requirements, and Communication skills- communication with prescribers and patients.

Unit-IV

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# Budget preparation and implementation:

Budget preparation and implementation. Clinical Pharmacy: Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring-medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern. Over the counter (OTC) sales: Introduction and sale of over the counter and rational use of common over the counter medications.

**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, haematology, and urine analysis.

# Recommended Books (Latest Edition):

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

BP704T: NOVEL DRUG DELIVERY SYSTEMS (NDDS)

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Course Category	Departmental Core (DC)	
Pre-requisite Subject	Pharmaceutical Technology	
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0	
No of Credits	4	
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.	
Course Objectives	<ul> <li>This subject is designed to impart fundamental knowledge on the area of novel drug delivery systems.</li> <li>To perform drug packaging and labeling principles, procedures and appropriate recordkeeping exercises associated with various pharmacy practices.</li> <li>Describe. Introduction, formulation, merits, demerits, application and evaluation of Novel Drug Delivery Systems</li> <li>To understand the importance of drug design and different techniques of drug design.</li> <li>To understand the chemistry of drugs with respect to their biological activity.</li> <li>To know the metabolism, adverse effects and therapeutic value of drugs.</li> <li>To provide an introduction to production methods, technology and quality systems that are used in the production of pharmaceutical forms with requirements for sterility.</li> </ul>	
Course Outcome	Upon completion of this course the student should be able to:	
	<ul> <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> <li>Describe the Fundamental Concept of Modified Drug Release and Prerequisites of drug candidates, along with various approaches and classification.</li> <li>Formulation development and evaluation of sustained release, transdermal, gastro retentive formulations.</li> <li>Explain concept of microencapsulation, merits, demerits and application, Types of Microencapsulation and Evaluation of microcapsules</li> </ul>	

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application and evaluation of Novel Drug Delivery Systems
 Explain Therapeutic Aerosols along with typical formulations from, metered dose, intranasal and topical applications

# Unit-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.

# Unit-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 implants and osmotic pump.

#### Unit-III

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

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

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

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# **Unit-IV**

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

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)

- Y W. Chien, Novel Drug Delivery Systems, 2<sup>nd</sup> edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
- Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
- 3. Encyclopaedia 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).
- S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

#### Journals

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

Course Category	Departmental Core (DC)- P	
Pre-requisite Subject	Pharmacy practice	
Contact hours/week	Practical: 12	

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No of Credits	6	
Course Assessment Methods	Continuous assessment through tutorials, attendance, hor assignments, quizzes and one minor test, one major theory a practical test.	
Course Objectives	*	
Course Outcome	Upon completion of this course the student should be able to:  O Understand the advanced instruments used and their applications in drug analysis.  O Understand the concepts and applications of alternative medicine.  O Learn to execute and utilize softwares of pharmaceutical importance.  O Understand the calibration of various analytical instruments.  O Know analysis of drugs using various analytical instruments.  O Describe formulation of cosmetics for eyes, manufacturing & evaluation of eye mascara, shadow etc.  O Understand formulation of manicure products like nail lacquer, remover etc.  O Learn formulation, manufacture & evaluation of baby cosmetics like baby oils, powders etc.  O Explain the concept of comseceuticals, history, difference between cosmetics & comseceuticals & comseceuticals agents	

Course content

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

# Domains (anyone to be opted):

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

# **Recommended Books (Latest Editions)**

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

REPORT ON PRACTICAL/INDUSTRIAL TRAINING

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Every candidate shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. The student shall submit satisfactory report of such work and certificate duly signed by the authority of training organization to the head of the institute.

### REPORT ON INDUSTRIAL TOUR

Visit of students to an industrial establishment or an approved research laboratory. The industrial/research laboratory visit shall include: in case of industry- visit to different sections and subsections of the industry, an idea about the functioning of the industry, product range of the industry and various approvals of the industry; in case of research laboratory- visit to different departments of the laboratory, an idea about the interdisciplinary coordination, contribution of the laboratory to the society and various approvals of the laboratory. A proper report of the same shall be submitted by the students, which shall be subsequently evaluated to assess the impact of the visit.

May be performed at the end of the 7th semester.

## SEMESTER VIII

BP801T: BIOSTATISITCS A	AND RESEARCH METHODOLOGY (Theory)	
Course Category	Departmental Core (DC)	
Pre-requisite Subject	Remedial Mathematics	
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0	
No of Credits	4	
Course Assessment Methods	t Continuous assessment through tutorials, attendance, home assignments quizzes and one minor test, one major theory and practical test.	
Course Objectives	Ounderstand the concepts and principles of biostatistics and define terms used.     Differentiate between quantitative and qualitative data, construct, and interpret frequency distribution tables and graphic displays.	

	<ul> <li>Calculate the measures of central tendency for a set of data.</li> <li>State the meaning and estimate the measures of variability for a given set of biologic measurements</li> </ul>
Course Outcome	Upon completion of this course the student should be able to:
	<ul> <li>Know the operation of M.S. Excel, SPSS, R and MINITAB *, DoE</li> <li>(Design of Experiment)</li> </ul>
	<ul> <li>Know the various statistical techniques to solve statistical problems</li> </ul>
	<ul> <li>Appreciate statistical techniques in solving the problems.</li> </ul>

### Course Content

### UNIT I

# Unit-I

Introduction: Statistics, Biostatistics, Frequency distribution Measures of central tendency:
Mean, Median, Mode- Pharmaceutical examples Measures of dispersion: Dispersion, Range,
standard deviation, Pharmaceutical problems Correlation: Definition, Karl Pearson's coefficient
of correlation, Multiple correlation - Pharmaceuticals examples

## Unit-II

Regression: Curve fitting by the method of least squares, fitting the lines y=a+bx and x=a+by, Multiple regression, standard error of regression– Pharmaceutical Examples

Probability:Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples Parametric test: t-test(Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference

### Unit-III

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test 156 Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

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Statistical Analysis Using Excel, SPSS, MINITAB ® , DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

# Unit-IV

Blocking and confounding system for Two-level factorials Regression modeling: Hypothesis testing in Simple and Multiple regressionmodels Introduction to Practical components of Industrial and Clinical Trials Problems, Design and Analysis of experiments: Factorial Design: Definition, 2 2, 23design. Advantage of factorial design Response Surface methodology: Central composite design, Historical design, Optimization Techniques

# Recommended Books (Latest edition):

- Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
- 2. Fundamental of Statistics Himalaya Publishing House- S.C.Guptha
- 3. Design and Analysis of Experiments -PHI Learning Private Limited, R. Pannerselvam,
- 4. Design and Analysis of Experiments Wiley Students Edition, Douglas and C. Montgomery

Course Category	Departmental Core (DC)
Pre-requisite Subject	HAP, Pharmacology
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	The objective of the course is-  O To introduce to students a number of health issues and their challenges.  O To introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.  O Relate various physicochemical properties of drug and excipient molecules in designing the dosage forms

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1 1	stability testing and determination of expiry date of formulations  o Demonstrate the behavior and mechanism of drugs and excipients in the formulation development and evaluation of dosage forms
Course Outcome	Upon completion of this course the student should be able to:  Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.  Have a critical way of thinking based on current healthcare development.  Evaluate alternative ways of solving problems related to health and pharmaceutical issues.  Understand the mechanism of drug action and its relevance in the treatment of different diseases  Appreciate correlation of pharmacology with related medical sciences
	<ul> <li>Study relation with nutrition and health, Balanced diet,</li> <li>Nutritional deficiencies, Vitamin deficiencies</li> </ul>

### Unit-I

Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health.

Hygiene and health: personal hygiene and health care; avoidable habits.

### Unit-II

**Preventive medicine:** General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse.

# Unit-III

National health programs, its objectives, functioning and outcome of the following:

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HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program.

### Unit V

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

# Recommended Books (Latest edition):

- Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2 Edition, 2010, ISBN: 9789380704104, JAYPEE Publications.
- Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4 Edition, 2013, ISBN: 9789350901878, JAYPEE Publications.
- 3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6 Edition, 2014, ISBN: 9789351522331, JAYPEE Publications.
- Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2 Edition, 2012, ISBN: 9789350250440, JAYPEE Publications.
- 5. Park Textbook of Preventive and Social Medicine, K Park, 21 Edition, 2011, ISBN-14: 9788190128285, Banarasidas Bhanot Publishers.
- 6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad.
- 7. Sociology for Pharmacist by Kevin Taylor, Sarah Nettleton and Geoffery Harding.

### Recommended Journals

· Research in Social and Administrative Pharmacy, Elsevier, Ireland.

BP803ET: Pharma Marketing Management\*

Course Category Departmental Core (DC)

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Pre-requisite Subject	Pharmaceutics, Pharmacology
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	Course is designed to impart knowledge of pharmaceutical marketing describes as below-  Explain the different pharmaceutical marketing channels Describe the concept of pharmaceutical marketing In the pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry.  The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.  It is hugely important for the success of the commercial activities of the pharmaceutical organisation To develop a community around the brand whereby audiences can interact with certain content
Course Outcome	Upon completion of this course the student should be able to:  Ounderstanding of marketing concepts and techniques and their applications in the pharmaceutical industry.  To study the activity by pharmaceutical sales representatives, provision of drug samples, and sponsoring continuing medical education (CME).  To discuss role of market research  Understand role and responsibility of professional sales representative.  To understand concept of product management  To know how 4p's are being composed and its significance in pharmaceutical market.

<sup>\*</sup> PE-Program elective

# Unit-I

# Marketing:

Definition, general concepts and scope of marketing, distinction between marketing & selling. Marketing environment. Industry and competitive analysis. Analysing consumer buying behaviour and industrial buying behaviour.

Pharmaceutical market:

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Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation & targeting. Consumer profile; Motivation and prescribing habits of the physician; patient's choice of physician and retail pharmacist. Analysing the Market; Role of market research.

### Unit-II

**Product decision:** Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

**Promotion:** Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

### Unit-III

**Pharmaceutical marketing channels:** Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

**Professional sales representative (PSR):** Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

# Unit-IV

Pricing: Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority). Emerging concepts in marketing: Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

# Recommended Books: (Latest Editions)

- Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi.
- Walker, Boyd and Larreche: Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
- 3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill.

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- 4. Arun Kumar and N Meenakshi: Marketing Management, Vikas Publishing, India.
- 5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition).
- Ramaswamy, U.S & Nanakamari, S: Marketing Management: Global Perspective, Indian Context, Macmillan India, New Delhi.
- 7. Shanker, Ravi: Service Marketing, Excel Books, New Delhi.
- Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT Excel series) Excel Publications.

9. Pharmaceutical marketing in India by Subba Rao Chaganti.

	EUTICAL REGULATORY SCIENCE *
Course Category	Departmental Core (DC)
Pre-requisite Subject	Pharmaceutical Jurisprudence
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	This course is designed to impart
	<ul> <li>the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India and other countries.</li> <li>It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.</li> <li>Explain the process of drug discovery, development and generic product development</li> <li>Understand the concept of pharmacovigilance and its significance</li> <li>Explain the Registration of Indian drug product in overseas market</li> <li>Learn the basic understanding the importance of Orange book, Federal Register, Code of Federal Regulatory, and Purple book</li> </ul>
Course Outcome	<ul> <li>Upon completion of this course the student should be able to:         <ul> <li>Know about the process of drug discovery and development.</li> <li>Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.</li> <li>Know the regulatory approval process and their registration in Indian and international markets.</li> <li>Discuss preclinical and non-clinical activities in new drug</li> </ul> </li> </ul>

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- Explain the basic ethical principles and ethical issues in clinical trials.
- Discuss the pharmacovigilence safety monitoring of clinical trials
- Explain the FDA regulatory guidelines for drug registration.

# \* PE-Program elective

# Unit-I

**New Drug Discovery and development-**Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

### Unit-II

Regulatory Approval Process-Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.Regulatory authorities and agencies Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications).

### Unit-III

Registration of Indian drug product in overseas market- Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.

# Unit IV

Clinical trials Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials.

**Regulatory Concepts-**Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book.

# Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.

2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol. 185. Informa Health care Publishers.

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- New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD, 5 edition, Drugs and the Pharmaceutical Sciences, Vol. 190.
- Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
- 5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
- Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
- Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
- 8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
- 9. Drugs: From Discovery to Approval, Second Edition by Rick Ng.
- Intellectual Property Rights in Pharmaceutical Industry Theory and practice by Bayya Subba Rao and Appaji.

Course Category	Departmental Core (DC)
Pre-requisite Subject	Pharmacology
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	<ul> <li>This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection.</li> <li>To study about the rational and safe use of medical drugs</li> <li>To study about the assessment and communication of the risks and benefits of drugs on the market</li> <li>Educating and informing of patients</li> <li>This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.</li> <li>To create an ADR database for the India population.</li> <li>To create awareness of ADR monitoring among people.</li> <li>To ensure optimum safety of drug product in Indian market.</li> <li>To create infrastructure for ongoing regulatory review of periodic</li> </ul>

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rse the student should be able to know, do, and nent of pharmacovigilance. ional scenario of pharmacovigilance.
ional scenario of pharmacovigilance.
and terminologies used in pharmacovigilance.
erse drug reactions and their assessment.
ds for classification of diseases and drugs.
on reporting systems and communication in
e safety data during pre-clinical, clinical and of drugs' life cycle.
ion in paediatrics, geriatrics, pregnancy and
rogram of India (PvPI) requirement for ADR
for ICSR, PSUR, expedited reporting, lanning.

<sup>\*</sup> PE-Program elective

# Unit-I

Introduction to Pharmacovigilance- History and development of Pharmacovigilance Importance of safety monitoring of Medicine WHO international drug monitoring programme Pharmacovigilance Program of India (PvPI). Introduction to adverse drug reactions- Definitions and classification of ADRs Detection and reporting Methods in Causality assessment Severity and seriousness assessment Predictability and preventability assessment, Management of adverse drug reactions.

Basic terminologies used in pharmacovigilance, Terminologies of adverse medication related events, Regulatory terminologies.

### Unit-II

Drug and disease classification - Anatomical, therapeutic and chemical classification of drugs International classification of diseases Daily defined doses International Non-proprietary names for drugs. Drug dictionaries and coding in pharmacovigilance.

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WHO adverse reaction terminologies MedDRA and Standardised MedDRA queries WHO drug dictionary EudraVigilance medicinal product dictionary. Information resources in pharmacovigilance Basic drug information resources Specialised resources for ADRs. Establishing pharmacovigilance programme.

Establishing in a hospital Establishment & operation of drug safety department in industry, Contract Research Organisations (CROs) Establishing a national programme.

### Unit-III

Vaccine safety surveillance- Vaccine Pharmacovigilance Vaccination failure, Adverse events following immunization. Pharmacovigilance methods, Passive surveillance – Spontaneous reports and case series Stimulated reporting Active surveillance – Sentinel sites, drug event monitoring and registries Comparative observational studies – Cross sectional study, case control study and cohort study. Targeted clinical investigations. Communication in pharmacovigilance-Effective communication in Pharmacovigilance Communication in Drug Safety Crisis management Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media.

### Unit-IV

Safety data generation: Pre clinical phase, Clinical phase, Post approval phase (PMS)

ICH Guidelines for Pharmacovigilance: Organization and objectives of ICH, Expedited reporting, Individual case safety reports, Periodic safety update reports, Post approval expedited reporting, Pharmacovigilance planning, Good clinical practice in pharmacovigilance studies. Pharmacogenomics of adverse drug reactions: Genetics related ADR with example focusing PK parameters. Drug safety evaluation in special population: Paediatrics, Pregnancy and lactation, Geriatrics CIOMS: CIOMS Working Groups CIOMS Form. CDSCO (India) and Pharmacovigilance: D & C Act and Schedule Y, Differences in Indian and global pharmacovigilance requirements.

### Recommended Books (Latest edition):

- 1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
- 2. Quintessence of Pharmacovigilance: Tapan Kumar Chatterjee, PharmaMed Press.
- Practical Drug Safety from A to Z by Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
- 4. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.

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- Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
- 6. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
- Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
- Textbook of Pharmaco-epidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
- A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata.
- 10. National Formulary of India.
- 11. Text Book of Medicine by Yashpal Munjal.
- 12. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna.
- 13. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn 3=7297
- 14. http://www.ich.org/
- 15. http://www.cioms.ch/
- 16. http://cdsco.nic.in/
- 17. http://www.who.int/vaccine\_safety/en/
- 18. http://www.ipc.gov.in/PvPI/pv home.html

Course Category	Departmental Core (DC)
Pre-requisite Subject	Pharmaceutical Analysis
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	<ul> <li>In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs.</li> <li>The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.</li> <li>Explain variousguidelines issued by WHO in relation with cultivation, collection, storage etc</li> <li>Understand raw material as source of herbal drugs from cultivation to herbal drug product</li> <li>Know the WHO and ICH guidelines for evaluation of herbal drugs</li> <li>Appreciate patenting of herbal drugs, GMP</li> </ul>

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Course Outcome	Upon completion of this course the student should be able to know, do, and appreciate-
	<ul> <li>Know WHO guidelines for quality control of herbal drugs.</li> </ul>
	<ul> <li>Know Quality assurance in herbal drug industry.</li> </ul>
	<ul> <li>Know the regulatory approval process and their registration</li> </ul>
	in Indian and international markets.
	<ul> <li>Appreciate EU and ICH guidelines for quality control of</li> </ul>
	herbal drugs.
	<ul> <li>Know the herbal cosmetics, natural sweeteners, nutraceuticals</li> </ul>
	<ul> <li>Explain in vitro screening methods and its applications for</li> </ul>
	biological evaluation of natural products
	<ul> <li>Explain the approaches and potentials of herbal new drug</li> </ul>
	delivery systems like liposomes, phytosomes, nanoparticles and
	vesicles

# \* PE-Program elective

# Unit-I

Basic tests for drugs- Pharmaceutical substances, Medicinal plants materials and dosage forms. WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use.

# Unit-II

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine. WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.

# Unit-III

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines.

Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products

## Unit-IV

Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions. Regulatory requirements for herbal medicines. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison

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of various Herbal Pharmacopoeias. Role of chemical and biological markers in standardization of herbal products.

# Recommended Books: (Latest Editions)

- 1. Pharmacognosy by Trease and Evans.
- 2. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
- 3. Pharmacognosy by Kokate, Purohit and Gokhale.
- Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I, Carrier Pub., 2006.
- 5. Aggarwal, S.S., Herbal Drug Technology. Universities Press, 2002.
- EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products.
- Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
- WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
- WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd Ed. World Health Organization, Geneva, 1981.
- WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
- 11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
- WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

Course Category	Departmental Core (DC)
Pre-requisite Subject	Pharmaceutical Chemistry
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments quizzes and one minor test, one major theory and practical test.

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Course Objectives	<ul> <li>This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.</li> <li>The course will cover structure and target based design, molecular modeling, quantum mechanics, drug likeness properties</li> <li>To study about how errors arise and propagate in biomolecular modelling.</li> <li>CADD can assist researchers studying interactions between drugs and receptors.</li> <li>Study about Molecular docking by <i>De novo</i> drug design.</li> </ul>
Course Outcome	Upon completion of this course the student should be able to:  Design and discovery of lead molecules.  The role of drug design in drug discovery process.  The concept of QSAR and docking.  Various strategies to develop new drug like molecules.  The design of new drug molecules using molecular modeling software.

<sup>\*</sup> PE-Program elective

### UNIT-I

Introduction to Drug Discovery and Development: Stages of drug discovery and development.

Lead discovery and Analogue Based Drug Design: Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analogue Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement.

Any three case studies.

### **UNIT-II**

# Quantitative Structure Activity Relationship (QSAR)

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Taft's steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

# **UNIT-III**

Molecular Modeling and virtual screening techniques:

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Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design.

## UNIT-IV

## Informatics & Methods in drug design:

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.

## Recommended Books (Latest Editions)

- 1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
- 2. Martin YC. "Quantitative Drug Design" Dekker, New York.
- 3. Delgado JN, Remers WA eds "Wilson & Gisvold's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
- 4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
- Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
- Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
- 7. Current Concepts in Drug Design by T. Durai and Ananda Kumar.
- 8. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
- Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
- Silverman R.B. "The Organic Chemistry of Drug Design and Drug Action" Academic Press, New York.

Course Category	Departmental Core (DC)
Pre-requisite Subject	Biology, Pharmacology
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	o Cell biology is a branch of biology that studies cells - their

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	<ul> <li>physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function. This is done both on a microscopic and molecular level.</li> <li>Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organisms such as humans, plants, and sponges</li> <li>equip students with a basic knowledge of the structural and functional properties of cells.</li> <li>Outline the structure of the biomolecules found in all living organisms.</li> <li>The course will provide a brief overview of Nucleic acid background comprising of salient features and models of DNA and RNA.</li> </ul>
Course Outcome	Upon completion of this course the student should be able to:
	Summarize cell and molecular biology history.
	<ul> <li>Summarize cellular functioning and composition.</li> </ul>
	<ul> <li>Describe the chemical foundations of cell biology.</li> </ul>
	<ul> <li>Summarize the DNA properties of cell biology.</li> </ul>
	<ul> <li>Describe protein structure and function.</li> </ul>
	<ul> <li>Describe cellular membrane structure and function.</li> </ul>
	<ul> <li>Describe basic molecular genetic mechanisms.</li> </ul>
	<ul> <li>Summarize the Cell Cycle.</li> </ul>

<sup>\*</sup> PE-Program elective

### Unit-I

Cell and Molecular Biology: Definitions theory and basics and Applications. History and Summation. Properties of cells and cell membrane., Prokaryotic versus Eukaryotic. Cellular Reproduction. Chemical Foundations – an Introduction and Reactions (Types).

### Unit-II

DNA and the Flow of Molecular Information. DNA Functioning. DNA and RNA. Types of RNA. Transcription and Translation.

Proteins: Defined and Amino Acids. Protein Structure. Regularities in Protein Pathways.

# Unit-III

Cellular Processes. Positive Control and significance of Protein Synthesis.

Science of Genetics. Transgenics and genomic analysis.

Cell cycle analysis. Mitosis and meiosis

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#### Unit-IV

Cellular Activities and checkpoints. Cell Signals: Introduction.

Receptors for Cell Signals. Signaling Pathways: Overview. Misregulation of Signaling Pathways. Protein-Kinases: Functioning.

### Recommended Books (latest edition):

- W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
- Prescott and Dunn., Industrial Microbiology, 4<sup>th</sup> edition, CBS Publishers & Distributors, Delhi.
- 3. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
- 4. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill Ed.
- 5. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
- 6. Rose: Industrial Microbiology.
- 7. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
- 8. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
- 9. Peppler: Microbial Technology.
- 10. Edward: Fundamentals of Microbiology.
- 11. N.K. Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
- Bergey's manual of systematic bacteriology, Williams and Wilkins- A Waverly company
- 13. RA Goldshy et. al.: Kuby Immunology.

BP809ET: COSMETIC SCIENCE*	
Course Category	Departmental Core (DC)
Pre-requisite Subject	Pharmaceutical Technology
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	<ul> <li>The Cosmetology course is designed to train the student in the practical skills, theoretical knowledge, and professional attitudes</li> </ul>

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	necessary to obtain licensure and for competency in entry-level positions in the Cosmetology profession.  Understand the concepts of cosmetics; anatomy of skin v/s hair, general excipients used in cosmetics.  Explain formulation of cosmetics for skin, manufacturing, equipments evaluation of creams like cold cream, vanishing cream etc. & powder cosmetics.  Explain formulation of cosmetics for hair, manufacturing & evaluation of hair shampoos, tonics etc.  Describe formulation of cosmetics for eyes, manufacturing & evaluation of eye mascara, shadow etc.  Understand formulation of manicure products like nail lacquer, remover etc.  Learn formulation, manufacture & evaluation of baby cosmetics like baby oils, powders etc.  Explain the concept of comseceuticals, history, difference between cosmetics & comseceuticals & comseceuticals agents
Course Outcome	Upon completion of this course the student should be able to:
7	<ul> <li>Develop professional attitude and knowledge of hair &amp; skin care.</li> <li>Produce a capable &amp; skilful workforce as required by the prevailing market demands.</li> <li>Equip the trainees with skills and knowledge to ensure adherence to safety measures in parlours and emphasize on fitness &amp; diet for a healthy look.</li> <li>State the correct use of various equipments in Pharmaceutics laboratory relevant to cosmetics.</li> <li>Perform formulation, evaluation and labeling of cosmetics like</li> </ul>
	moisturizing cream, vanishing cream etc.  o Perform formulation, evaluation of eye cosmetics, nail lacquer &shampoo.  o Perform formulation, evaluation & labeling of shaving cream, after
	shave & baby products.  o Describe use of ingredients in formulation and category of formulation. Prepare labels as per regulatory requirements

\* PE-Program elective

# Unit-I

Classification of cosmetic and cosmeceutical products. Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.

**Cosmetic excipients:** Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application

Skin: Basic structure and function of skin.

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Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

#### Unit-II

Principles of formulation and building blocks of skin care products: Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

Antiperspirants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products: Conditioning shampoo, Hair conditioner, anti-dandruff shampoo. Hair oils.

Chemistry and formulation of para phenylenediamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

### Unit-III

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics: Skin Care: Aloe and turmeric. Hair care: Henna and amla.

Oral care: Neem and clove.

**Analytical cosmetics:** BIS specification and analytical methods for shampoo, skin-cream and toothpaste.

#### Unit-IV

Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Colour, Hair tensile strength, Hair combing properties. Soaps and syndet bars. Evolution and skin benefits. Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis. Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic

problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odour.

# Recommended Books (latest edition):

1. Harry's Cosmetology, Wilkinson, Moore, Seventh Edition, George Godwin.

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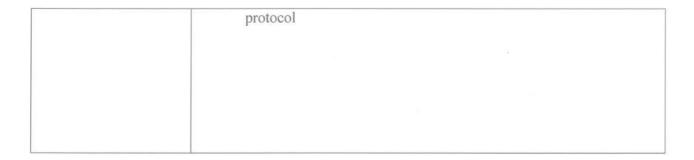
- 2. Poucher's Perfumes, Cosmetic & Soaps by Poucher W.A., Butler, H., Springer India Pvt. Ltd, New Delhi.
- Cosmetics Formulations, Manufacturing and Quality Control, P.P. Sharma, 4 Edition, Vandana Publications Pvt. Ltd., Delhi.
- 4. Text book of cosmetology by Sanju Nanda & Roop K. Khar, Tata Publishers.
- 5. Cosmeceuticals by Madhusudan Rao.
- Cosmetics: Science and technology by Balsam M.S., Sagarin, E., Wiley Interscience, New York.
- 7. Handbook of Cosmetic science and Technology by Pave M., Basel, A.O., Maibach H.I., Informa Healthcare, New York.
- 8. Cosemeceuticals by Rao Y.N., Shayeda, PharmaMed Press, Hyderabad.

Course Category	Departmental Core (DC)
Pre-requisite Subject	Pharmaceutical Chemistry, Pharmacology
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments quizzes and one minor test, one major theory and practical test.
Course Objectives	<ul> <li>This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.</li> <li>The regulations and ethics concerning animal studies and experiments on human beings.</li> <li>Carry out screening of new drugs.</li> <li>To perform Bioassays official in IP/BP/USP.</li> <li>Participate in drug development process</li> <li>Concepts of kinetics and various pharmacokinetic models</li> </ul>
Course Outcome	<ul> <li>Upon completion of this course the student should be able to: <ul> <li>Appreciate the applications of various commonly used laboratory animals</li> <li>Appreciate and demonstrate the various screening methods used in preclinical research.</li> <li>Appreciate and demonstrate the importance of biostatistics and research methodology.</li> <li>Design and execute a research hypothesis independentl.</li> <li>Use of isolated tissue preparations for bioassay methods.</li> <li>Basic aspects to carryout Critical appraisal of marketed fixed dose combinations (FDC).</li> <li>Understanding Prescription auditing and standard treatment</li> </ul> </li> </ul>

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\* PE-Program elective

#### Unit-I

Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals.

Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.

#### Unit-II

Preclinical screening models Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study.

Study of screening animal models for: Diuretics, nootropics, anti-Parkinson's, anti-asthmatics.

**Preclinical screening models:** for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, Alzheimer's disease.

## Unit-III

**Preclinical screening models:** for ANS activity- sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics for CVS activity – anti-hypertensives, diuretics, antiarrhythmic, anti-dyslipidemic, anti-aggregatory, coagulants, and anticoagulants. Preclinical screening models for other important drugs like antiulcer, anti-diabetic, anticancer and anti-asthmatics.

#### Unit-IV

Research methodology and Bio-statistics:

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Selection of research topic, review of literature, research hypothesis and study design.

Pre-clinical data analysis and interpretation using Students't' test and One-way

ANOVA. Graphical representation of data.

# Recommended Books (latest edition):

- 1. Fundamentals of experimental Pharmacology by M.N. Ghosh.
- 2. Hand book of Experimental Pharmacology by S.K. Kulkarni.
- 3. CPCSEA guidelines for laboratory animal facility.
- 4. Drug discovery and Evaluation by Vogel H.G.
- 5. Drug Screening Methods by Suresh Kumar Gupta and S.K. Gupta.
- 6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard.

BP811ET: ADVANCED INSTRUMENTATION TECHNIQUES *	
Course Category	Departmental Core (DC)
Pre-requisite Subject	Pharmaceutical Analysis
Contact hours/week	Lecture: 3, Tutorial:1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	<ul> <li>The Course Objective is-         <ul> <li>This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs</li> <li>This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques.</li> <li>This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.</li> <li>Explain principles, instrumentation of NMR &amp; ESR spectroscopy, Mass Spectrometry and their applications in Pharmaceutical research, quality control of APIs &amp; formulations</li> </ul> </li> </ul>
Course Outcome	<ul> <li>Upon completion of this course the student should be able to:</li> <li>Understand the advanced instruments used and its applications in drug analysis.</li> <li>Understand the chromatographic separation and analysis of drugs.</li> <li>Understand the calibration of various analytical instruments.</li> <li>Know analysis of drugs using various analytical instruments.</li> <li>Characterize the synthesized compounds using IR and NMR spectra's.</li> <li>Independently operate and calibrate various analytical instruments for the assay of various APIs and formulations as per</li> </ul>

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- Pharmacopeial standards.
- o Independently process, interpret the data obtained through experimentation and report the results as per regulatory requirements.
- o Take appropriate safety measures while handling instruments, chemicals and Apparatus

### Unit-I

Nuclear Magnetic Resonance spectroscopy Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry- Principles, Fragmentation, Ionization techniques - Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications.

#### Unit-II

Thermal Methods of Analysis: Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC).

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

#### Unit-III

Calibration and validation- as per ICH and USFDA guidelines.

Calibration of following Instruments: Electronic balance, UV-Visible spectrophoto-meter, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC.

#### Unit-IV

Radio immune assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay.

Extraction techniques: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction.

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<sup>\*</sup> PE-Program elective

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# Hyphenated techniques- LC-MS/MS, GC-MS/MS, HPTLC-MS.

# 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. tenlake.
- 6. Organic Chemistry by I.L. Fin
- 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.

Departmental Core (DC)
Pharmacology
Lecture: 3, Tutorial:1, Practical: 0
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Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
<ul> <li>This subject covers foundational topic that are important for</li> <li>understanding the need and requirements of dietary supplements among different groups in the population.</li> <li>Describe about source, chemistry and uses of several natural nutraceuticals</li> <li>Describe occurrence, chemical nature and medicinal benefits of natural nutraceuticals belong to different phytochemical categories.</li> <li>Explain the role of free radicals in development of different diseases and aging</li> <li>Explain the role of natural and synthetic antioxidants</li> <li>Role of functional foods in prevention of chronic diseases.</li> </ul>
<ul> <li>Upon completion of this course the student should be able to:</li> <li>Understand the need of supplements by the different group of people to maintain healthy life.</li> <li>Understand the outcome of deficiencies in dietary supplements.</li> <li>Appreciate the components in dietary supplements and the application.</li> <li>Appreciate the regulatory and commercial aspects of dietary</li> </ul>

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- Explain effects of processing, storage, environmental factors and regulatory aspects for maintaining quality of nutraceuticals.
- Explain about different free radical which generate in body and their effects and different dietary fibres and complex carbohydrate as functional food ingredients.

## \* PE-Program elective

#### UNIT I

- a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.
- b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community. c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

### UNIT II

Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following a) Carotenoids-  $\alpha$  and  $\beta$ -Carotene, Lycopene, Xanthophylls, leutin b) Sulfides: Diallyl sulfides, Allyl trisulfide. c) Polyphenolics: Reservetrol d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum f) Phyto estrogens: Isoflavones, daidzein, Geebustin, lignans g) Tocopherols h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

## UNIT III

- Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
- b) Dietary fibres and complex carbohydrates as functional food ingredients.
- Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.

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### UNIT IV

- a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
- b) Antioxidants: Endogenous antioxidants enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α-Lipoic acid, melatonin Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.
- c) Functional foods for chronic disease prevention
- d) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods. c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

# Recommended Books (Latest Edition):

- Dietetics by Sri Lakshmi
- Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
- 3. Advanced Nutritional Therapies by Cooper. K.A., (1996). 4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
- 5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2 nd Edn., Avery Publishing Group, NY (1997).
- 6. G. Gibson and C.williams Editors 2000 Functional foods Woodhead Publ.Co.London.
- 7. Goldberg, I. Functional Foods. 1994. Chapman and Hall, New York.
- 8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in Essentials of Functional Foods M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
- 9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
- 10. Shils, ME, Olson, JA, Shike, M. 1994 Modern Nutrition in Health and Disease. Eighth edition. Lea and Febiger

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BP13ET: PHARMACEUTICAL PRODUCT DEVELOPMENT *	
Course Category	Departmental Core (DC)
Pre-requisite Subject	Pharmaceutical Technology, NDDS
Contact hours/week	Lecture: 3, Tutorial: 1, Practical: 0
No of Credits	4
Course Assessment Methods	Continuous assessment through tutorials, attendance, home assignments, quizzes and one minor test, one major theory and practical test.
Course Objectives	This subject covers foundational topic that are important for  o understanding the need and requirements of dosage form development with recent advanced technologies.  o Quality control tests o Stability studies o Experimental designing and optimization o Role of various excipients in product development o Targeted drug delivery and various approaches for this o Knowledge of various evaluation parameters of developed product.
Course Outcome	Upon completion of this course the student should be able to:  Explain the various regulations related to preformulation, formulation development  Learn quality control testing for different types of dosage forms  Explain various Pharmaceutical excipients in pharmaceutical product development such as Solvents and solubilizers, Suspending and emulsifying agents  Explain cyclodextrins & Non - ionic surfactants and their applications  Learn selection and application of excipients in pharmaceutical formulations  Explain optimization by factorial designs and their applications.  Learn the application of QbDin pharmaceutical product development.  Explain regulatory considerations of packaging materials for

<sup>\*</sup> PE-Program elective

# Unit-I

Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms.

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#### Unit-II

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories i. Solvents and solubilizers ii. Cyclodextrins and their applications iii. Non - ionic surfactants and their applications iv. Polyethylene glycols and sorbitols v. Suspending and emulsifying agents vi. Semi solid excipients

## Unit-III

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories i. Tablet and capsule excipients ii. Directly compressible vehicles iii. Coat materials iv. Excipients in parenteral and aerosols products v. Excipients for formulation of NDDS Selection and application of excipients in pharmaceutical formulations with specific industrial applications.

#### Unit-IV

Optimization techniques in pharmaceutical product development. A study of various optimization techniques for pharmaceutical product development with specific examples. Optimization by factorial designs and their applications. A study of QbD and its application in pharmaceutical product development.

Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.

# Recommended Books (Latest editions)

- Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, Charles Bon; Marcel Dekker Inc.
- Encyclopaedia of Pharmaceutical Technology, edited by James Swarbrick, Third Edition, Informa Healthcare publishers.
- 3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
- The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop K Khar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt. Ltd. 2013.
- 5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by
- 6. Patrick J. Sinko, BI Publications Pvt. Ltd.

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- Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K. Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
- Pharmaceutical Dosage Forms and Drug Delivery Systems, Lloyd V. Allen Jr., Nicholas B. Popovich, Howard C. Ansel, 9th Ed. 40
- Aulton's Pharmaceutics The Design and Manufacture of Medicines, Michael E. Aulton, 3rd Ed.
- 10. Remington The Science and Practice of Pharmacy, 20th Ed.
- 11. Pharmaceutical Dosage Forms Tablets Vol 1 to 3, A. Liebermann, Leon Lachman and Joseph B. Schwartz.
- 12. Pharmaceutical Dosage Forms Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
- 13. Role of Dietary Fibres and Nutraceuticals in Preventive Diseases by KT Augusti et. Al.
- Pharmaceutical Dosage Forms Parenteral Medication Vol 1 & 2, Kenneth E. Avis and H.A. Liebermann.
- Advanced Review Articles related to the topics.

## **BP814PW PROJECT WORK (On Elective)**

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subjects opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).