



The Indian Pharmaceutical Association-Maharashtra State Branch's Bombay College of Pharmacy-Autonomous

Kalina, Santacruz (E) Mumbai 400098 (Approved by AICTE, PCI and affiliated to University of Mumbai) Accredited by NBA

> Detailed Syllabus structure and Syllabus for B. Pharm Choice Based Credit System (CBCS)

#### Effective

F. Y. B. Pharm. from Academic Year 2019-2020 S. Y. B. Pharm. from Academic Year 2020-2021 T. Y. B. Pharm. from Academic Year 2021-2022 Final. Y. B. Pharm. from Academic Year 2022-2023





Course code	Name of the course	No. of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology I–Theory	3	1	4
BP102T	Pharmaceutical Analysis I – Theory	3	1	4
BP103T	Pharmaceutics I – Theory	3	1	4
BP104T	Pharmaceutical Inorganic Chemistry – Theory	3	1	4
BP105T	Communication skills – Theory	2	-	2
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics – Theory	2	-	2
BP107P	Human Anatomy and Physiology –Practical	4	-	2
BP108P	Pharmaceutical Analysis I – Practical	4	-	2
BP109P	Pharmaceutics I – Practical	4	-	2
BP110P	Pharmaceutical Inorganic Chemistry – Practical	4	-	2
BP111P	Communication skills – Practical	4	-	1
BP112RBP	Remedial Biology – Practical	4	-	1
	Total	34/36 <sup>\$</sup> /40	4	27/29 <sup>\$</sup> /30 <sup>#</sup>

#### Table-I: Course of study for Semester I

<sup>#</sup>Applicable ONLY for the students who have studied Mathematics/Physics/Chemistry at HSC and will be appearing for the Remedial Biology (RB) course.

<sup>\$</sup>Applicable ONLY for the students who have studied Physics/Chemistry/Botany/Zoology at HSC and will be appearing for the Remedial Mathematics (RM) course.





Course Code	Name of the course	No. of hours	Tutorial	Credit points
BP201T	Human Anatomy and Physiology II – Theory	3	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3	1	4
BP203T	Biochemistry – Theory	3	1	4
BP204T	Pathophysiology – Theory	3	1	4
BP205T	Computer Applications in Pharmacy – Theory	3	-	3
BP206T	Environmental sciences – Theory	3	-	3
BP207P	Human Anatomy and Physiology II –Practical	4	-	2
BP208P	Pharmaceutical Organic Chemistry I– Practical	4	-	2
BP209P	Biochemistry – Practical	4	-	2
BP210P	Computer Applications in Pharmacy – Practical	2	-	1
	Total	32	4	29

#### Table-II: Course of study for Semester II





Course code	Name of the course	No. of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry II – Theory	3	1	4
BP302T	Physical Pharmaceutics I – Theory	3	1	4
BP303T	Pharmaceutical Microbiology – Theory	3	1	4
BP304T	Pharmaceutical Engineering – Theory	3	1	4
BP305P	Pharmaceutical Organic Chemistry II – Practical	4	-	2
BP306P	Physical Pharmaceutics I – Practical	4	-	2
BP307P	Pharmaceutical Microbiology – Practical	4	-	2
BP308P	Pharmaceutical Engineering –Practical	4	-	2
	Total	28	4	24

#### Table-III: Course of study for Semester III





Course code	Name of the course	No. of hours	Tutorial	Credit points
BP401T	Pharmaceutical Organic Chemistry III– Theory	3	1	4
BP402T	Medicinal Chemistry I – Theory	3	1	4
BP403T	Physical Pharmaceutics II – Theory	3	1	4
BP404T	Pharmacology I – Theory	3	1	4
BP405T	Pharmacognosy and Phytochemistry I– Theory	3	1	4
BP406P	Medicinal Chemistry I – Practical	4	-	2
BP407P	Physical Pharmaceutics II – Practical	4		2
BP408P	Pharmacology I – Practical	4	-	2
BP409P	Pharmacognosy and Phytochemistry I – Practical	4	-	2
	Total	31	5	28

#### Table-IV: Course of study for Semester IV





Course code	Name of the course	No. of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3	1	4
BP502T	Industrial Pharmacy I– Theory	3	1	4
BP503T	Pharmacology II – Theory	3	1	4
BP504T	Pharmacognosy and Phytochemistry II- Theory	3	1	4
BP505T	Pharmaceutical Jurisprudence – Theory	3	1	4
BP506P	Industrial Pharmacy I – Practical	4	-	2
BP507P	Pharmacology II – Practical	4	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4	-	2
	Total	27	5	26

#### Table-V: Course of study for Semester V





Course code	Name of the course	No. of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3	1	4
BP602T	Pharmacology III – Theory	3	1	4
BP603T	Herbal Drug Technology – Theory	3	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3	1	4
BP605T	Pharmaceutical Biotechnology – Theory	3	1	4
BP606T	Quality Assurance – Theory	3	1	4
BP607P	Medicinal chemistry III – Practical	4	-	2
BP608P	Pharmacology III – Practical	4	-	2
BP609P	Herbal Drug Technology – Practical	4	-	2
	Total	30	6	30

#### Table-VI: Course of study for Semester VI





Course code	Name of the course	No. of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3	1	4
BP702T	Industrial Pharmacy II – Theory	3	1	4
BP703T	Pharmacy Practice – Theory	3	1	4
BP704T	Novel Drug Delivery System – Theory	3	1	4
BP705P	Instrumental Methods of Analysis – Practical	4	-	2
BP706PS	Practice School	12	-	6
	Total	28	5	24

#### Table-VII: Course of study for Semester VII





Course code	Name of the course	No. of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3	1	4
BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET- BP813ET	Elective I*+ Elective II*	3+3	1+1	4+4
BP813PW	Project Work	12	-	6
	Total	24	4	22

#### Table-VIII: Course of study for Semester VIII

\*Students may select any two electives from those listed in the Syllabus.

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# SEMESTER I<br/>BP101THUMAN ANATOMY AND PHYSIOLOGY-I (Theory)45 Hours

#### **Course Objectives:**

To impart fundamental knowledge on the anatomy, physiology, and functions of the various systems of the human body.

#### **Course Outcomes:**

The learner should be able to:

- 1. Explain the gross morphology, structure, and functions of various organs of the human body with respect to the levels of organisation and communication
- 2. Explain the various homeostatic mechanisms and their imbalances of the lymphatic, nervous and cardiovascular systems in relation to the knowledge of the pathophysiology of diseases.
- 3. Discuss the composition and functions of blood, explain the process of haemostasis, and correlate the knowledge to haematological disorders.
- 4. Understand coordinated working pattern of different muscles and organs of each system.

Unit	Details	Hours
1	Introduction to human body	1
	• Definition and scope of anatomy and physiology	
	<ul> <li>Levels of structural organization and body systems</li> </ul>	
	Basic life processes, homeostasis	
2	Cellular level of organization	2
	• Structure and functions of cell	
	<ul> <li>Transport across cell memorane, cell division, cell junctions</li> <li>General principles of cell communication: intracellular signaling pathway activation extracellular signal molecule, Forms of intracellular signaling:</li> </ul>	
	a) Contact-dependent by b) Paracrine c) Synaptic d) Endocrine	
3	Tissue level of organization	2
	• Structural and functional characteristics of following tissues: Epithelial, Connective, Nervous, Muscle	
4	Integumentary system	2
	• Structure and functions of skin	
5	Skeletal system and Joints	8
	• Divisions of skeletal system	
	• Types of bone, salient features, and functions of bones	
	Organization of skeletal muscle	
	Physiology of muscle contraction, neuromuscular junction	
	Structural and functional classification of joints	
	• Types of joints movements and its articulation	
6	Body fluids and blood	6

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	Body fluids	
	Composition and functions of blood	
	Hemopoeisis, formation of haemoglobin, anaemia	
	Mechanisms of coagulation	
	• Blood grouping, Rh factors, transfusion, its significance	
	Leucopoiesis	
	Immunity: Basics and types	
	Disorders of blood, reticuloendothelial system	
7	I ymphatic system	3
,	Components and functions of lymphatic system	5
	Lymphatic organs and tissues	
	Organization of lymph vessels	
	<ul> <li>Formation and flow of lymph</li> </ul>	
8	Peripheral Nervous System	9
	• Classification of peripheral nervous system	
	• Structure and functions of sympathetic and parasympathetic nervous	
	system	
	Origin and functions of spinal and cranial nerves	
	Methods to measure electrical activity of brain	
9	Structure and Function of following sensory organs and their disorders:	5
	• Eye	
	• Ear	
	• Tongue	
	• Nose	
10	Cardiovascular system	7
	• Functional anatomy of heart	
	• Conducting system of heart, Cardiac cycle, Electrocardiogram (ECG)	
	Physiology of blood circulation, Functional anatomy of blood vessels	
	• Blood pressure and factors regulating blood pressure, baroreceptors,	
	chemoreceptors, vasomotor centre, humoral and neuronal control of blood	
	pressure and circulation disorders of heart.	
		45
	TOTAL	45

- 1. Waugh A, and Grant A, Ross & Wilson, Anatomy & Physiology in Health & Illness, 9<sup>th</sup> edition, Churchill Livingstone, New York, 2001.
- Tortora G. J. & Derrickson B, Principals of Anatomy & Physiology, 15<sup>th</sup> edition, John Wiley and Sons, Inc., New Jersey, 2016
- Guyton A. C., Hall J. E., Textbook of Medical Physiology, 12<sup>th</sup> edition, W. B. Saunders Company, USA/Prism Books Ltd. India, 2010.
- 4. Mackenna B. R. & Callander R., McNaught & Callander's, Illustrated Physiology, 5<sup>th</sup> edition Churchill Livingstone, New York, 2012.





- 5. Kaplan, Jack, Opheim, Toivola, Lyon, Clinical Chemistry: Interpretation & Techniques,4<sup>th</sup> edition Lippincott, Williams and Wilkins, USA,1995.
- 6. Godkar P.B., Godkar, D.P., Textbook of Medical Laboratory Technology,3<sup>rd</sup> edition, Bhalani Publishing House, Mumbai, India, 2014.
- 7. Mohan H, Textbook of Pathology, 6<sup>th</sup> edition, Jaypee Brothers Medical Publishers Pvt. Ltd., New Delhi, 2010.
- 8. Chatterjee, C.C., Human Physiology (vol 1 and 2), 11<sup>th</sup> edition, CBS Publishers and Distributors, Kolkata., 2017.

# BP102TPHARMACEUTICAL ANALYSIS (Theory)45 Hours

#### **Course Objectives**:

This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

#### **Course Outcomes:**

Upon completion of the course student shall be able to:

- 1. Understand the principles of volumetric and electro chemical analysis
- 2.Carryout various volumetric and electrochemical titrations
- 3.Perform experiments involving these principles of analysis

Unit	Details	Hours
1	(a) Pharmaceutical analysis- Definition and scope	10
	i) Different techniques of analysis (Instrumental and Non-Instrumental).	
	ii) Methods of expressing concentration - Molarity, Molality, percent	
	concentration, ppm, ppb, Normality, Numericals.	
	iii) Primary and secondary standards.	
	iv) 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.	
	(b) Errors: Sources of errors, types of errors, methods of minimizing errors,	
	accuracy, precision, Concepts and numerical of Mean, Median, Standard	
	deviation, Relative standard deviation and Significant figures.	
	(c) Pharmacopoeia - Introduction to Pharmacopoeial monographs and their	
	significance (relevance of all the tests to be discussed), Sources of	
	impurities in medicinal agents, limit tests.	
2	(a) Titrations (Theoretical terms) - Titrimetric analysis, Titrant, Titrand,	10
	Theoretical end point or equivalence point, End point of titration, Titration	
	error, Conditions for titrimetric analysis, Classification of reactions for	
	titrimetric analysis.	
	(b) Law of Mass Action, Equilibrium Constant, pH, pKa, pKb, hydrolysis of	
	salts, Buffer solutions, Buffer Capacity, Numericals for pH calculation.	
	(c) Acid base titration: Theories of acid base indicators (Ostwald's theory,	
	Resonance theory), Mixed indicators, concept of range of indicators, Choice	
	of indicators; Classification of acid base titrations and theory involved in	
	titrations of strong, weak, and very weak acids and bases, Neutralization	





	curves; Methods of titration (Direct titration, back titration, blank	
	determination, Factor calculation for assays); Assay of benzoic acid.	
	(d) Non aqueous titration: Solvents (aprotic, protophilic, protogenic,	
	amphiprotic), characteristics of solvents for non-aqueous titrations (acid-	
	base character, dielectric constant, leveling and differentiating effect),	
	Indicators for non-aqueous titrations, Acidimetry and alkalimetry titration	
	and estimation of Sodium benzoate and Ephedrine HCl.	
3	(a) <b>Precipitation titrations</b> : Common Ion Effect, Solubility Product, Factors	10
	affecting solubility of precipitates, Fractional precipitation; Mohr's method,	
	Volhard's, Modified Volhard's, Fajans method, Standardization of silver	
	nitrate, Estimation of sodium chloride.	
	(b) <b>Complexometric titration</b> : Terms - Complex. Complexing agents	
	(Complexones), Chelate, Ligand, Co-ordination number, Chelating agent,	
	Sequestering agent Metal-ligand complex: Formations of complexes:	
	Classification (Direct method back titration replacement titration) Metal	
	ion indicators (pM indicators) masking and demasking reagents, estimation	
	of Magnesium sulphate and calcium gluconate. Determination of mixture of	
	lead zinc and magnesium in a sample	
	(c) <b>Gravimetry</b> : Principle and steps involved in gravimetric analysis Organic	
	and inorganic precipitants. Purity of the precipitate: co precipitation and	
	and morganic precipitants, Furity of the precipitate. co-precipitation and	
	Weimern ratio). Estimation of harium subsets. Assay of Aluminium by	
	weinarn ratio), Estimation of bartuin supplate, Assay of Aluminium by	
	Oxine reagent.	
	(d) Nitrite titrations: Basic Principles, methods and application of	
	diazotisation titration, Concept of external indicator, Assay of	
	Sulphacetamide sodium.	
4	(a) Redox titrations	8
	i) Concepts of oxidation and reduction - Oxidising and reducing agents.	-
	Standard reduction potential. Nernst equation. Redox titration curve and	
	Equivalence point	
	ii) Types of redox titrations (Principle Titrants Indicators and	
	Application) – Permanganometry (Assay of hydrogen perovide)	
	Carimetry (Assay of Paracetamol and Dried Ferrous sulphate)	
	Indimetry (Assay of Ascorbic acid API) Indometry (Assay of potassium	
	nermanganate) Bromatometry (Assay of Isoniazid) Dichrometry (Iron)	
	Titration with notassium iodate (Assay of Potassium iodide)	
5	(a) Electrochamical methods of analysis	7
5	i) Conductometry. Introduction Conductivity call Conductometric	1
	titrations applications	
	iii) <b>Detentionativ</b> Electrochemical call construction and working of	
	ii) rotentionetry - Electrochemical cell, construction and Working of	
	reference (Standard hydrogen, silver chloride electrode and calomel	
1	waarmagay and indicator algorigade instal algorigades and algorigades	
	electrode) and indicator electrodes (inetal electrodes and glass	
	electrode) and indicator electrodes (inetal electrodes and glass electrode), methods to determine end point of potentiometric titration	
	electrode) and indicator electrodes (inetal electrodes and glass electrode), methods to determine end point of potentiometric titration (aqueous acid-base titrations -Strong acid vs strong base, strong acid vs	
	electrode) and indicator electrodes (inetal electrodes and glass electrode), methods to determine end point of potentiometric titration (aqueous acid-base titrations -Strong acid vs strong base, strong acid vs weak base, weak acid vs strong base, weak acid vs weak base) and	
	electrode) and indicator electrodes (inetal electrodes and glass electrode), methods to determine end point of potentiometric titration (aqueous acid-base titrations -Strong acid vs strong base, strong acid vs weak base, weak acid vs strong base, weak acid vs weak base) and applications.	

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of dropping mercury electrode and rotating platinum electrode, Current Voltage curve (Polarogram), supporting electrolyte, Oxygen wave polarographic maxima, factors affecting limiting current, half wave potential, applications, Pulse polarography-Normal pulse polarography Differential pulse polarography and square wave polarography	,
TOTAL	45

- 1. Beckett, A. H. And J. B. Stenlake. Practical Pharmaceutical Chemistry: Part I and II, CBS Publishers and Distributors, India.
- 2. G. D. Christian, Analytical Chemistry, 6<sup>th</sup> edition, John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd, 2003.
- 3. Connors, K. A., A Textbook of Pharmaceutical Analysis,3<sup>rd</sup> edition, John Wiley and Sons, Canada, 2007.
- 4. Skoog, D. A., F. J. Holler and S. R. Crouch. Principles of Instrumental Analysis, 6<sup>th</sup> edition, Brooks Cole, 2006
- 5. Skoog, D. A., and D. M. West. Fundamentals of Analytical Chemistry, 7<sup>th</sup> edition, Brooks Cole, USA, 1995.
- 6. Watson, D. G. Pharmaceutical Analysis: A Textbook for Pharmacy Students and Pharmaceutical Chemists, Elsevier Health Sciences, London.
- 7. J. Mendham, R. C. Denney, J. D. Barnes, M. J. K. Thomas, B. Sivasankar, Vogel's Textbook of Quantitative Chemical Analysis, 6<sup>th</sup> edition, Pearson Education, New Delhi, 2009.
- 8. Kar, A. Pharmaceutical Drug Analysis, New Age International India.
- 9. Mahajan S. S. Instrumental Methods of Analysis, Popular Prakashan Pvt Ltd, India.
- 10. Chatwal, G. R., and M. Arora. Analytical Chemistry, Himalaya Publishing House.
- 11. Indian Pharmacopoeia, Indian Pharmacopoeia Commission, India.
- 12. Willard, H. H., L. Merritt, F. Settle and J. A. Dean. Instrumental Methods of Analysis, CBS Publishers & Distributors, India.
- 13. Ewing, G. W. Instrumental Methods of Chemical Analysis, Mcgraw-Hill Book Company, New York.
- 14. Robinson, J. W., E. M. S. Frame and G. M. Frame. Undergraduate Instrumental Analysis, Skelly Frame and G.M. Frame II, Publication.
- 15. Kellner, R., J. M. Mermet, M. Otto, M. Valcárcel and H. M. Widmer. Analytical Chemistry, John Wiley & Sons Australia, Limited.

# BP103TPHARMACEUTICS - I (Theory)45 Hours

#### **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.

#### **Course Outcomes:**

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





- 1. Know the history of profession of pharmacy and official compendia
- 2. Understand the basics of different dosage forms, pharmaceutical incompatibilities, and pharmaceutical calculations
- 3. Understand the professional way of handling the prescription and dispensing of medications
- 4. Describe formulation and evaluation aspect of monophasic liquid formulations
- 5. Understand the dispensing aspects of dosage forms like powders, monophasic liquids, biphasic systems, suppositories, and semisolids

Unit	Details	Hours
1	Historical background and development of profession of pharmacy: History of	10
	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.	
	<b>Dosage forms:</b> Introduction to dosage forms, classification, and definitions	
	<b>Prescription:</b> Definition, Parts of prescription, handling of Prescription and Errors	
	in prescription.	
	<b>Posology:</b> Definition, Factors affecting posology. Pediatric dose calculations based	
	on age, body weight and body surface area.	10
2	Pharmaceutical calculations: Weights and measures – Imperial & Metric system,	10
	Calculations involving percentage solutions, alligation, proof spirit and isotonic	
	solutions based on freezing point and molecular weight.	
	<b>Powders:</b> Definition, classification, advantages and disadvantages, Simple &	
	efflorescent and hydroscopic powders, eutectic mixtures Geometric dilutions	
	Liquid dosage forms: Advantages and disadvantages of liquid dosage forms	
	Excipients used in formulation of liquid dosage forms. Solubility enhancement	
	techniques	
3	Monophasic liquids: Definitions and preparations of Gargles, Mouthwashes,	9
	Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and	
	Lotions.	
	Biphasic liquids:	
	Suspensions: Definition, advantages and disadvantages, classifications, Preparation	
	of suspensions; Flocculated and Deflocculated suspension & stability problems and	
	methods to overcome.	
	<b>Emulsions:</b> Definition, classification, emulsifying agents, tests for identification of	
	type of Emulsion, Methods of preparation, stability problems and methods to	
4	overcome	0
4	<b>Suppositories</b> : Definition, types, advantages and disadvantages, types of bases,	9
	methods of preparations. Displacement value & its calculations, evaluation of	
	Suppositiones. Pharmacautical incompatibilities: Definition classification physical chemical	
	and therapeutic incompatibilities with examples	
5	Semisolid dosage forms: Definitions, classification mechanisms and factors	7
	influencing dermal penetration of drugs. Preparation of ointments, pastes, creams.	
	and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid	
I		

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dosages forms	
TOTAL	45

#### **Reference Books (Latest Editions to be adopted):**

- 1. Ansel H.C., Allen L.V., Pharmaceutical Dosage Forms and Drug Delivery Systems, 10<sup>th</sup> edition, Lippincott Williams and Walkins, USA, 2014.
- 2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, 12<sup>th</sup> edition, CBS Publishers and Distributors, New Delhi, 2008.
- 3. Taylor, K., Aulton M.E., Pharmaceutics: The Science of Dosage Form Design, 2<sup>nd</sup> edition, Churchill Livingstone, Edinburgh, 2001.
- 4. Indian Pharmacopoeia.
- 5. British Pharmacopoeia.
- 6. Lachman, L, Lieberman H.A., Kanig, J.L., The Theory and Practice of Industrial Pharmacy, 1<sup>st</sup> edition, Lea & Febiger, Philadelphia,1986
- Khar, R.K., Vyas, S.P., Ahmad F.J., Jain G.K., Lieberman, Lachman's The Theory and Practice of Industrial Pharmacy, 4<sup>th</sup> edition, CBS Publishers and Distributors, New Delhi, 2020.
- 8. Gennaro A.R., Remington : The Science and Practice of Pharmacy, 21st edition, Lippincott Williams and Wilkins, Philadelphia, 2005.
- 9. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, 6<sup>th</sup> edition, CBS Publishers and Distributors Pvt. Ltd, Delhi, 2005.
- 10. Rawlins E.A., Bentley's Textbook of Pharmaceutics, 8<sup>th</sup> edition, Elsevier India, 2010.
- Ghebre-Sellassie I., Pharmaceutical Pelletization Technology, 1<sup>st</sup> edition, Marcel Dekker, Inc., New York, 1990
- 12. Parikh D.M., Handbook of Pharmaceutical Granulation Technology, 1<sup>st</sup> edition, Marcel Dekker, Inc., New York, 1997.
- 13. Nieloud F and Gilberte M., Pharmaceutical Emulsions and Suspensions, 1<sup>st</sup> edition, Marcel Dekker, Inc., New York, 2000.

# BP104T PHARMACEUTICAL INORGANIC CHEMISTRY (Theory) 45 Hours

#### **Course Objectives:**

This subject deals with the monographs of inorganic drugs and pharmaceuticals.

#### **Course Outcomes:**

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

- 1. Know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals.
- 2. Understand the medicinal and pharmaceutical importance of inorganic compounds

Unit	Details	Hours
1	Impurities in pharmaceutical substances: History of Pharmacopoeia, Sources and	10
	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	
	General methods of preparation, assay for the compounds superscripted with	
	asterisk (*), properties and medicinal uses of inorganic compounds belonging to	

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the following classes	
Acids, Bases and Buffers: Buffer equations and buffer capacity in general, buffers	10
in pharmaceutical systems, preparation, stability, buffered isotonic solutions,	
measurements of tonicity, calculations, and methods of adjusting isotonicity.	
<b>1. Major extra and intracellular electrolytes</b> : 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.	
2. Dental products: Dentifrices, role of fluoride in the treatment of dental caries,	
Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol	
cement.	
Gastrointestinal agents	10
Acidifiers: Ammonium chloride* and dil. HCl	
Antacid: Ideal properties of antacids, combinations of antacids, Sodium	
Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture.	
Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite	
Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid,	
Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations.	
Miscellaneous compounds	8
Expectorants: Potassium iodide, Ammonium chloride*.	
<b>Emetics</b> : Copper sulphate*, Sodium potassium tartarate	
Haematinics: Ferrous sulphate*, Ferrous gluconate	
Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium	
nitrite	
Astringents: Zinc Sulphate, Potash Alum	
Radiopharmaceuticals: Radio activity, Measurement of radioactivity, Properties of	7
$\alpha$ , $\beta$ , $\gamma$ radiations, Half-life, radio isotopes and study of radio isotopes - Sodium	
iodide I <sup>131</sup> , Storage conditions, precautions & pharmaceutical application of	
radioactive substances.	
TOTAL	45
	the following classes. Acids, Bases and Buffers: 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. 1. Major extra and intracellular electrolytes: 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. 2. Dental products: Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement. Gastrointestinal agents Acidifiers: Ammonium chloride* and dil. HCI Antacid: Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture. Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations. Miscellaneous compounds Expectorants: Potassium iodide, Ammonium chloride*. Emetics: Copper sulphate*, Sodium potassium tartarate Haematinics: Ferrous sulphate*, Ferrous gluconate Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium nitrite Astringents: Zinc Sulphate, Potash Alum Radiopharmaceuticals: Radio activity, Measurement of radioactivity, Properties of $\alpha$ , $\beta$ , $\gamma$ radiations, Half-life, radio isotopes and study of radio isotopes - Sodium iodide 1 <sup>131</sup> , Storage conditions, precautions & pharmaceutical application of radioactive substances. TOTAL

#### **Reference Books (Latest Editions to be adopted):**

- 1. Beckett A. H., Stenlake J. B., Practical Pharmaceutical Chemistry, Vol. I & II, 2<sup>nd</sup> edition, Athlone Press, University of London, London, 1970.
- Vogel A.I., Textbook of Quantitative Inorganic Analysis, 2<sup>nd</sup> edition, Longman Green and Co., London, 1951.
- 3. Gundu Rao P., Inorganic Pharmaceutical Chemistry, 1<sup>st</sup> edition, Vallabh Prakashan, Delhi, India, 2013.
- 4. Bentley AO, Atherden LM, Driver JE, Textbook of Pharmaceutical Chemistry, 4th edition, Oxford University Press, London, New York, and Toronto, 1945.
- 5. Kennedy J. H., Principles of Analytical Chemistry, 2<sup>nd</sup> edition, Saunders College Publishing, USA, 1990.

6. Indian Pharmacopoeia.

# BP105T COMMUNICATION SKILLS (Theory) 30 Hours

**Course Objectives:** 





This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists, and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

#### **Course Outcomes:**

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

1. Understand the behavioral needs for a pharmacist to function effectively in the areas of pharmaceutical operation

- 2. Communicate effectively (Verbal and Non-verbal)
- 3. Effectively manage the team as a team player
- 4. Develop interview skills
- 5. Develop Leadership qualities and essentials

Unit	Details	Hours
1	Communication Skills: Introduction, Definition, The Importance of	7
	Communication, The Communication Process - Source, Message, Encoding,	
	Channel, Decoding, Receiver, Feedback, Context.	
	1. Barriers to communication: Physiological Barriers, Physical Barriers,	
	Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers,	
	Psychological Barriers, Emotional barriers.	
	<b>2. Perspectives in Communication:</b> Introduction, Visual Perception, Language,	
	Other factors affecting our perspective - Past Experiences, Prejudices, Feelings,	
	Environment.	
2	<b>1. Elements of Communication:</b> Introduction, Face to Face Communication -	7
	Tone of Voice, Body Language (Non-verbal communication), Verbal	
	Communication, Physical Communication for each -Direct Communication	
	Style, Spirited Communication Style, Systematic Communication Style,	
	Considerate Communication Style.	
3	Basic Listening Skills: Introduction, Self-Awareness, Active Listening,	7
	Becoming an Active Listener, Listening in Difficult Situations.	
	<b>1. Effective Written Communication:</b> Introduction, When and When Not to	
	Use Written Communication - Complexity of the Topic, Amount of Discussion'	
	Required, Shades of Meaning, Formal Communication.	
	2. Writing Effectively: Subject Lines, Put the Main Point First, Know Your	
-	Audience, Organization of the Message.	_
4	<b>Interview Skills:</b> Purpose of an interview, Do's and Don'ts of an interview <b>1</b> Civing Presentational Decline with Economic planning your Presentation	5
	1. Giving Presentations: Dealing with Fears, planning your Presentation,	
	Delivery	
_	Commentation Delivery.	4
5	Group Discussion: Introduction, Communication skills in group discussion,	4
	Do s and Don is of group discussion.	20
	TUTAL	30

#### **Reference Books (Latest Editions to be adopted):**

- 1. Ruther Foord A.J., Basic Communication Skills for Technology, 2<sup>nd</sup> Edition, Pearson Education, Delhi, 2011
- 2. Sanjay Kumar, Pushp lata, Communication skills, 2<sup>nd</sup> Edition, Oxford Press, Lucknow 2015.





- 3. Robbins S.P., Organizational Behaviour, 1<sup>st</sup> Edition, Pearson, San Diego, USA, 2013.
- 4. Hasson G., Brilliant- Communication skills, 1st Edition, Pearson Life, UK, 2011
- 5. Gopala S.W., The Ace of Soft Skills: Attitude, Communication and Etiquette for success, 5<sup>th</sup> Edition, Pearson Education, Delhi, 2013.
- 6. Dalley D, Burton Lois, Greenhall M., Developing your influencing skills,1st Edition Universe of Learning Ltd, Manchester, United Kingdom, 2010.
- 7. Konar N., Communication skills for Professionals, 2<sup>nd</sup> Edition, New arrivals –PHI Learning Pvt. Ltd, New Delhi, 2011.
- 8. Mitra, B.K., Personality development and soft skills, 1<sup>st</sup> Edition, Oxford Press, Lucknow, 2011.
- 9. Butter Field, J., Soft skill for everyone, 1st Edition, Cengage Learning India Pvt. Ltd, New Delhi, 2011.
- 10. Francis Peters SJ, Soft skills and professional communication, 1<sup>st</sup> Edition, McGraw Hill Education, New York, 2011.
- 11. Adair John, Effective communication, 4<sup>th</sup> Edition, Pan Mac Millan, 2009.
- 12. Daniels A.C, Bringing out the best in people, 2<sup>nd</sup> Edition, Mc Graw Hill Education, New York, 1999.

## BP106RBTRemedial Biology (Theory)30 Hours

#### **Course Objectives:**

To get the learner acquainted with the facets of biology in the plant and animal kingdom.

#### **Course Outcomes:**

The learner should be able to:

- 1. Understand the classification and features of plant and animal kingdom.
- 2. Know the anatomy and physiology of plants.
- 3. Appreciate the anatomy & physiology in animals especially the human body

Unit	Details	Hours
1	Living world:	5
	<ul> <li>Definition and characters of living organism</li> </ul>	
	• 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	
2	Morphology of Flowering plants	2
	<ul> <li>Morphology of different parts of flowering plants – Root, stem,</li> </ul>	
	inflorescence, flower, leaf, fruit, seed	
	General Anatomy of root, stem, leaf of monocotyledons & dicotylidones	
3	Body fluids and circulation	7
	<ul> <li>Composition of blood, blood groups, coagulation of blood</li> </ul>	
	Composition and functions of lymph	
	Human circulatory system	
	• Structure of human heart and blood vessels	
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	• 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	
4	Excretory products and their elimination	7
	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	
5	Plants and mineral nutrition	5
	• Essential mineral, macro, and micronutrients.	
	• Nitrogen metabolism. Nitrogen cycle, biological nitrogen fixation.	
	Photosynthesis	
	• Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors	
	affecting photosynthesis.	
6	Plant respiration	4
	• Respiration, glycolysis, fermentation (anaerobic)	
	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 organelle, cell division	
	Tissues	
	• Definition, types of tissues, location, and functions.	
	TOTAL	30

Page **20** of **138** 





- 1. Gokhale S.B, Kalaskar M.G, Kulkarni Y.A, Remedial Biology (Pharmaceutical Biology), 1<sup>st</sup> edition, Nirali Prakashan, Pune, 2017.
- 2. Seetharam P.L, Thulajappa Y, Chavan R.R, Textbook of Biology,1<sup>st</sup> edition, Expert Educational Publishers, Bangalore, 1995.
- 3. Naidu B.V.S, Renukumar B.M, Textbook of Biology, 1<sup>st</sup> edition, Sri Renuka Publications, Davangere, 1972.
- 4. Naidu B.V.S, Murthy P.K, Textbook of Biology, 1<sup>st</sup> edition, Prakash Sahithye, Bangalore, 1972.
- 5. Dutta A.C, Botany for Degree students, 6<sup>th</sup> edition, MKM Publishers Pvt. Ltd, New Delhi, 1998.
- 6. Ayyar E.K; T N Anathakrishnan, A Manual of Zoology, 5<sup>th</sup> edition, S. Viswanathan Pvt. Ltd, Madras, 1992.
- 7. Gokhale S.B, Kalaskar M.G, Kulkarni Y.A, A Practical book of Remedial Biology, 1<sup>st</sup> edition, Nirali Prakashan, Pune, 2018.

# BP106RMT REMEDIAL MATHEMATICS (Theory) 30 Hours

#### **Course Objectives:**

This is an introductory course in mathematics. This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.

#### **Course Outcomes:**

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

- 1. Know the theory and their application in Pharmacy
- 2. Solve the different types of problems by applying theory
- 3. Appreciate the important application of mathematics in Pharmacy

Unit	Details	Hours
1	<b>Partial fraction</b> Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction, Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics. <b>1. Logarithms</b> Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems. <b>2. Function</b> : Real Valued function, Classification of real valued functions, <b>3. Limits and continuity</b> : Introduction, Limit of a function, Definition of limit of a function ( $\varepsilon - \delta$ definition), $\lim_{x \to a} \frac{x^n - a^n}{x - a} = na^{n-1},  \lim_{\theta \to 0} \frac{\sin \theta}{\theta} = 1,$	6
2	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	6



Syllabus B.Pharm (Choice Based Credit System)



	square matrix, Cayley–Hamilton theorem, Application of Matrices in solving Pharmacokinetic equations.	
3	<b>Calculus</b> <b>Differentiation</b> : 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) – <b>Without</b> <b>Proof</b> , 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 ( <b>without Proof</b> ), Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point. Application.	6
4	<ul> <li>Analytical Geometry</li> <li>Introduction: Signs of the Coordinates, Distance formula,</li> <li>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.</li> <li>Integration: Introduction, Definition, Standard formulae, Rules of integration, Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application.</li> </ul>	6
5	<ul> <li>Differential Equations: Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations, Application in solving Pharmacokinetic equations.</li> <li>1. 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.</li> </ul>	6
	TOTAL	30

- 1. Shanti Narayan, Mittal P.K, Differential Calculus, revised edition, S. Chand and Co. Pvt. Ltd, New Delhi, 2013.
- 2. Panchaksharappa Gowda D. H , Pharmaceutical Mathematics with application to Pharmacy, 1<sup>st</sup> Edition, PharmaMed Press, 2014
- 3. Shanti Narayan, Mittal P.K, Integral Calculus, 11th edition, S. Chand and Co. Pvt. Ltd, 2013.
- 4. Grewal B. S, Higher Engineering Mathematics, 44<sup>th</sup> edition, Khanna Publishers, New Delhi, 2020.

#### BP107P Human Anatomy and Physiology (Practical)

#### **Course Objectives**:

To get the learner acquainted with the diagnostic methods employed in detection of the pathology of some disease states.

#### **Course Outcomes**

The learner should be able to:

1. Perform haematology tests, record the heart rate, pulse and blood pressure and relate the results with clinical conditions.





- 2. Identify and postulate the position of the bones in human skeleton.
- 3. Identify and describe the various body tissues and organs based on the structure and organisation of cells.

Unit	Details
1	Study of compound microscope.
2	<ul> <li>Microscopic study of permanent slides of tissues: Discussion on the normal as well as pathological changes with the help of charts / images.</li> <li>Columnar, Cuboidal, Squamous, Ciliated Epithelium</li> <li>Cardiac, Skeletal, Smooth muscle</li> <li>Ovary, Testis, Liver, Pancreas, Thyroid, Tongue, Stomach, Intestine, Kidney, Lung, Spinal Cord, Cerebrum, Artery, Vein</li> </ul>
3	Study of bones: • Axial • Appendicular
4	<ul> <li>Introduction to hemocytometry: Determination of the hematology studies and discussion of the pathological deviations from baseline values <ol> <li>Red Blood cell (RBC) Count</li> <li>Total Leukocyte Count</li> <li>Differential Leukocyte (WBC) Count</li> <li>Haemoglobin content of blood</li> <li>Bleeding / Clotting Time</li> <li>Blood groups</li> <li>Erythrocyte Sedimentation Rate (ESR) / Hematocrit (Demonstration)</li> </ol> </li> </ul>
5	Determination of heart rate and pulse rate.
6	Recording of blood pressure.

- 1. Mackenna B. R. & Callander R., McNaught & Callander's, Illustrated Physiology, 5<sup>th</sup> edition Churchill Livingstone, New York, 2012.
- 2. Kaplan, Jack, Opheim, Toivola, Lyon, Clinical Chemistry: Interpretation & Techniques,4<sup>th</sup> edition Lippincott, Williams and Wilkins, USA,1995.
- 3. Godkar P.B., Godkar, D.P., Textbook of Medical Laboratory Technology,3<sup>rd</sup> edition, Bhalani Publishing House, Mumbai, India, 2014.
- 4. Ghai C. L., Textbook of Practical Physiology, Jaypee Brothers Medical Publishers Pvt. Ltd., New Delhi
- 5. Mohan H, Textbook of Pathology, 6<sup>th</sup> edition, Jaypee Brothers Medical Publishers Pvt. Ltd., New Delhi, 2010.
- 6. Chatterjee, C.C., Human Physiology (vol 1 and 2), 11<sup>th</sup> edition, CBS Publishers and Distributors, Kolkata., 2017.

#### <u>BP108P</u> PHARMACEUTICAL ANALYSIS (Practical)

**Course Objectives:** 





This course deals with the fundamentals of analytical chemistry and principles of titrimetry, turbidometry, electrochemical analysis and gravimetry.

#### **Course Outcomes:**

Upon completion of the course student shall be able to:

- Understand the principles of volumetric, turbidometric, electrochemical and gravimetric analysis.
- Carryout various analysis.
- Develop skills to analyse the data obtained and make conclusions.

#### I Preparation and standardization of -

- (1) Sodium hydroxide.
- (2) Sulphuric acid.
- (3) Sodium thiosulfate.
- (4) Potassium permanganate.
- (5) Ceric ammonium sulphate.

#### II Assay of the following compounds along with Standardization of Titrant -

- (1) Ammonium chloride by acid base titration.
- (2) Ferrous sulphate by Cerimetry.
- (3) Copper sulphate by Iodometry / Sodium metabisulphite.
- (4) Calcium gluconate by complexometry.
- (5) Hydrogen peroxide by permanganometry.
- (6) Sodium benzoate by non-aqueous titration.
- (7) Sodium Chloride by precipitation titration.
- (8) Assay of Aspirin (Back titration).
- (9) Assay of Sulphacetamide sodium (Nitrite titration).
- (10) Assay of Ascorbic acid (Iodimetry).

#### III Determination of Normality by electro-analytical methods

- (1) Conductometric titration of strong acid against strong base.
- (2) Conductometric titration of strong acid and weak acid against strong base.
- (3) Potentiometric titration of strong acid against strong base.
- (4) Potentiometric titration of weak acid against strong base.

#### IV Gravimetric analysis

(1) Determination of Barium as Barium sulphate.

#### **Reference Books (Latest Editions to be adopted):**

- 1. Beckett A. H., Stenlake J. B., Practical Pharmaceutical Chemistry, Vol. I & II, 2<sup>nd</sup> edition, Athlone Press, University of London, London, 1970
- 2. Vogel A.I., Textbook of Quantitative Inorganic Analysis, 2<sup>nd</sup> edition, Longman Green and Co., London, 1951
- 3. Gundu Rao P., Inorganic Pharmaceutical Chemistry, 1<sup>st</sup> edition, Vallabh Prakashan, Delhi, India, 2013
- 4. Bentley AO, Atherden LM, Driver JE, Textbook of Pharmaceutical Chemistry, 4th edition, Oxford University Press, London, New York, and Toronto, 1945
- 5. Kennedy J. H., Principles of Analytical Chemistry, 2<sup>nd</sup> edition, Saunders College Publishing, USA, 1990





- 6. Indian Pharmacopoeia
- 7. Christian, G. D., Dasgupta, P.K., Schug, K.A., Analytical Chemistry, 7<sup>th</sup> edition, Wiley India Pvt. Limited, 2013.
- 8. J. Mendham, R. C. Denney, J. D. Barnes, M. J. K. Thomas, B. Sivasankar, Vogel's Textbook of Quantitative Chemical Analysis, 6<sup>th</sup> edition, Pearson Education, New Delhi, 2009.

#### <u>BP109P</u> PHARMACEUTICS - I (Practical)

#### **Course Objectives:**

This course is designed to impart a fundamental knowledge for preparing selected conventional dosage forms.

#### **Course Outcomes:**

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

1. Understand the basics of different dosage forms, pharmaceutical incompatibilities, and pharmaceutical calculations.

2. Prepare some simple and conventional dosage forms.

Unit	Details
1	Syrups
	a) Syrup IP'66
	b) Compound syrup of Ferrous Phosphate BPC'68
2	Elixirs a) Piperazine citrate elixir
	b) Paracetamol pediatric elixir
3	Linctus a) Terpin Hydrate Linctus IP'66
4	Solutions
	b) Iodine Throat Paint (Mandles Paint)
	a) Strong solution of ammonium acetate
	b) Cresol with soap solution
	c) Lugol's solution
5	Suspensions
	a) Calamine lotion
	b) Magnesium Hydroxide mixture
	c) Aluminum Hydroxide gel
6	Emulsions a) Turpentine Liniment
	b) Liquid paraffin emulsion
7	Powders and Granules
	a) ORS powder (WHO)
	b) Effervescent granules
	c) Dusting powder
	d) Divided powders
8	Suppositories
	a) Glycero gelatin suppository
	b) Coca butter suppository

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	c) Zinc Oxide suppository
9	Semisolids         a) Sulphur ointment         b) Non-staining-iodine ointment with methyl salicylate
10	<ul> <li>c) Carbopol gel</li> <li>Gargles and Mouthwashes <ul> <li>a) Iodine gargle</li> <li>b) Chlorhexidine mouthwash</li> </ul> </li> </ul>

- 1. Ansel H.C., Allen L.V., Pharmaceutical Dosage Forms and Drug Delivery Systems, 10<sup>th</sup> edition, Lippincott Williams and Walkins, USA, 2014.
- 2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, 12<sup>th</sup> edition, CBS Publishers and Distributors, New Delhi, 2008.
- 3. Taylor, K., Aulton M.E., Pharmaceutics: The Science of Dosage Form Design, 2<sup>nd</sup> edition, Churchill Livingstone, Edinburgh, 2001.
- 4. Indian Pharmacopoeia.
- 5. British Pharmacopoeia.
- 6. Lachman, L, Lieberman H.A., Kanig, J.L., The Theory and Practice of Industrial Pharmacy, 1<sup>st</sup> edition, Lea & Febiger, Philadelphia,1986
- 7. Khar, R.K., Vyas, S.P., Ahmad F.J., Jain G.K., Lieberman, Lachman's The Theory and Practice of Industrial Pharmacy, 4<sup>th</sup> edition, CBS Publishers and Distributors, New Delhi, 2020.
- 8.Gennaro A.R., Remington: The Science and Practice of Pharmacy, 21st edition, Lippincott Williams and Wilkins, Philadelphia, 2005.
- 9.Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, 6<sup>th</sup> edition, CBS Publishers and Distributors Pvt. Ltd, Delhi, 2005.
- 10. Rawlins E.A., Bentley's Textbook of Pharmaceutics, 8th edition, Elsevier India, 2010.
- 11.Ghebre-Sellassie I., Pharmaceutical Pelletization Technology, 1<sup>st</sup> edition, Marcel Dekker, Inc., New York, 1990
- 12.Parikh D.M., Handbook of Pharmaceutical Granulation Technology, 1<sup>st</sup> edition, Marcel Dekker, Inc., New York, 1997.
- 13.Nieloud F and Gilberte M., Pharmaceutical Emulsions and Suspensions, 1<sup>st</sup> edition, Marcel Dekker, Inc., New York, 2000.

#### <u>BP110P</u> PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

#### **Course Objectives:**

This course is designed to impart a fundamental knowledge for preparation of salts and testing the presence of different ions, salts, and their purity

#### **Course Outcomes:**

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

- 1. Understand the basics of ways of testing for the identification and quantitation of ions and salts
- 2. Prepare some simple inorganic pharmaceuticals.





#### I Limit tests for following ions

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

#### **II Identification test**

Magnesium hydroxide Ferrous sulphate Sodium bicarbonate Calcium gluconate Copper sulphate

#### **III** Test for purity

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

#### IV Preparation of inorganic pharmaceuticals

Boric acid Potash alum Ferrous sulphate

#### **Reference Books (Latest Editions to be adopted):**

- 1. Beckett A. H., Stenlake J. B., Practical Pharmaceutical Chemistry, Vol. I & II, 2<sup>nd</sup> edition, Athlone Press, University of London, London, 1970.
- 2. Vogel A.I., Textbook of Quantitative Inorganic Analysis, 2<sup>nd</sup> edition, Longman Green and Co., London, 1951.
- 3. Gundu Rao P., Inorganic Pharmaceutical Chemistry, 1<sup>st</sup> edition, Vallabh Prakashan, Delhi, India, 2013.
- 4. Bentley AO, Atherden LM, Driver JE, Textbook of Pharmaceutical Chemistry, 4th edition, Oxford University Press, London, New York, and Toronto, 1945.
- 5. Kennedy J. H., Principles of Analytical Chemistry, 2<sup>nd</sup> edition, Saunders College Publishing, USA, 1990.
- 6. Indian Pharmacopoeia.

#### <u>BP111P</u> <u>COMMUNICATION SKILLS (Practical)</u>

The following learning modules are to be conducted English language lab software (preferably using wordsworth  $^{\circledast)}$ 

#### **1.** Basic communication covering the following topics

- a. Meeting People
- b. Asking Questions
- c. Making Friends
- d. What did you do?





e. Do's and Dont's

#### 2. **Pronunciations covering the following topics**

- a. Pronunciation (Consonant Sounds)
- b. Pronunciation and Nouns
- c. Pronunciation (Vowel Sounds)

#### 3. Advanced Learning

- a. Listening Comprehension / Direct and Indirect Speech
- b. Figures of Speech
- c. Effective Communication
- d. Writing Skills
- e. Effective Writing
- f. Interview Handling Skills
- g. E-Mail etiquette
- h. Presentation Skills

#### **Reference Books (Latest Editions to be adopted):**

- 1. Ruther Foord A.J., Basic Communication Skills for Technology, 2<sup>nd</sup> Edition, Pearson Education, Delhi, 2011
- 2. Sanjay Kumar, Pushplata, Communication skills, 2<sup>nd</sup> Edition, Oxford Press, Lucknow 2015.
- 3. Robbins S.P., Organizational Behaviour, 1<sup>st</sup> Edition, Pearson, San Diego, USA, 2013.
- 4. Hasson G., Brilliant- Communication skills, 1st Edition, Pearson Life, UK, 2011
- 5. Gopala S.W., The Ace of Soft Skills: Attitude, Communication and Etiquette for success, 5<sup>th</sup> Edition, Pearson Education, Delhi, 2013.
- 6. Dalley D, Burton Lois, Greenhall M., Developing your influencing skills,1st Edition Universe of Learning Ltd, Manchester, United Kingdom, 2010.
- 7. Konar N., Communication skills for Professionals, 2<sup>nd</sup> Edition, New arrivals –PHI Learning Pvt. Ltd, New Delhi, 2011.
- 8. Mitra, B.K., Personality development and soft skills, 1<sup>st</sup> Edition, Oxford Press, Lucknow, 2011.
- 9. Butter Field, J., Soft skill for everyone, 1st Edition, Cengage Learning India Pvt. Ltd, New Delhi, 2011.
- 10.Francis Peters SJ, Soft skills and professional communication, 1<sup>st</sup> Edition, McGraw Hill Education, New York, 2011.
- 11. Adair John, Effective communication, 4th Edition, Pan Mac Millan, 2009.
- 12. Daniels A.C, Bringing out the best in people, 2<sup>nd</sup> Edition, Mc Graw Hill Education, New York, 1999.

#### **<u>BP112RBP</u>** Remedial Biology (Practical)

#### **Course Objectives**:

To give the learner preliminary knowledge of biology.

#### **Course Outcomes**

The learner should be able to:





- 1. Have knowledge of microscope and microscopic study of tissues.
- 2. Identify plant parts and modification.
- 3. Explain some body processes.

Unit	Details
1	Introduction to experiments in biology
	a) Study of Microscope
	b) Section cutting techniques
	c) Mounting and staining
	d) 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
6	Identification of bones
7	Determination of blood group
8	Determination of blood pressure
9	Determination of tidal volume

- 1. Kale. S.R. and Kale R.R, Practical Human Anatomy and Physiology, 10<sup>th</sup> edition, Nirali Prakashan, Pune, 2020.
- 2. Gokhale S.B., Kokate C.K. and Shriwastava, S.P. A Manual of Pharmaceutical biology practical.
- 3. Shafi M, Biology practical manual according to National core curriculum. Biology forum of Karnataka.

#### SEMESTER II BP201T

#### Human Anatomy and Physiology - II (Theory)45 Hours

#### **Course Objectives**:

To give the learner in-depth information on the organ systems and homeostatic mechanisms.

#### **Course Outcomes:**

The learner should be able to:

- 1. Elucidate the gross morphology, structure, and functions of various organs of the human body.
- 2. Understand the coordinated working pattern of different organs of each system.
- 3. Correlate the mechanisms in the maintenance of homeostasis of human body by cross functioning of the various systems.

Unit	Details	Hours
1	Nervous system	10
	Organization of nervous system	
	• Neuron, neuroglia, classification, and properties of nerve fibre,	
	Electrophysiology, action potential, nerve impulse	

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	Receptors, synapse, and 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)	
2	Digestive system	5
	• Anatomy and physiology of the gastrointestinal tract and associated	
	organs	
	• Functions of stomach	
	• Digestion and absorption of carbohydrates, proteins, and fats	
3	Respiratory System	5
	• Anatomy and physiology of respiratory system	
	• Exchange of gases	
	• External and internal respiration	
	• Mechanism and regulation of respiration	
	• Lung volumes and lung capacities	
	Artificial respiration and resuscitation methods	
4	Urinary system	7
	• Anatomy of urinary tract with special reference to anatomy of kidney and	
	• Eurotions of kidney and principal tract	
	<ul> <li>Functions of kidney and urmary tract,</li> <li>Dbysiology of uring formation micturition rafley</li> </ul>	
	<ul> <li>Physiology of unne formation, inicial function reflex</li> <li>Pole of kidneys in acid base belance</li> </ul>	
	<ul> <li>Role of rannin angiotensin system</li> </ul>	
5	Endogring system	Q
5	Classification of hormonos	o
	<ul> <li>Classification of hormone action</li> </ul>	
	<ul> <li>Mechanism of normone action</li> <li>Structure and functions of endocrine tissues and glands</li> </ul>	
	<ul> <li>Disorders associated with endocrine system</li> </ul>	
6	Parroductive system	10
U	• Anatomy of male and female reproductive system	10
	<ul> <li>Functions of male and female reproductive system</li> </ul>	
	<ul> <li>Sex hormones</li> </ul>	
	<ul> <li>Physiology of menstruation</li> </ul>	
	• Fertilization spermatogenesis oogenesis pregnancy and parturition	
	<ul> <li>Introduction to genetics: chromosomes genes and DNA protein</li> </ul>	
	synthesis, genetic pattern of inheritance	
	TOTAL	45
		-

- 1. Waugh A, and Grant A, Ross & Wilson, Anatomy & Physiology in Health & Illness, 9<sup>th</sup> edition, Churchill Livingstone, New York, 2001.
- Tortora G. J. & Derrickson B, Principals of Anatomy & Physiology, 15<sup>th</sup> edition, John Wiley and Sons, Inc., New Jersey, 2016





- 3. Guyton A. C., Hall J. E., Textbook of Medical Physiology, 12<sup>th</sup> edition, W. B. Saunders Company, USA/Prism Books Ltd. India, 2010.
- 4. Mackenna B. R. & Callander R., McNaught & Callander's Illustrated Physiology, 5<sup>th</sup> edition Churchill Livingstone, New York, 2012.
- 5. Kaplan, Jack, Opheim, Toivola, Lyon, Clinical Chemistry: Interpretation & Techniques,4<sup>th</sup> edition Lippincott, Williams and Wilkins, USA,1995.
- 6. Godkar P.B., Godkar, D.P., Textbook of Medical Laboratory Technology, 3<sup>rd</sup> edition, Bhalani Publishing House, Mumbai, India, 2014.
- 7. Mohan H, Textbook of Pathology, 6<sup>th</sup> edition, Jaypee Brothers Medical Publishers Pvt. Ltd., New Delhi, 2010.
- 8. Chatterjee, C.C., Human Physiology (vol 1 and 2), 11<sup>th</sup> edition, CBS Publishers and Distributors, Kolkata., 2017.

#### <u>BP202T</u> PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

45 Hours

#### **Course Objectives:**

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 syllabus also emphasizes on mechanisms and orientation of reactions.

#### **Course Outcomes:**

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

- 1. Write the structure, name, and the type of isomerism of the organic compound
- 2. Write the reaction, name the reaction and orientation of reactions
- 3. Account for reactivity/stability of compounds,
- 4. Identify/confirm the identification of organic compound

Unit	Details	Hours
	Course Content:	
	General methods of preparation and reactions of compounds superscripted with	
	asterisk (*) to be explained.	
	To emphasize on definition, types, classification, principles/mechanisms,	
	applications, examples and differences.	
1	Classification, nomenclature, and isomerism	6
	Classification of organic compounds, common and IUPAC systems of	
	nomenclature of organic compounds (up to 10 Carbons open chain and	
	carbocyclic compounds) Structural isomerism in organic compounds.	
2	Alkanes*, Alkenes* and Conjugated dienes*	10
	SP <sup>3</sup> hybridization in alkanes, halogenation of alkanes, uses of paraffins.	

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	Stabilities of alkenes, SP <sup>2</sup> hybridization in alkenes	
	E1 and E2 reactions - kinetics, order of reactivity of alkyl halides, rearrangement	
	of carbocations, Saytzeffs orientation and evidence. E1 verses E2 reactions,	
	Factors affecting E1 and E2 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.	
3	Alkyl halides*	10
	SN1 and SN2 reactions - kinetics, order of reactivity of alkyl halides,	
	stereochemistry, and rearrangement of carbocations.	
	SN1 versus SN2 reactions, factors affecting SN1 and SN2 reactions.	
	Structure and uses of ethyl chloride, chloroform, trichloroethylene,	
	tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.	
	Alcohols*- Qualitative tests, Structure and uses of ethyl alcohol, methyl alcohol,	
	chlorobutanol, cetosteryl alcohol, benzyl alcohol, glycerol, propylene glycol.	
4	Carbonyl compounds* (Aldehydes and ketones)	9
	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,	
	vanillin, cinnamaldehyde.	
5	Carboxylic acids*	10
	Acidity of carboxylic acids, effect of 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.	
	Aliphatic amines* basicity, effect of substituent on basicity, qualitative test,	
	structure and uses of ethanolamine, ethylenediamine, amphetamine.	
	TOTAL	45

- 1. Morrison R. T., Boyd R. N., Organic Chemistry, 6th edition, Prentice Hall, New Jersey, 1992
- Finar I. L., Organic Chemistry, Vol. 1, 4<sup>th</sup> edition, Longman, 1963
   Bahl B. S., Bahl A., Textbook of Organic Chemistry, 22<sup>nd</sup> edition, S. Chand publishing, Delhi, India, 2017
- 4. Soni P. L., Organic Chemistry, 29th edition, S. Chand publishing, Delhi, India, 2007
- 5. Mann F. G., Practical Organic Chemistry, 4th Edition, Bernard Charles Saunders, Longman, London, New York, and Toronto, 1960
- 6. Vogel A.I., Vogel's textbook of Practical Organic Chemistry, 5th edition, Pearson Publishing House, India, 1989
- 7. Vishnoi N. K., Advanced Practical Organic Chemistry, 1st edition, Vikas Publishing House, Mumbai, 1979
- 8. Engel R. G., Pavia D. L., Lampman G. N., Kriz G. S., Introduction to Organic Laboratory Techniques, Cengage Learning, India, 2010





9. Ahluwalia V. K., Parashar R. K., Organic Reaction Mechanisms, 4<sup>th</sup> edition, Narosa Publishing House, 2010

#### BP203T BIOCHEMISTRY (Theory) 45 Hours

#### **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. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

#### **Course Outcomes:**

Upon completion of course student shell able to:

- 1. Understand the catalytic role of enzymes, importance of enzyme inhibitors in
- design of new drugs, therapeutic and diagnostic applications of enzymes.
- 2. Understand the metabolism of nutrient molecules in physiological and pathological conditions.
- 3. Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

Unit	Details	Hours
1	Biomolecules	8
	Introduction, classification, chemical nature, and biological role of	
	carbohydrate, lipids, nucleic acids, amino acids, and proteins.	
	Bioenergetics	
	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.	
2	Carbohydrate metabolism	10
	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.	
	Biological oxidation	
	Electron transport chain (ETC) and its mechanism.	
	Oxidative phosphorylation & its mechanism and substrate.	
	Phosphorylation Inhibitors ETC and oxidative phosphorylation/uncouplers Level.	
3	Lipid metabolism	10
	$\beta$ -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.	





	Amino acid metabolism	
	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.	
4	Nucleic acid metabolism and genetic information transfer	10
	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.	
5	Enzymes	7
	Introduction, properties, nomenclature and IUB classification of enzymes	
	Enzyme kinetics (Michaelis plot, Lineweaver Burke plot, Eadie Hofstee 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.	
	TOTAL	45

- 1 Lehninger AL, Nelson DL, Cox MM. Lehninger Principles of Biochemistry,7th edition, Macmillan, New York, 2017.
- 2. Murry RK, Granner DK, Mayes PA, Rodwell VW, Harper's Biochemistry, 23rd edition, Appleton & Lange, Connecticut, 1993.
- 3. Berg JM, Tymoczko JL, Stryer L. Biochemistry, 9th edition, WH Freeman, New York, 2019.
- 4. Satyanarayan, U and Chakrapani, U. Biochemistry, 4th edition, Elsevier, New Delhi, 2013.
- 5. Rao AR. Textbook of Biochemistry,11<sup>th</sup> edition, UBS Publishers and Distributors, 2009.

- Deb AC, Fundamentals of Biochemistry, 7<sup>th</sup> edition, New Central Book Agency, Kolkatta, 2001.
   Conn E, Stumpf P, Outlines of Biochemistry, 5<sup>th</sup> edition, John Wiley & Sons, Newyork, 1987.
   Gupta RC and Bhargava S, Practical Biochemistry, 5<sup>th</sup> edition, CBS Publishers and Distributors (P), Ltd, New Delhi.
- 9. Plummer DT, Introduction of Practical Biochemistry (3<sup>rd</sup> Edition), Tata McGraw-Hill Education Pvt. Ltd., 2004.
- 10. Rajagopal, G. Ramakrishnan, Practical Biochemistry for Medical students, 1<sup>st</sup> edition, K. K. Publications, New Delhi, 1983.
- 11. Varley H, Gowenlock A H McMurray JR; McLauchlan DM, Practical Biochemistry, 6th edition, CBS Publishers and Distributors, New Delhi, 2006.





 BP204T

 Pathophysiology (Theory)
 45 Hours

#### **Course Objectives**:

To impart to the learner the knowledge of pathophysiology and apply it to development of pharmacotherapeutics.

#### **Course Outcomes**

The learner should be able to:

- 1. Describe the etiology and pathogenesis of the selected disease states.
- 2. Explain the signs and symptoms of the diseases.
- 3. Deduce the complications of the pathology on health.

Unit	Details	Hours
1	Cell injury and Adaptation:	6
	Basic principles of Introduction, definitions	
	<ul> <li>Homeostasis: components and types of feedback systems</li> </ul>	
	Causes of cellular injury.	
	• Mechanisms of cell injury: cell membrane damage, mitochondrial	
	damage, ribosome damage, nuclear damage.	
	• Morphology of cell injury: adaptive changes (atrophy, hypertrophy,	
	hyperplasia, metaplasia, dysplasia), cell swelling, intra cellular	
	accumulation, calcification, enzyme leakage.	
	• Cell Death and apoptosis.	
	Acidosis & Alkalosis.	
	• Electrolyte imbalance.	
2	Inflammation and repair	4
	• Basic mechanism involved in the process of inflammation and repair:	
	• 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.	
3	Cancer	2
	• Classification.	
4	Etiology and pathogenesis of cancer.	(
4	Cardiovascular System	0
	• Hypertension, congestive near failure, ischemic heart disease (anglia, myocardial infarction, atherosclerosis and arteriosclerosis)	
5	Respiratory system	2
5	• Asthma chronic obstructive airways diseases	4
6	Panal system	2
U	• Acute and chronic renal failure	4
7	Haematological Diseases	4
'	• Iron deficiency megaloblastic anemia (Vit R12 and folic acid) sickle cell	-
	- non denetercy, megalobiastic anemia (vit b12 and tone acid), siekte cen	

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	anemia, thalassemia, hereditary acquired anemia, haemophilia.	
8	Endocrine system	4
	• Diabetes, thyroid diseases, disorders of sex hormones.	
9	Nervous system	6
	• Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression,	
	schizophrenia and Alzheimer's disease.	
10	Gastrointestinal system	3
	Peptic ulcer, inflammatory bowel diseases, jaundice, hepatitis	
	(A,B,C,D,E,F) alcoholic liver disease.	
11	Disease of bones and joints	2
	• Rheumatoid arthritis, osteoporosis, and gout.	
12	Infectious diseases	2
	• Meningitis, typhoid, leprosy, tuberculosis, urinary tract infections.	
13	Sexually transmitted diseases	2
	• AIDS, syphilis, gonorrhoea.	
	TOTAL	45

- 1. Kumar Vinay, Abbas A.K., Aster, J.C. Robbins & Cotran Pathologic Basis of Disease; 10<sup>th</sup> edition, South Asia edition; Elsevier, India, 2014.
- 2. Mohan H, Textbook of Pathology, 6<sup>th</sup> edition, Jaypee Brothers Medical Publishers Pvt. Ltd., New Delhi, 2010.
- 3. Brunton, L.L., Hilal-Dandan R, Knollman, B., Goodman and Gilman's The Pharmacological Basis of Therapeutics; 13th edition, McGraw-Hill Education, New York, 2017.
- 4.Best C.H., Taylor N.B., West J.B, Best and Taylor's Physiological Basis of Medical Practice; 12th edition, William and Wilkins, Baltimore, USA,1991.
- 5. Walker, B., College, N.R., Ralston S., Penman, I., Davidson's Principles and Practice of Medicine; 22nd edition, Churchill Livingstone, New York, 2014.
- 6.Guyton A. C., Hall J. E., Textbook of Medical Physiology, 12<sup>th</sup> edition, Saunders, USA/Prism Books Ltd. India, 2010.
- 7. Di Piro J.T., Talbert, R.L., Yee, G.C., Matzke, G.R., Wells, B.G., Posey, L.M., Pharmacotherapy: A Pathophysiological Approach; 9th edition, McGraw-Hill Medical, London, 2014.
- 8. Kumar V., Cotran R.S, Robbins S. L, Basic Pathology; 7th edition; WB Saunders Company, Philadelphia/Harcourt (India) Pvt. Ltd., New Delhi, 2003.
- 9. Walker R, Edwards, Clinical Pharmacy and Therapeutics, 3rd edition; Churchill Livingstone Edinburgh, New York, 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)
- 4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online)
- 5. Indian Journal of Pathology and Microbiology. ISSN-0377-4929.

#### <u>BP205T</u> COMPUTER APPLICATIONS IN PHARMACY (Theory)

<u>30 hours</u>

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#### **Course Objectives**:

This subject deals with the introduction databases, database management systems, computer application in clinical studies and use of databases.

#### **Course Outcomes:**

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

Unit	Details	Hours
1	<b>Number system</b> : Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary <i>etc</i> , binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division. <b>Concept of Information Systems and Software:</b> Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project.	6
2	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.	6
3	<b>Application of computers in Pharmacy</b> – 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.	6
4	<b>Bioinformatics:</b> Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery.	6
5	<b>Computers as data analysis in Preclinical development</b> : Chromatographic dada analysis (CDS), Laboratory Information management System (LIMS) and Text Information Management System (TIMS).	6
	TOTAL	30

#### **Reference Books (Latest Editions to be adopted):**

- 1. Fassett, W.E., Computer Application in Pharmacy, 1<sup>st</sup> edition, Lea and Febiger, Philadelphia, USA, 1986.
- 2. Sean E, Binghe W., Computer Application in Pharmaceutical Research and Development, 1st edition, John Willey and Sons, Inc., New Jersey, USA, 2006.
- 3. Rastogi, S.C., Mendiratta, N, Rastogi, P., Bioinformatics (Concept, Skills and Applications), 2<sup>nd</sup> edition, CBS Publishers and Distributors, New Delhi, 2008.
- 4. Prague, C.N., Irwin, M.R., Reardon, J., Microsoft office Access 2003, Application Development Using VBA, SQL Server, DAP and Infopath, Wiley India Pvt. Ltd, New Delhi.

<u>BP2061</u>	
<b>ENVIRONMENTAL SCIENCES (Theor</b>	·y)

**30 hours** 

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#### DDAACT





#### **Course Objectives:**

Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

#### **Course Outcomes:**

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.

Unit	Details	Hours
1	The Multidisciplinary nature of environmental studies.	10
	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.	
2	Ecosystems.	10
	-Concept of an ecosystem.	
	-Structure and function of an ecosystem.	
	-Introduction, types, characteristic features, structure, and function of the	
	ecosystems: forest ecosystem; grassland ecosystem; desert ecosystem; Aquatic	
	ecosystems (ponds, streams, lakes, rivers, oceans, estuaries).	
3	Environmental Pollution: air pollution; water pollution; soil pollution.	10
	TOTAL	30

#### **Reference Books (Latest Editions to be adopted):**

- 1. Singh Y.K., Environmental Science, 1<sup>st</sup> edition, New Age International Pvt, Publishers, Bangalore, 2006.
- 2. Agarwal, K.C., Environmental Biology, 2<sup>nd</sup> edition, Nidhi Publishers, Bikaner, 2008.
- 3. Bharucha E, The Biodiversity of India, 1<sup>st</sup> edition, Mapin Publishing Pvt. Ltd., Ahmedabad, India, 2002.
- 4. Brunner C.R., Hazardous Waste Incineration, McGraw Hill Inc, USA, 1989
- 5. Clark R.S., Marine Pollution, Clanderson Press Oxford
- 6. Cunningham, W.P. Cooper, T.H. Gorham, E & Hepworth, M.T., Environmental Encyclopedia, 2nd edition, Cengage Gale, USA, 2001.
- 7. De A.K., De A.K., Environmental Chemistry, New Age International Publishers Ltd, New Delhi, 1990.
- 8. Narain S, Down to Earth- fortnightly magazine focused on politics of environment and development of Centre for Science and Environment, New Delhi, India,

#### <u>BP207P</u> Human Anatomy and Physiology II (Practical)





#### **Course Objectives**:

To get the learner adept with anatomy, physiology and pathology of body systems.

#### **Course Outcomes**

The learner should be able to:

- 1. Be proficient with the working of the systems of the body including the process of homeostasis.
- 2. Identify and describe the various body tissues and the pathological changes in diseased states.

Unit	Details
1	Study of the systems with the help of models, charts, and specimens:
	• Nervous system
	Endocrine system
	• Digestive
	• Respiratory
	• Cardiovascular
	• Urinary
	• Reproductive
2	To demonstrate the general neurological examination.
3	To study the integumentary and special senses using specimen, models, etc.:
	• Touch
	Olfaction
	• Taste
	Vision and visual acuity
4	To demonstrate the reflex activity.
5	Recording of body temperature.
6	To demonstrate positive and negative feedback mechanism.
7	Determination of tidal volume and vital capacity.
8	Recording of basal mass index.
10	Study of family planning devices and pregnancy diagnosis test.
11	Demonstration of total blood count by cell analyser
12	Permanent slides of vital organs and gonads:
	• Ovary, Testis, Liver, Pancreas, Thyroid, Tongue, Stomach, Intestine, Kidney, Lung,
10	Spinal Cord, Cerebrum, Artery, Vein
13	Discussion on some common investigational procedures used in diagnostics:
	<ol> <li>2) Positron emission tomography (PET)</li> </ol>
	3) Computed tomography scan (CT Scan)
	4) Flow cytometry as a diagnostic tool
	5) Polymerase chain reaction as a diagnostic tool
	6) Electrocardiogram (ECG) in diagnosis of cardiac arrhythmia
	7) Liver Function tests
	8) Kidney Function tests
	9) Blood Glucose
	10) Serum Cholesterol / Triglycerides
	11) Serum Calcium 12) Thuroid Eunction tests





13) Diagnostic tests for infectious diseases like - Malaria, Tuberculosis, Dengue, H1N1 swine flu, Typhoid and Covid19.

#### **Reference Books (Latest Editions to be adopted):**

- 1. Mackenna B. R. & Callander R., McNaught & Callander's, Illustrated Physiology, 5<sup>th</sup> edition Churchill Livingstone, New York, 2012.
- 2. Kaplan, Jack, Opheim, Toivola, Lyon, Clinical Chemistry: Interpretation & Techniques,4<sup>th</sup> edition Lippincott, Williams and Wilkins, USA,1995.
- 3. Godkar P.B., Godkar, D.P., Textbook of Medical Laboratory Technology,3<sup>rd</sup> edition, Bhalani Publishing House, Mumbai, India, 2014.
- 4. Ghai C. L., Textbook of Practical Physiology, 6<sup>th</sup> edition, Jaypee Brothers Medical Publishers Pvt. Ltd., New Delhi, 2005.
- 5. Mohan H, Textbook of Pathology, 6<sup>th</sup> edition, Jaypee Brothers Medical Publishers Pvt. Ltd., New Delhi, 2010.
- 6. Waugh A, and Grant A, Ross & Wilson, Anatomy & Physiology in Health & Illness, 9<sup>th</sup> edition, Churchill Livingstone, New York, 2001.
- 7. Tortora G. J. & Derrickson B, Principals of Anatomy & Physiology, 15<sup>th</sup> edition, John Wiley and Sons, Inc., New Jersey, 2016
- 8. Guyton A. C., Hall J. E., Textbook of Medical Physiology, 12<sup>th</sup> edition, W. B. Saunders Company, USA/Prism Books Ltd. India, 2010.

#### <u>BP208P</u> PHARMACEUTICAL ORGANIC CHEMISTRY - I (Practical)

#### **Course Objectives**:

To get the learner introduced to the basic principles of qualitative organic analysis

#### **Course Outcomes**

The learner should be able to:

- 1. Conduct simple test to detect the physicochemical nature of organic compounds and the elemental composition of organic compounds
- 2. Identify presence of different functional groups in organic compounds by specific tests, identify compounds and conduct confirmatory tests.

Unit	Details
1	Systematic qualitative analysis of unknown organic compounds like
	1. Preliminary test: color, odour, aliphatic/aromatic compounds, saturation, and unsaturation,
	etc.
	2. Detection of elements like nitrogen, sulphur, and halogen by Lassaigne's test.
	3. Solubility test.
	4. Functional group test like phenols, amides/ urea, carbohydrates, amines, carboxylic acids,
	aldehydes and ketones, alcohols, esters, aromatic and halogenated Hydrocarbons, nitro
	compounds and anilides.





5. Melting point/boiling point of organic compounds.
 6. Identification of the unknown compound from the literature using melting point/ boiling point.
 7. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
 8. Minimum five unknown organic compounds to be analyzed systematically.
 2 Preparation of suitable solid derivatives from organic compounds.
 3 Construction of molecular models.

#### **Reference Books (Latest Editions to be adopted):**

- 1. Morrison R. T., Boyd R. N., Organic Chemistry, 6th edition, Prentice Hall, New Jersey, 1992
- 2. Finar I. L., Organic Chemistry, Vol. 1, 4th edition, Pearson Publishing House, Longman, 1963
- 3. Bahl B. S., Bahl A., Textbook of Organic Chemistry, 22<sup>nd</sup> edition, S. Chand publishing, Delhi, India, 2017
- 4. Soni P. L., Organic Chemistry, 29th edition, S. Chand publishing, Delhi, India, 2007
- 5. Mann F. G., Practical Organic Chemistry, 4<sup>th</sup> Edition, Bernard Charles Saunders, Longman, London, New York and Toronto, 1960
- Vogel A.I., Vogel's textbook of Practical Organic Chemistry, 5<sup>th</sup> edition, Pearson Publishing House, India, 1989
- Vishnoi N. K., Advanced Practical Organic Chemistry, 1<sup>st</sup> edition, Vikas Publishing House, Mumbai, 1979
- 8. Engel R. G., Pavia D. L., Lampman G. N., Kriz G. S., Introduction to Organic Laboratory Techniques, Cengage Learning, India, 2010
- 9. Ahluwalia V. K., Parashar R. K., Organic Reaction Mechanisms, 4<sup>th</sup> edition, Narosa Publishing House, 2010

#### BP209P BIOCHEMISTRY (Practical)

#### **Course Objectives**:

To get the learner introduced to the basic principles of qualitative and quantitative determination of important biomolecules.

#### **Course Outcomes**

The learner should be able to:

- 1. Conduct tests for qualitative determination of simple biochemical compounds.
- 2. Conduct assays for quantitative determination of simple biochemical compounds.
- 3. Conduct simple experiments to analyse properties of enzymes.

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

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- 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

- 1 Lehninger AL, Nelson DL, Cox MM. Lehninger Principles of Biochemistry,7<sup>th</sup> edition, Macmillan, New York, 2017.
- 2. Murry RK, Granner DK, Mayes PA, Rodwell VW, Harper's Biochemistry, 23rd edition, Appleton & Lange, Connecticut, 1993.
- 3. Berg JM, Tymoczko JL, Stryer L. Biochemistry, 9<sup>th</sup> edition, WH Freeman, New York, 2019.
- 4. Satyanarayan, U and Chakrapani, U. Biochemistry, 4<sup>th</sup> edition, Elsevier, New Delhi, 2013.
- 5. Rao AR. Textbook of Biochemistry,11<sup>th</sup> edition, UBS Publishers and Distributors, 2009.
- 6. Deb AC, Fundamentals of Biochemistry, 7th edition, New Central Book Agency, Kolkatta, 2001
- 7. Conn E, Stumpf P, Outlines of Biochemistry,5<sup>th</sup> edition, John Wiley & Sons, Newyork,1987
- 8. Gupta RC and Bhargava S, Practical Biochemistry, 5<sup>th</sup> edition, CBS Publishers and Distributors(P), Ltd, New Delhi.
- 9. Plummer DT, Introduction of Practical Biochemistry (3<sup>rd</sup> Edition), Tata McGraw-Hill Education Pvt. Ltd., 2004
- 10.Rajagopal, G. Ramakrishnan, Practical Biochemistry for Medical students, 1<sup>st</sup> edition, K. K. Publications, New Delhi, 1983.
- 11. Varley H, Gowenlock A H McMurray JR; McLauchlan DM, Practical Biochemistry, 6<sup>th</sup> edition, CBS Publishers and Distributors, New Delhi, 2006.

#### <u>BP210P</u> <u>COMPUTER APPLICATIONS IN PHARMACY (Practical)</u>

Unit	Details
1	Design a questionnaire using a word processing package to gather information about a
	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	Creating mailing labels Using Label Wizard, generating label in MS WORD
6	Create a database in MS Access to store the patient information with the required fields Using
	MS Access
7	Design a form in MS Access to view, add, delete, and modify the patient record in the
	database
8	Generating report and printing the report from patient database
9	Creating invoice table using – MS Access
10	Drug information storage and retrieval using MS Access
11	Creating and working with queries in MS Access
12	Exporting Tables, Queries, Forms and Reports to web pages





#### 13 Exporting Tables, Queries, Forms and Reports to XML pages

- 1. Fassett, W.E., Computer Application in Pharmacy, 1<sup>st</sup> edition, Lea and Febiger, Philadelphia, USA, 1986.
- 2. Sean, E, Binghe W., Computer Application in Pharmaceutical Research and Development, 1<sup>st</sup> edition, John Willey and Sons, Inc., New Jersey, USA, 2006.
- 3. Rastogi, S.C., Mendiratta, N, Rastogi, P., Bioinformatics (Concept, Skills and Applications), 2<sup>nd</sup> edition, CBS Publishers and Distributors, New Delhi, 2008.
- 4. Prague, C.N., Irwin, M.R., Reardon, J., Microsoft office Access 2003, Application Development Using VBA, SQL Server, DAP and Infopath, Wiley India Pvt. Ltd, New Delhi





#### <u>SEMESTER III</u> <u>BP301T</u> PHARMACEUTICAL ORGANIC CHEMISTRY-II (Theory)

45 Hours

#### **Course Objectives:**

To introduce the leaner to

- 1. The general methods of preparation and reactions of some organic compounds.
- 2. Reactivity of organic compounds.
- 3. Mechanisms and orientation of reactions.
- 4. Chemistry of fats and oils.

#### **Course Outcomes:**

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

- 1. Write the structure, name and the type of isomerism of the organic compound
- 2. Write the reaction, name the reaction and orientation of reactions
- 3. Give an account of the reactivity/stability of compounds,
- 4. Understand the scheme for the preparation of organic compounds

Unit	Details	Hours
	General methods of preparation and reactions of compounds superscripted with	
	asterisk (*) to be explained.	
	To emphasize on definition, types, classification, principles/mechanisms,	
1	applications, examples and afferences. Benzene and its derivatives	10
L	Denzene and its derivatives	10
1.1	Analytical, synthetic, and other evidence in the derivation of structure of benzene,	3
	Orbital picture, resonance in benzene, aromatic characters, Huckel's rule.	
1.2	Reactions of benzene - nitration, sulphonation, halogenation-reactivity, Friedel-	3
	Crafts alkylation- reactivity, limitations, Friedel-Crafts acylation.	
1.3	Substituents, effect of substituents on reactivity and orientation of mono substituted	3
1.4	benzene compounds towards electrophilic substitution reaction.	1
1.4	Structure and uses of DDT, Saccharin, BHC and Chloramine.	1
2		10
2.1	<b>Phenols</b> * - Acidity of phenols, effect of substituents on acidity, qualitative tests,	5
	Su ucture and uses of phenol, cresois, resorcinol, naphtnois.	•
2.2	Aromatic Amines <sup>*</sup> - Basicity of amines, effect of substituents on basicity, and support of any diagonium salts	3
22	Arometic Acids* Acidity effect of substituents on acidity and important reactions	2
2.3	of benzoic acid	2
3	Fats and Oils	10
3.1	Fatty acids – reactions.	4
3.2	Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.	3
3.3	Analytical constants – Acid value, Saponification value, Ester value, Iodine value,	3
	Acetyl value, Reichert Meissl (RM) value - significance and principle involved in	
	their determination.	
4	Polynuclear hydrocarbons:	08
4.1	Synthesis, reactions.	4

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4.2	Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene,	4
	Diphenylmethane, Triphenylmethane and their derivatives.	
5	Cycloalkanes	07
	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.	
	TOTAL	45

- 1. Morrison R. T., Boyd R. N., Organic Chemistry, 6<sup>th</sup> edition, Prentice Hall, New Jersey, 1992.
- 2. Pine, Stanley H.; Hendrickson, James B.; Cram, Donald J.; Hammond, George S., Organic Chemistry, 4th edition, McGraw Hill Publications, USA, 1982.
- 3. Finar I. L., Organic Chemistry, Vol. 1, 4th edition, Pearson Publishing House, Longman, 1963.
- 4. March J., Smith M. B., Advanced Organic Chemistry: Reactions, Mechanisms, Structures, 6<sup>th</sup> edition, John Wiley and Sons publication, USA, 2007.
- 5. Carey F. A., Sundberg R. J., Organic Chemistry, Part A: Structures and Mechanism, Part B: Reactions and Synthesis, 4<sup>th</sup> edition Kluwer Academic Publishers, USA, 2002.
- 6. Sykes P., A Guidebook to Mechanism in Organic Chemistry, 6th edition, Pearson Education, India, 1960.
- 7. Dewick P., Essentials of Organic chemistry, 1<sup>st</sup> edition, John Wiley and Sons, New Jersey, 2006.
- 8. Wade L.G. Jr., Maya Shankar Singh, Advanced Organic Chemistry: Reactions and Mechanism, 9<sup>th</sup> edition, Pearson Education, India, 2019.
- 9. Eliel E. L., Wilen S. H., Stereochemistry of Organic Compounds, 1<sup>st</sup> edition, John Wiley and Sons, USA, 1994.
- 10. Sorrell T. N., Organic Chemistry, 2<sup>nd</sup> edition, University Science Books, USA, 2005.
- 11. Kalsi P. S., Stereochemistry: Conformation and Mechanism, Organic Reactions and Their Mechanisms, New Age International Publishers, New Delhi, 2017.
- 12. Brahmachari G., Organic Chemistry through Solved Problems, revised edition, Alpha Science International Ltd., Morgan & Claypool Publishers, 2007.
- 13. Brahmachari G., Organic Name Reactions: A Unified Approach, Alpha Science International Ltd., Morgan, and Claypool Publications, 2006.

### BP302TPHYSICAL PHARMACEUTICS-I (Theory)45 Hours

#### **Course Objectives:**

The objective of the course is to train the learner for understanding the basic physical principles underlying pre-formulation testing, formulation development and finished product testing of drug delivery systems.

#### **Course Outcomes:**

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

- 1. Understand various physicochemical properties of drug molecules in in the formulation development and evaluation of dosage forms.
- 2. Demonstrate pharmaceutical applications of surface and interfacial phenomenon.
- 3. Apply knowledge of solubility aspects in developing stable dosage form.
- 4. Acquire understanding of mechanism of diffusion, dissolution, and dissolution kinetics.
- 5. Know about drug complexes, protein binding and their applications.





Unit	Details	Hours
1	UNIT - I	10
	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,	6
	aerosols - inhalers, relative humidity, liquid complexes, liquid crystals, glassy	
	states, solid crystalline, amorphous & polymorphism.	
	Physicochemical properties of drug molecules:	
	Additive, constitutive, and colligative properties with examples; Concept of	4
	tonicity in pharmacy, methods to adjust isotonicity; Refractive index and molar	
	refraction, optical rotation, dielectric constant, dipole moment, determinations,	
-	and applications	
2		8
	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. Adsorption isotherms, Freundlich	
	adsorption isotherm, Langmuir adsorption isotherm Wetting, wetting agents and	
	contact angle	
3	UNIT - III	14
	Solubility of drugs:	
	Solubility expressions, mechanisms of solute solvent interactions,	
	ideal solubility parameters, solvation & association, quantitative approach to the	-
	factors influencing solubility of drugs, Solubility of gas in liquids, solubility of	7
	Inquids in liquids, (Binary solutions, ideal solutions)	
	kaoult's law, real solutions. Partially miscible liquids, Critical solution	
	Diffusion and Dissolutions. Distribution law, its initiations and applications	
	Diffusion: diffusion through biological mombranes. Figh's Laws of diffusion	
	Steady state diffusion driving forces for diffusion in pharmaceutical systems	7
	nermeability Measurement of diffusion: Concept of dissolution dissolution	/
	mechanism: Noves Whitney equation factors affecting dissolution: Intrinsic	
	Dissolution Rate, Hixson – Crowell Law measurement of dissolution rates	
4	UNIT - IV	6
•	pH, buffers and Isotonic solutions:	~
	Theory of dissociation, dissociation constant, 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.	
5	UNIT - V	7
	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	
	TOTAL	45





- 1. Martin A, Swarbrick. J, Cammarata A, Physical Pharmacy: Physical Chemical Principles in the Pharmaceutical Sciences, 3<sup>rd</sup> edition, BI Waverly. Pvt Ltd, New Delhi, 1993.
- 2. Sinko PJ, Singh Y. Martin's Physical Pharmacy and Pharmaceutical Sciences: Physical Chemical and Biopharmaceutical Principles in the Pharmaceutical Sciences, 6<sup>th</sup> edition, Walter Kluer, Philadelphia, 2011.
- 3. Parrott E.L, Saski W, Experimental Pharmaceutics, 4<sup>th</sup> edition, Burgess Publishing Company, Minneapolis,1971
- 4. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, 6<sup>th</sup> edition, CBS Publications, New Delhi, 2005.
- 5. Stocklosa M. J. Pharmaceutical Calculations, 6<sup>th</sup> edition, Lea & Febiger, Philadelphia,1974
- 6. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms—tablets, Vol.1,2,3/edited by Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz, 2<sup>nd</sup> edition, Marcel Dekker Inc., Newyork,1990.
- 7. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3/edited by Herbert A. Lieberman, Martin, M., and Gilbert S. Banker, 2<sup>nd</sup> edition, Marcel Dekker Inc. New York,1998.
- 8. Ramasamy C, and Manavalan R, Physical Pharmaceutics,1st edition, PharmaMed Press, 2017
- 9. C.V.S. Subramanyam, J. Thimma settee, Laboratory Manual of Physical Pharmaceutics, 2<sup>nd</sup> edition, Vallabh Prakashan, Delhi, 2014.
- 10. C.V.S. Subrahmanyam, Textbook of Physical Pharmaceutics, 3<sup>rd</sup> edition, Vallabh Prakashan, Delhi, 2015
- 11. C.V.S. Subrahmanyam, Essentials of Physical Pharmaceutics, 2<sup>nd</sup> edition, Vallabh Prakashan, Delhi, 2017
- 12. Jain G, Khar RK, Ahmad FJ, Theory and Practice of Physical Pharmacy, 1<sup>st</sup> Edition, Elsevier India, 2013
- 13. Bahl A, Bahl B. S, Tuli G. D, Essentials of Physical Chemistry, 28<sup>th</sup> edition, S Chand Publications, New Delhi, 2000.

### BP303T PHARMACEUTICAL MICROBIOLOGY (Theory) 45 Hours

#### **Course Objectives:**

Study morphology, classification, and reproduction of all categories of microorganisms especially which cause diseases, microbiological tests, aseptic handling, and sterilization aspects.

#### **Course Outcomes:**

- Upon completion of the subject student shall be able to:
- 1. Illustrate methods of identification, cultivation, and preservation of various microorganisms
- 2. Understand the disease-causing microorganisms, symptoms, and treatment avenues.
- 3. Recognize the importance and implementation of sterilization in pharmaceutical processing and industry and sterility testing of pharmaceutical products.
- 4. Comprehend out microbiological standardization of Pharmaceuticals.
- 5. Know the cell culture technology and its applications in pharmaceutical industries.



### Syllabus B.Pharm (Choice Based Credit System)



Unit	Details	Hours
1	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). Study of the different types of simple & compound microscope, phase contrast microscopy, dark field microscopy and electron microscopy.	08
2	<ul> <li>Study of morphology, classification, reproduction/replication and cultivation of Bacteria, Fungi, Viruses and Rickettsiae and Chlamydiae.</li> <li>Overview of bacterial diseases and pathogens causing them. Mycobacteria, shigella, pseudomonas, klebsiella, streptococcus, staphylococcus, clostridium vibrio.</li> <li>Viral diseases including new emerging viral diseases -COVID, ZICA, SARS, EBOLA.</li> <li>Fungal diseases.</li> <li>Protozoal diseases- Amoeba, Paramecium, Trichomonas, Plasmodium.</li> <li>Rickettsial &amp; Chlamydial diseases.</li> <li>Protozoa- Morphological characteristics and classification, reproduction, pathogenic protozoa like Amoeba, Paramecium, Trichomonas, Plasmodium.</li> <li>Algae - Classification, Morphological characteristics, reproduction, economic significance of algae.</li> <li>Pattern of microbial death.</li> </ul>	13
3	Identification of bacteria using staining techniques (simple, Gram's & Acid-fast staining) and biochemical tests (IMViC). Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins, and amino acids. Assessment of a new antibiotic.	06
4	Classification and mode of action of disinfectants. Factors influencing disinfection, antiseptics, and their evaluation. For bacteriostatic and bactericidal actions, Evaluation of bactericidal & Bacteriostatic. Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP. 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. Designing of aseptic area, laminar flow equipment; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.	10
5	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,	08





established and transformed cell cultures. Application of cell cultures in pharmaceutical industry and research. Disposal of Microbial waste	
TOTAL	45

- 1. Hugo W.B. and Russel A.D, Pharmaceutical Microbiology, 8<sup>th</sup> Edition, Blackwell Scientific publications, Oxford, London, 2013.
- 2. Reed G., Prescott, and Dunn's., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi, 2004.
- 3. Pelczar MJ, Chan ECS, Kreig NR. Microbiology, 6<sup>th</sup> Edition, Tata McGraw Hill Education Pvt. Ltd, Delhi,1993
- 4. Harris M, Tindall B, and Cox, Pharmaceutical Microbiology, 1<sup>st</sup> edition, 1964, The Williams and Wilkins, Baltimore, 1964.
- 5. Rose AH, Industrial Microbiology, 1<sup>st</sup> edition, Butterworths (Elsevier), Oxford, 1961.
- 6. Frobisher M, HinsDill RD, Crabtrea KT, Good Heart CR, Fundamentals of Microbiology, 9th edition, Japan, 1974.
- 7. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, 6<sup>th</sup> edition, CBS Publications, New Delhi, 2005.
- 8. Peppler HJ, Microbial Technology, 2<sup>nd</sup> Edition, Academic Press (Elsevier), Massachusetts , 1979.
- 9. I.P., B.P., U.S.P.- latest editions.
- 10. Reba Kanungo, Ananthnarayan and Paniker's Textbook of Microbiology,10<sup>th</sup> Edition, Orient-Longman, Chennai, 2017.
- 11. Pommerville, J.C., Alcamo's Fundamentals of Microbiology, 3rd Edition, Jones and Bartlett, Burlington, Massachusetts, 2014.
- 12. Jain N.K, Pharmaceutical Microbiology, 3<sup>rd</sup> Edition, Vallabh Prakashan, Delhi, 2001.
- 13. Garry G.M., Bergey's Manual of Systematic Bacteriology, 2<sup>nd</sup> Edition, Springer publishing, New York, 2005.

### BP304T PHARMACEUTICAL ENGINEERING (Theory) 45 Hours

#### **Course Objectives:**

This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry.

**Course Outcomes:** Upon completion of the course student shall be able:

- 1. To Understand mechanics of fluid, fluid flow, and its measurements
- 2. To know various unit operations used in pharmaceutical manufacturing and material handling systems
- 3. To appreciate the various preventive methods used for corrosion control in pharmaceutical industries.
- 4. Define and categorize the different industrial hazards.

Unit	Details	Hours
	UNIT - I	10
1	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	





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.         Material handling systems: Conveyers and Pumps       10         2       • Heat and Mass Transfer: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers. Temperature measurement-basic principles and devices. Mass transfer in turbulent and laminar flow. Concept of interfacial mass transfer.         • 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.         • Distillation: Basic Principles and methodology of simple distillation, flash distillation, fractional distillation.       10         • Drying: Objectives, applications & mechanism of drying process, measurements & 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.       10         • Drying: 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 Palate af, rotary d		affecting size reduction, principles, construction, working, uses, merits and demerits of	
Size Separation: Objectives, applications & mechanism of size separation, official standards of powders, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.         Material handling systems: Conveyers and Pumps       10         2       • Heat and Mass Transfer: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers. Temperature measurement-basic principles and devices. Mass transfer in turbulent and laminar flow. Concept of interfacial mass transfer.         • 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. Easier Principles and methodology of simple distillation, flash distillation & molecular distillation.       10         3       UNRT - III       10         • Drying: Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, fund myer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.       10         • 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, Fiborb blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier.       8 <th></th> <th>Hammer mill, ball mill, fluid energy mill. Edge runner mill &amp; end runner mill.</th> <th></th>		Hammer mill, ball mill, fluid energy mill. Edge runner mill & end runner mill.	
standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.       Material handling systems: Conveyers and Pumps       10         2       Heat and Mass Transfer: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers. Temperature measurement-basic principles and devices. Mass transfer in turbulent and laminar flow. Concept of interfacial mass transfer.       10         2       Heat and Mass Transfer: 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, Economy of multiple effect evaporator.       10         3       UNIT - III       10         • Distillation, fractional distillation, distillation under reduced pressure, steam distillation, fractional distillation.       10         • Distillation, semolecular distillation, distillation under reduced pressure, steam odistillation, fractional distillation.       10         • Orying: Objectives, applications & mechanism of drying process, measurements & 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.       10         • Distillation: Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and Demerits of		<b>Size Separation:</b> Objectives, applications & mechanism of size separation, official	
merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & clutriation tank.       Material handling systems: Conveyers and Pumps         UNIT - II       10         2       • Heat and Mass Transfer: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers. Temperature measurement-basic principles and devices. Mass transfer in turbulent and laminar flow. Concept of interfacial mass transfer.         • Evaporation: Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed ketth, horizontal tube evaporator. Climbing film evaporator, forced circulation evaporator, multiple effect evaporator.         • Distillation Basic Principles and methodology of simple distillation, flash distillation, fractional distillation.       10         • Orying: Objectives, applications & mechanism of drying process, measurements & 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, louds mixing and semisolds 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.       8         • Filtration: Objectives, applications, Theories & Factors influencing filtration, filter aids, filter m		standards of powders, sieves, size separation Principles, construction, working, uses,	
elutriation tank.         Material handling systems: Conveyers and Pumps         10           2         • Heat and Mass Transfer: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers. Temperature measurement-basic principles and devices. Mass transfer in turbulent and laminar flow. Concept of interfacial mass transfer.         10           2         • Heat and Mass Transfer: 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. (Timbing film evaporator, forced circulation evaporator, multiple effect evaporator. Embining film evaporator, forced circulation evaporator, multiple effect evaporator. Basic Principles and methodology of simple distillation, flash distillation & molecular distillation.         10           3         UNIT - III         10           • Drying: Objectives, applications & mechanism of drying process, measurements & 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.         10           • Mixing: Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semiolids mixing, Principles, Construction, Working, Uses, Merits and Demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filter, stard selidz filter.         8           • Filtration: Objectives, a		merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter &	
Material handling systems: Conveyers and Pumps         10           2         • Heat and Mass Transfer: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers. Temperature measurement-basic principles and devices. Mass transfer in turbulent and laminar flow. Concept of interfacial mass transfer.         • 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, fractional distillation, distillation under reduced pressure, steam distillation fractional distillation.         10           3         UNIT - III         10           • Drying: Objectives, applications & mechanism of drying process, measurements & 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 liqui 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.         8           • 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,		elutriation tank.	
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- 1. Badger W.L. & Banchero J., Introduction to chemical engineering, Published by Tata McGraw Hill, International edition, New Delhi, 1955
- 2. Perry R.H., Green D.W., Maloney O, Perry's Chemical Engineer's Handbook -.7th Edition, McGraw Hill Inc., New York, 1998.
- 3. McCabe, Smith & Harriott. Unit Operations of Chemical Engineering, Published by McGraw Hill Inc., 5th edition, 1993.
- 4. Subramanyam C.V.S., Pharmaceutical Engineering: Unit Operations Principles and Practice, Vallabh Prakashan, Delhi., 3rd edition, 2019.
- 5. Remington A, The Science & Practice of Pharmacy. Lippincott, Williams & Wilkins Philadelphia. 21st edition, 2006.
- 6. Lachman L., Lieberman H.A. & Kanjig J.L, The Theory & Practice of Industrial Pharmacy, 3rd edition, Varghese Publishing House, Bombay, 1990.
- 7. K. Sambamurthy, Pharmaceutical Engineering, New Age International Publishers, Delhi, 2005.
- 8. Subrahmanyam C.V.S., Textbook of Physical Pharmaceutics, 3rd edition, Vallabh Prakashan, Delhi, 2015.
- 9. Subrahmanyam C.V.S., Essentials of Physical Pharmaceutics, 2nd edition, Vallabh Prakashan, Delhi, 2017.
- 10. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, 6th edition, CBS Publications, New Delhi, 2005.
- 11. Sona P.S., A Practical Manual of Pharmaceutical Engineering, University Science Press, New Delhi, India.
- 12. Simpson N.J.K., Solid phase extraction, Principles, techniques, and applications, Marcel Dekker Inc. USA, 2000.

#### <u>BP305P</u> PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

#### **Course Objectives:**

To get the learner introduced to the basic principles of organic synthesis.

#### **Course Outcomes**

The learner should be able to:

- 1. Prepare simple organic compounds by following GLP and Safety practice.
- 2. Conduct some simple assays for determination of some properties of samples.

T	Experiments involving laboratory techniques
1	Experiments involving involutory teeninques.
	• 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.
- 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 Claisen Schmidt reaction.
- Cinnamic acid from Benzaldehyde by Perkin reaction.
- *P*-Iodo benzoic acid from *P*-amino benzoic acid.

#### **Reference Books (Latest Editions to be adopted):**

- 1. Morrison R. T., Boyd R. N., Organic Chemistry, 6<sup>th</sup> edition, Prentice Hall, New Jersey, 1992.
- 2. Finar I. L., Organic Chemistry, Vol. 1, 4th edition, Pearson Publishing House, Longman, 1963.
- 3. Bahl B. S., Bahl A., Textbook of Organic Chemistry, 22<sup>nd</sup> edition, S. Chand publishing, Delhi, India, 2017.
- 4. Soni P. L., Organic Chemistry, 29th edition, S. Chand publishing, Delhi, India, 2007
- 5. Mann F. G., Practical Organic Chemistry, 4<sup>th</sup> Edition, Bernard Charles Saunders, Longman, London, New York and Toronto, 1960.
- 6. Vogel A.I., Vogel's textbook of Practical Organic Chemistry, 5<sup>th</sup> edition, Pearson Publishing House, 7. India, 1989.
- 8. Vishnoi N. K., Advanced Practical Organic Chemistry, 1<sup>st</sup> edition, Vikas Publishing House, Mumbai, 1979.
- 9. Engel R. G., Pavia D. L., Lampman G. N., Kriz G. S., Introduction to Organic Laboratory Techniques, Cengage Learning, India, 2010.

#### <u>BP306P</u> PHYSICAL PHARMACEUTICS – I (Practical)

#### **Course Objectives:**

The objective of the course is to teach the learner the methods for the determination of different physical parameters underlying pre-formulation testing, formulation development and finished product testing of drug delivery systems.

#### **Course Outcomes:**

The learner should be able to:

- 1. To understand the principles and methods for the determination of various physical parameters of drugs and formulations.
- 2. To carry out various physical tests involved in characterization of drugs.
- 3. To demonstrate testing of various physical parameters involved in pre-formulation and formulation development and evaluation.





#### LIST OF EXPERIMENTS

- 1 Determination the solubility of drug at room temperature.
- 2 Determination of pKa value by Half Neutralization/ Henderson Hassel balch equation.
- 3 Determination of Partition co- efficient of benzoic acid in benzene and water.
- 4 Determination of Partition co- efficient of Iodine in CCl<sub>4</sub> and water (Demonstration).
- 5 Determination of CST of phenol water system and % composition of NaCl in a solution using phenol-water system by CST method.
- 6 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 charcoal.
- 9 Determination of critical micellar concentration of surfactants.
- 10 Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method.
- 11 Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method (Demonstration).
- 12 To determine the refractive index of liquids using Abbe's Refractometer.
- 13 To determine the concentration of an unknown solution of an optically active substance using polarimeter.
- 14 To determine the molecular weight of ionizable and nonionizable solute by ebullioscopy (Lands Berger Method).

#### **Recommended Books (Latest Editions to be adopted):**

- 1. Martin A, Swarbrick. J, Cammarata A, Physical Pharmacy: Physical Chemical Principles in the Pharmaceutical Sciences, 3<sup>rd</sup> edition, BI Waverly. Pvt Ltd, New Delhi, 1993.
- 2. Sinko PJ, Singh Y. Martin's Physical Pharmacy and Pharmaceutical Sciences: Physical Chemical and Biopharmaceutical Principles in the Pharmaceutical Sciences, 6<sup>th</sup> edition, Walter Kluer, Philadelphia, 2011.
- 3. Parrott E.L, Saski W, Experimental Pharmaceutics, 4<sup>th</sup> edition, Burgess Publishing Company, Minneapolis,1971
- 4. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, 6<sup>th</sup> edition, CBS Publications, New Delhi, 2005.
- 5. Stocklosa M. J. Pharmaceutical Calculations, 6th edition, Lea & Febiger, Philadelphia, 1974
- Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms—tablets, Vol.1,2,3/edited by Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz, 2<sup>nd</sup> edition, Marcel Dekker Inc., Newyork,1990.
- Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3/edited by Herbert A. Lieberman, Martin, M., and Gilbert S. Banker, 2<sup>nd</sup> edition, Marcel Dekker Inc. New York,1998.
- 8. Ramasamy C, and Manavalan R, Physical Pharmaceutics,1st edition, Pharma Med Press, 2017
- 9. C.V.S. Subramanyam, J. Thimma settee, Laboratory Manual of Physical Pharmaceutics, 2<sup>nd</sup> edition, Vallabh Prakashan, Delhi, 2014.
- 10. C.V.S. Subrahmanyam, Textbook of Physical Pharmaceutics, 3<sup>rd</sup> edition, Vallabh Prakashan, Delhi, 2015
- 11. C.V.S. Subrahmanyam, Essentials of Physical Pharmaceutics, 2<sup>nd</sup> edition, Vallabh Prakashan, Delhi, 2017





- 12. Jain G, Khar RK, Ahmad FJ, Theory and Practice of Physical Pharmacy, 1<sup>st</sup> Edition, Elsevier India, 2013
- 13. Bahl A, Bahl B. S, Tuli G. D, Essentials of Physical Chemistry, 28<sup>th</sup> edition, S Chand Publications, New Delhi, 2000.

#### <u>BP307P</u> PHARMACEUTICAL MICROBIOLOGY (Practical)

#### **Course Objectives:**

To introduce the learner to some of the common techniques used in microbiological techniques and experiments.

#### **Course Outcomes:**

Upon completion of the course the student will be able to:

1. Characterization and identification of bacteria using various staining techniques (morphological study), colony characterization, serological and biochemical characteristics.

- 2. Analyze quality of raw material, food and water and assessment of extent of microbial contamination using counting technique and Evaluate sterility of products.
- 3. To impart the knowledge of bioassay of antibiotic and test antibiotic sensitivity of few antibiotics.

#### LIST OF EXPERIMENTS

1	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.
4	Staining methods- Simple, Grams staining and acid-fast staining (Demonstration with practical), negative staining, capsule staining, cell wall staining.
5	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.
11	Microbial Total counts by Breeds smear method (Demo), Microbial Growth by optical
	density, total plate count (Demo).

#### **Recommended Books (Latest edition to be adopted):**

- 1. Hugo W.B. and Russel A.D, Pharmaceutical Microbiology, 8<sup>th</sup> Edition, Blackwell Scientific publications, Oxford, London, 2013.
- 2. Reed G., Prescott and Dunn's., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi, 2004.
- Pelczar MJ, Chan ECS, Kreig NR. Microbiology, 6<sup>th</sup> Edition, Tata McGraw Hill Education Pvt. Ltd, Delhi,1993





- 4. Harris M, Tindall B, and Cox, Pharmaceutical Microbiology, 1<sup>st</sup> edition, 1964, The Williams and Wilkins, Baltimore, 1964.
- 5. Rose AH, Industrial Microbiology, 1<sup>st</sup> edition, Butterworths (Elsevier), Oxford, 1961.
- 6. Frobisher M, Hinsdill RD, Crabtrea KT, Good Heart CR, Fundamentals of Microbiology, 9th edition, Japan, 1974.
- 7. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, 6<sup>th</sup> edition, CBS Publications, New Delhi, 2005.
- Peppler HJ, Microbial Technology, 2<sup>nd</sup> Edition, Academic Press (Elsevier), Massachusetts, 1979.
- 9. I.P., B.P., U.S.P.- latest editions.
- 10. Reba Kanungo, Ananthnarayan and Paniker's Textbook of Microbiology,10<sup>th</sup> Edition, Orient-Longman, Chennai, 2017.
- 11. Pommerville, J.C., Alcamo's Fundamentals of Microbiology, 3rd Edition, Jones and Bartlett, Burlington, Massachusetts, 2014.
- 12. Jain N.K, Pharmaceutical Microbiology, 3<sup>rd</sup> Edition, Vallabh Prakashan, Delhi, 2001.
- 13. Garry G.M., Bergey's Manual of Systematic Bacteriology, 2<sup>nd</sup> Edition, Springer publishing, New York, 2005.

#### BP308P PHARMACEUTICAL ENGINEERING (Practical)

#### **Course objectives:**

To familiarize the learner with unit operations encountered in manufacturing of pharmaceuticals and provide training in operating and handling of instruments and equipment and an understanding of manufacturing processes.

#### **Course Outcomes:**

The learner should be able to:

1. Understand the construction and operation of various machines and equipment encountered in pharmaceutical manufacturing unit operations

2. Analyze various unit processes and factors involved to design and apply it to solve problems encountered in manufacturing

3. Understand and apply the calculation of various coefficients and variables that govern unit operations in order to maximise efficiency of the processes.

#### LIST OF EXPERIEMENTS

1	Determination of radiation constant of brass, iron, unpainted and painted glass.
2	Simple distillation – To calculate the efficiency of simple distillation.
3	Steam distillation – (Demonstration).
4	To determine the overall heat transfer coefficient by heat exchanger.
5	Construction of drying curves (for calcium carbonate and starch).
6	Determination of moisture content and loss on drying.
7	Determination of humidity of air $-i$ ) From wet and dry bulb temperatures –use of
	Dew point method.
8	Description of Construction working and application of pharmaceutical machinery such as

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	fluid energy mill, de humidifier.
9	Size analysis by sieving – To evaluate size distribution of tablet granulations –
	Construction of various size frequency curves including arithmetic and logarithmic
	probability plots.
10	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.
11	Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer
	and such other major equipment.
12	Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration
	and Thickness/ viscosity.
13	To study the effect of time on the Rate of Crystallization.
14	To calculate the uniformity Index for given sample by using Double Cone Blender

#### **Recommended Books: (Latest Editions to be adopted):**

- 1. Badger W.L. & Banchero J., Introduction to chemical engineering, Published by Tata McGraw Hill, International edition, New Delhi, 1955
- 2. Perry R.H., Green D.W., Maloney O, Perry's Chemical Engineer's Handbook -.7th Edition, McGraw Hill Inc., New York, 1998.
- 3. McCabe, Smith & Harriott. Unit Operations of Chemical Engineering, Published by McGraw Hill Inc., 5th edition, 1993.
- 4. Subramanyam C.V.S., Pharmaceutical Engineering: Unit Operations Principles and Practice, Vallabh Prakashan, Delhi., 3rd edition, 2019.
- 5. Remington A, The Science & Practice of Pharmacy. Lippincott, Williams & Wilkins Philadelphia. 21st edition, 2006.
- 6. Lachman L., Lieberman H.A. & Kanjig J.L, The Theory & Practice of Industrial Pharmacy, 3rd edition, Varghese Publishing House, Bombay, 1990.
- 7. K. Sambamurthy, Pharmaceutical Engineering, New Age International Publishers, Delhi, 2005.
- 8. C.V.S Subrahmanyam, Textbook of Physical Pharmaceutics, 3rd edition, Vallabh Prakashan, Delhi, 2015.
- 9. C.V.S Subrahmanyam, Essentials of Physical Pharmaceutics, 2nd edition, Vallabh Prakashan, Delhi, 2017.
- 10. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, 6th edition, CBS Publications, New Delhi, 2005.
- 11. Sona P.S., A Practical Manual of Pharmaceutical Engineering, University Science Press, New Delhi, India.
- 12. Simpson N.J.K., Solid phase extraction, Principles, techniques, and applications, Marcel Dekker Inc. USA, 2000.





# SEMESTER IVBP401TPHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)45 Hours

#### **Course Objectives:**

This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, and chemistry of important hetero cyclic compounds. It also emphasizes on the medicinal and other uses of organic compounds.

#### **Course Outcomes:**

At the end of the course, the student shall be able to:

- 1. Understand the methods of preparation and properties of organic compounds
- 2. Explain the stereo chemical aspects of organic compounds and stereo chemical reactions
- 3. Know the medicinal uses and other applications of organic compounds

Unit	Details	Hours
	Note: To emphasize on definition, types, mechanisms, examples,	
	uses/applications.	
1		10
	<ul> <li>Stereoisomerism</li> <li>Optical isomerism –</li> <li>i. Optical activity, enantiomers, diastereoisomers, meso compounds.</li> <li>ii. Elements of symmetry, chiral and achiral molecules.</li> <li>iii. DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers.</li> <li>iv. Reactions of chiral molecules (Stereospecific and stereoselective aspects).</li> </ul>	
	v. Racemic modification and resolution of racemic mixture. vi. Asymmetric synthesis: partial and absolute.	
2		10
	<ul> <li>Geometrical isomerism</li> <li>i. Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems).</li> <li>ii. Methods of determination of configuration of geometrical isomers.</li> <li>iii. Conformational isomerism in Ethane, n-Butane and Cyclohexane.</li> <li>iv. Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity.</li> </ul>	
3		10
	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.	
4		08
	<b>Synthesis, reactions and medicinal uses of following compounds/derivatives</b> 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.	





5	Reactions of synthetic importance	07
5.1	Metal hydride reduction (NaBH <sub>4</sub> and LiAlH <sub>4</sub> ), Clemmensen reduction, Birch	2
	reduction, Wolff Kishner reduction.	
5.2	Oppenauer-oxidation and Dakin reaction.	2
5.3	Beckmann rearrangement and Schmidt rearrangement.	2
5.4	Claisen-Schmidt condensation.	1
	TOTAL	45

- 1. Finar I. L., Organic Chemistry, Vol. 1, 4th edition, Pearson Publishing House, Longman, 1963
- 2. Bahl B. S., Bahl A., Textbook of Organic Chemistry, 22<sup>nd</sup> edition, S. Chand publishing, Delhi, India, 2017
- 3. Bansal R. K., Heterocyclic Chemistry, 4th edition, Anshan Limited, India, 2008
- 4. Morrison R. T., Boyd R. N., Organic Chemistry, 6<sup>th</sup> edition, Prentice Hall, New Jersey, 1992
- 5. Gilchrist T.L., Heterocyclic Chemistry, 3rd edition, Prentice Hall, New Jersey, 1997

### BP402TMEDICINAL CHEMISTRY – I (Theory)45 Hours

#### **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.

#### **Course Outcomes:**

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

- 1. Understand the chemistry of drugs with respect to their pharmacological activity.
- 2. Understand the drug metabolic pathways, adverse effect, and therapeutic value of drugs.
- 3. Know the Structural Activity Relationship (SAR) of different class of drugs.
- 4. Write the chemical synthesis of some drugs.

Unit	Details	Hours
	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*.	
1	Introduction to Medicinal Chemistry	10
1.1	History and development of medicinal chemistry	1
1.2	Physicochemical properties in relation to biological action	4
	Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding,	
	Chelation, Bioisosterism, Optical and Geometrical isomerism.	
1.3	Drug metabolism	5
	• Drug metabolism principles- Phase I and Phase II.	

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### Syllabus B.Pharm (Choice Based Credit System)



	• Factors affecting drug metabolism including stereo chemical aspects.	
2	Drugs acting on Autonomic Nervous System	10
2.1	Adrenergic Neurotransmitters:	2
	Biosynthesis and catabolism of catecholamine.	
	• Adrenergic receptors (Alpha & Beta) and their distribution.	
2.2	Sympathomimetic agents: SAR of Sympathomimetic agents	4
	• Direct acting: Norepinephrine, 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.	
2.3	Adrenergic Antagonists:	4
	• 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.	
3	Cholinergic neurotransmitters	10
3.1	Biosynthesis and catabolism of acetylcholine.	2
	Cholinergic receptors (Muscarinic & Nicotinic) and their distribution	
3.2	Parasympathomimetic agents: SAR of Parasympathomimetic agents	4
	• <b>Direct acting agents:</b> 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.	
3.3	Cholinergic Blocking agents: SAR of cholinolytic agents	4
	• 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 hydrochioride, Procychaine	
	hydrochloride", Thuinexettiyi chioride, isopropaniide iodide, Europropazite	
	Drugs acting on Control Nervous System	08
- <del>-</del> <u>4</u> 1	Sedatives and Hypnotics.	2
7.1	Benzodiazenines: SAR of Benzodiazenines Chlordiazenovide Diazenam*	3
	Oxazenam Chlorazenate Lorazenam Alprazolam Zolnidem	
	Barbiturates: SAR of harbiturates: Barbital* Phenoharbital Menhobarbital	
	Amoharbital Butabarbital Pentobarbital Secobarbital	
	<ul> <li>Miscellaneous:</li> </ul>	
	Amides and imides: Glutethimide	
	Alcohol & their carbamate derivatives: Meprobamate. Ethchloryvnol	
L		



### Syllabus B.Pharm (Choice Based Credit System)



	Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.	
4.2	Antipsychotics	3
	• <b>Phenothiazines:</b> SAR of Phenothiazines - Promazine hydrochloride,	
	Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride,	
	Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine	
	hydrochloride.	
	• <b>Ring Analogues of Phenothiazines:</b> Chlorprothixene, Thiothixene, Loxapine	
	succinate, Clozapine.	
	• Fluro buterophenones: Haloperidol, Droperidol, Risperidone.	
	Beta amino ketones: Molindone hydrochloride.	
	Benzamides: Sulpiride.	
4.3	Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action	2
	• Barbiturates: Phenobarbitone, Methabarbital.	
	Hydantoins: Phenytoin*, Mephenytoin, Ethotoin.	
	Oxazolidine diones: Trimethadione, Paramethadione.	
	• Succinimides: Phensuximide, Methsuximide, Ethosuximide*	
	• Urea and monoacylureas: Phenacemide, Carbamazepine*	
	Benzodiazepines: Clonazepam.	
	• Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate.	
5	Drugs acting on Central Nervous System	07
5.1	General anesthetics:	3
	• Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane,	
	Isoflurane, Desflurane.	
	• Ultra short acting barbiturates: Methohexital sodium*, Thiamylal sodium,	
	Thiopental sodium.	
	Dissociative anesthetics: Ketamine hydrochloride.*	
5.2	Narcotic and non-narcotic analgesics	2
	• 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.	
5.3	Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid*,	2
	Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepirac, Diclofenac,	
	Ketorolac, Ibuproten <sup>*</sup> , Naproxen, Piroxicam, Phenacetin, Acetaminophen,	
1		
	Antipyrine, Phenylbutazone.	15

- Beale J. M., Block J. H., Wilson and Gisvold's Textbook of Organic medicinal and Pharmaceutical Chemistry, 20<sup>th</sup> edition, Lippincott Williams & Wilkins Publishers, 2004.
- Lemke T. L., Williams D. A., Roche V. F., Zito., S. W., Foye's Principles of Medicinal Chemistry, 7<sup>th</sup> edition, Lippincott Williams and Wilkins Publishers, 2001.
- Abraham D. J., Burger's Medicinal Chemistry and Drug Discovery, Vol I to IV, 6<sup>th</sup> edition, John Wiley and Sons, Inc., Publication, 2003.





- 4. Smith H. J., Smith and Williams' Introduction to Principles of Drug Design and Action, 4<sup>th</sup> edition, Taylor and Francis Publications, CRC Press, 2005.
- 5. Remington, The Science and Practice of Pharmacy, 21<sup>st</sup> edition, Lippincott Williams and Wilkins Publication, 2005.
- 6. Robert Buckingham, Martindale: The Extra Pharmacopoeia, 40<sup>th</sup> edition, Pharmaceutical Press, 2020.
- 7. Finar I. L., Organic Chemistry, Vol. II, 4th edition, Pearson Publishing House, Longman, 1963
- 8. Lednicer D., The Organic Chemistry of Drug Synthesis, Vol. 1-7, Wiley-Blackwell, 2007
- 9. Indian Pharmacopoeia.
- 10. Vogel A.I., Vogel's textbook of Practical Organic Chemistry, 5<sup>th</sup> edition, Pearson Publishing House, India, 1989.

### BP403TPHYSICAL PHARMACEUTICS-II (Theory)45 Hours

#### **Course objectives:**

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, and stability studies of pharmaceutical dosage forms.

**Course outcomes:** Upon the completion of the course student shall be able:

- 1. To understand the basic principles of coarse and colloidal dispersions.
- 2. To know the rheological and micromeritic concepts in pharmacy.
- 3. To principles chemical kinetics in stability of drug molecule.
- 4. To describe the laws of thermodynamics and applications of thermochemistry.

Unit	Details	Hours
1	UNIT - I	5
	Thermodynamics:	
	First law and second law of thermodynamics; Concept of enthalpy, entropy and	
	free energy, Gibbs equation, thermochemistry.	
2	UNIT - II	8
	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.	
3	UNIT - III	7
	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.	
4	UNIT - IV	7
	Rheology:	
	Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-	

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	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	
5	UNIT - V	8
	Micromeritics:	
	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.	
6	UNIT - VI	10
6	UNIT - VI Drug stability:	10
6	UNIT - VI Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate	10
6	UNIT - VI Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors	10
6	UNIT - VI 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,	10
6	UNIT - VI 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,	10
6	UNIT - VI 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.	10
6	UNIT - VI 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 &	10
6	UNIT - VI 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	10
6	UNIT - VI 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.	10

- 1. Martin A, Swarbrick. J, Cammarata A, Physical Pharmacy: Physical Chemical Principles in the Pharmaceutical Sciences, 3<sup>rd</sup> edition, BI Waverly. Pvt Ltd, New Delhi, 1993.
- 2. Sinko PJ, Singh Y. Martin's Physical Pharmacy and Pharmaceutical Sciences: Physical Chemical and Biopharmaceutical Principles in the Pharmaceutical Sciences, 6<sup>th</sup> edition, Walter Kluer, Philadelphia, 2011.
- 3. Parrott E.L, Saski W, Experimental Pharmaceutics, 4<sup>th</sup> edition, Burgess Publishing Company, Minneapolis,1971
- 4. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, 6<sup>th</sup> edition, CBS Publications, New Delhi, 2005.
- 5. Stocklosa M. J. Pharmaceutical Calculations, 6<sup>th</sup> edition, Lea & Febiger, Philadelphia, 1974
- Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms—tablets, Vol.1,2,3/edited by Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz, 2<sup>nd</sup> edition, Marcel Dekker Inc., Newyork,1990.
- 7. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3/edited by Herbert A. Lieberman, Martin, M., and Gilbert S. Banker, 2<sup>nd</sup> edition, Marcel Dekker Inc. New York,1998.
- 8. Ramasamy C, and Manavalan R, Physical Pharmaceutics, 1st edition, Pharma Med Press, 2017
- 9. Bahl A, Bahl B. S, Tuli G. D, Essentials of Physical Chemistry, 28<sup>th</sup> edition, S Chand Publications, New Delhi, 2000.
- 10.C.V.S. Subrahmanyam, Textbook of Physical Pharmaceutics, 3<sup>rd</sup> edition, Vallabh Prakashan, Delhi, 2015





11.C.V.S. Subrahmanyam, Essentials of Physical Pharmaceutics, 2<sup>nd</sup> edition, Vallabh Prakashan, Delhi, 2017

### BP404TPHARMACOLOGY-I (Theory)45 Hours

#### **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. The subject will impart information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism, and excretion (pharmacokinetics), routes of administration of different classes of drugs along with the adverse effects, clinical uses, interactions, doses and contraindications that can bridged to the clinical settings.

#### **Course Outcomes:**

Upon completion of this course the student should be able to

- 1. Understand the pharmacological actions of different categories of drugs and comprehend the pharmacokinetic and pharmacodynamic principles.
- 2. Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
- 3. Understand autonomic transmission and discuss the pharmacology of drugs acting on ANS and rationalize their therapeutic applications.
- 4. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
- 5. Explain the features of adverse drug reactions and drug interactions and appreciate correlation of pharmacology in bio medical disciplines like drug discovery and pharmacovigilance.

Unit	Details	Hours
1	General Pharmacology	8
1.1	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 and teratogenicity	4
1.2	Pharmacokinetics- Membrane transport, absorption, distribution, metabolism, and excretion of drugs. Enzyme induction, enzyme inhibition, kinetics of elimination.	4
2	General Pharmacology	12
2.1	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.	6
2.2	Adverse drug reactions.	2
2.3	Drug interactions (pharmacokinetic and pharmacodynamic).	2
2.4	Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.	2
3	Pharmacology of peripheral nervous system	10

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#### Syllabus B.Pharm (Choice Based Credit System)



3.1	Organization and function of ANS, Neurohumoral transmission, co-transmission	1
	and classification of neurotransmitters.	
3.2	Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.	3
3.3	Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).	2
3.4	Local anesthetic agents.	3
3.5	Drugs used in myasthenia gravis and glaucoma.	1
4	Pharmacology of central nervous system	08
4.1	Neurohumoral transmission in the C.N.S. special emphasis on importance of	1
	various neurotransmitters like with GABA, Glutamate, Glycine, serotonin,	
	dopamine.	
4.2	General anesthetics and pre-anesthetics.	2
4.3	Sedatives, hypnotics and centrally acting muscle relaxants.	2
4.4	Anti-epileptics.	2
4.5	Alcohols and disulfiram.	1
5	Pharmacology of central nervous system	07
5.1	Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety	2
	agents, anti-manics and hallucinogens.	
5.2	Drugs used in Parkinson's disease and Alzheimer's disease.	1
5.3	CNS stimulants and nootropics.	1
5.4	Opioid analgesics and antagonists.	2
5.5	Drug addiction, drug abuse, tolerance and dependence.	1
	TOTAL	45

- 1. Ritter J. M., Flower R. J., Henderson G, Loke Y, MacEwan D, Rang H., Rang and Dale's Pharmacology, 9<sup>th</sup> edition, Elsevier Health, London 2019.
- 2. Katzung B. G., Masters S. B., Trevor A. J., Basic and Clinical Pharmacology, 14<sup>th</sup> edition, Tata Mc Graw-Hill Education, Pvt. Ltd, 2017
- 3.Brunton, L.L., Hilal-Dandan R, Knollman, B., Goodman and Gilman's The Pharmacological Basis of Therapeutics; 13th edition, McGraw-Hill Education, New York, 2017.
- 4. 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
- 5. Zeind C.S, Carvahlo M.G., Applied Therapeutics: The Clinical Use of Drugs, 11<sup>th</sup> edition, Wolters Kluwer, Philadelphia,2018
- 6. Harvey R, Clark MA, Finkel R., Rey, J.A., Whalen, K., Lippincott's Illustrated Reviews-Pharmacology, 5<sup>th</sup> edition, Wolter's Kruwer, 2011.
- 7. Tripathi K.D., Essentials of Medical Pharmacology, 8<sup>th</sup> edition, Jaypee Brothers Medical Publishers (P) Ltd, New Delhi, 2019.
- 8. Sharma H. L., Sharma K. K., Principles of Pharmacology, 1<sup>st</sup> edition, Paras Medical Publisher, 2017.
- 9. Craig C.R., Stitzel, R.E, Modern Pharmacology with clinical Applications, 1<sup>st</sup> edition, Lippincott Williams and Wilkins, Philadelphia, 2004
- 10. Ghosh MN. Fundamentals of Experimental Pharmacology, 6<sup>th</sup> edition, Hilton & Company, Kolkata, 2015.
- 11. Kulkarni SK. Handbook of experimental pharmacology, 4<sup>th</sup> edition, Vallabh Prakashan, 2012.
- 12. Walker R, Edwards, Clinical Pharmacy and Therapeutics, 3rd edition; Churchill Livingstone Edinburgh, New York, 2003





- 13. Tipnis and Bajaj, Clinical Pharmacy, 3<sup>rd</sup> edition, Career Publications, Nasik, 2017.
- 14. Bennett PN, Brown MJ, Clinical Pharmacology, 12<sup>th</sup> edition, Elsevier, Edinburg, 2019.
- 15. Parthisarathi G., Nyfort-Hansen K., Nahata M. C., 1<sup>st</sup> edition, Textbook of Clinical Pharmacy Practice; Essential Skills and Concepts, Orient Longman Pvt, Ltd, Hyderabad, 2004.

### BP405TPHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)45 Hours

#### **Course Objectives:**

The subject involves the fundamentals like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

#### **Course Outcomes:**

Upon completion of the course, the student shall be able:

- 1. To know the techniques in the cultivation and production of crude drugs.
- 2. To know the crude drugs, their uses and chemical nature.
- 3. Know the evaluation techniques for the herbal drugs.
- 4. To carry out the microscopic and morphological evaluation of crude drugs.

Omt	Details	Hours
1		10
1.1	Introduction to Pharmacognosy:	3
	(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).	
1.2	Classification of drugs:	2
	Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and	
	sero taxonomical classification of drugs.	
1.3	Quality control of Drugs of Natural Origin:	5
	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, leaf	
	constants, camera lucida and diagrams of microscopic objects to scale with camera	
	lucida.	
2		12
2.1	Cultivation, Collection, Processing, and storage of drugs of natural origin:	10
	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,	
2.2	Conservation of medicinal plants	2
3		7
	Plant tissue culture:	
	Historical development of plant tissue culture, types of cultures, Nutritional	
	requirements, growth, and their maintenance.	

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#### Syllabus B.Pharm (Choice Based Credit System)



	Applications of plant tissue culture in pharmacognosy. Edible vaccines.	
4		10
4.1	Pharmacognosy in various systems of medicine:	3
	Role of Pharmacognosy in allopathy and traditional systems of medicine namely,	
	Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine.	
4.2	Introduction to secondary metabolites:	7
	Definition, classification, properties, and test for identification of Alkaloids,	
	Glycosides, Flavonoids, Tannins, Volatile oil and Resins.	
5	Study of biological source, chemical nature and uses of drugs of natural origin	08
	containing following drugs	
	(a) Plant Products:	3
	Fibers - Cotton, Jute, Hemp.	
	Hallucinogens, Teratogens, Natural allergens.	
	(b) Primary metabolites:	3
	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 Primary	
	metabolites:	
	(c) <b>Carbohydrates:</b> Acacia, Agar, Tragacanth, Honey.	
	(d) Proteins and Enzymes: Gelatin, casein, proteolytic enzymes (Papain,	
	bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).	
	(e) Lipids (Waxes, fats, fixed oils): Castor oil, Chaulmoogra oil, Wool Fat, Bees	2
	Wax	
	(f) Marine Drugs:	
	Novel medicinal agents from marine sources.	
	TOTAL	45

#### **Reference Books (Latest Editions to be adopted):**

- 1. Evans W.C, Trease and Evans, Pharmacognosy, 16<sup>th</sup> edition, W.B. Sounders & Co., London, 2009.
- 2. Tyler, V.E, Brady, L.R. and Robbers, J.E., Pharmacognosy, 9<sup>th</sup> Edn., Lea and Febiger, Philadelphia, 1988.
- 3. Wallis T.E, Textbook of Pharmacognosy, 5<sup>th</sup> edition, J & A Churchill Ltd, London, 2005.
- 4. Mohammad Ali, Pharmacognosy and Phytochemistry, 1<sup>st</sup> edition, CBS Publishers & Distributors, New Delhi, 2018 reprint.
- 5. Kokate C.K., Purohit A. P., Gokhale S.B., Textbook of Pharmacognosy, 37<sup>th</sup> Edition, Nirali Prakashan, New Delhi, 2007
- 6. Choudhary R.D, Herbal Drug Industry, 1<sup>st</sup> edition, Eastern Publishers, New Delhi. 1996
- 7. Ansari S. H., Essentials of Pharmacognosy, 2<sup>nd</sup> edition, Birla Publications, New Delhi, 2007
- 8. Kokate C.K., Purohit A. P., Gokhale S.B, Practical Pharmacognosy, 13<sup>th</sup> edition, Nirali Prakashan, New Delhi, 2009.
- 9. Iyengar M.A and Nayak S.G.K, Anatomy of Crude Drugs, 12<sup>th</sup> edition, PharmaMed Press, A unit of BSP books Pvt. Ltd, Hyderabad, 2011.
- 10. Khandelwal K. R. and Vrunda Sethi, Practical Pharmacognosy: Techniques and Experiments, 24<sup>th</sup> edition, Nirali Prakashan, 2014.
- 11. Vasudevan T. N. Laddha K. S, Practical Pharmacognosy, New Vrinda Publishing House, Jalgaon, 1987.

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12. Shah B.A., Seth A, Textbook of Pharmacognosy and Phytochemistry, 1st edition, Elsevier Publications, A division of Reed Elsevier India Pvt. Ltd, New Delhi, 2010.

#### <u>BP406P</u> <u>MEDICINAL CHEMISTRY – I (Practical)</u>

#### **Course Objectives**:

To get the learner introduced to the basic principles of organic synthesis.

#### **Course Outcomes**

The learner should be able to:

- 1. Prepare simple organic compounds by following GLP and Safety practice.
- 2. Conduct some simple assays for determination of quantitative estimation of some organic compounds.

#### LIST OF EXPERIMENTS

A. Preparation of drugs/ intermediates	
1,3-pyrazole.	
1,3-oxazole.	
Benzimidazole.	
Benztriazole.	
2,3- diphenyl quinoxaline.	
Benzocaine.	
Phenytoin.	
Phenothiazine.	
Barbiturate.	
B. Assay of drugs	
Chlorpromazine.	
Phenobarbitone.	
Atropine.	
Ibuprofen.	
Aspirin.	
Furosemide.	
C. Determination of Partition coefficient for any two drugs	

- 1. Beale J. M., Block J. H., Wilson and Gisvold's Textbook of Organic medicinal and Pharmaceutical Chemistry, 20<sup>th</sup> edition, Lippincott Williams & Wilkins Publishers, 2004.
- Lemke T. L., Williams D. A., Roche V. F., Zito., S. W., Foye's Principles of Medicinal Chemistry, 7<sup>th</sup> edition, Lippincott Williams and Wilkins Publishers, 2001
- 3. Abraham D. J., Burger's Medicinal Chemistry and Drug Discovery, Vol I to IV, 6<sup>th</sup> edition, John Wiley and Sons, Inc., Publication, 2003
- 4. Smith H. J., Smith and Williams' Introduction to Principles of Drug Design and Action, 4<sup>th</sup> edition, Taylor and Francis Publications, CRC Press, 2005
- 5. Remington, The Science and Practice of Pharmacy, 21<sup>st</sup> edition, Lippincott Williams and Wilkins Publication, 2005
- 6. Robert Buckingham, Martindale: The Extra Pharmacopoeia, 40<sup>th</sup> edition, Pharmaceutical Press, 2020.
- 7. Finar I. L., Organic Chemistry, Vol. II, 4th edition, Pearson Publishing House, Longman, 1963





- 8. Lednicer D., The Organic Chemistry of Drug Synthesis, , Vol. 1-7, Wiley-Blackwell, 2007
- 9. Indian Pharmacopoeia
- 10. Vogel A.I., Vogel's textbook of Practical Organic Chemistry, 5<sup>th</sup> edition, Pearson Publishing House, India, 1989

#### <u>BP407P</u> PHYSICAL PHARMACEUTICS- II (Practical)

#### **Course Objectives:**

To familiarize the learner with methods to evaluate particle size, and flow properties, shelf life and physical stability of solutions and suspensions and teach the learner characterization methods and protocols for determination of physical parameters.

#### **Course Outcomes:**

The learner should be able to:

- 1. Determine reaction rate constant, order of a reaction for different reactions.
- 2. Predict shelf life by carrying out accelerated stability studies.
- 3. Calculate physical parameters such as stability constants, particle size, density, flow properties, molecular weight, viscosity, and sedimentation rate.

#### LIST OF EXPERIMENTS

- 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 and concentration of unknown 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 (Demonstration).
- 9 Determination of reaction rate constant first order and determine relative strength of acids.
- 10 Determination of reaction rate constant second order (both a=b and  $a \neq b$ ).
- 11 Accelerated stability studies and determination of shelf life.
- 12 Determination of order of reaction using Ostwald Isolation Method (Demonstration).
- 13 Determination of molecular weight of a polymer using Intrinsic viscosity.

- 1. Martin A, Swarbrick. J, Cammarata A, Physical Pharmacy: Physical Chemical Principles in the Pharmaceutical Sciences, 3<sup>rd</sup> edition, BI Waverly. Pvt Ltd, New Delhi, 1993.
- 2. Sinko PJ, Singh Y. Martin's Physical Pharmacy and Pharmaceutical Sciences: Physical Chemical and Biopharmaceutical Principles in the Pharmaceutical Sciences, 6<sup>th</sup> edition, Walter Kluer, Philadelphia, 2011.
- 3. Parrott E.L, Saski W, Experimental Pharmaceutics, 4<sup>th</sup> edition, Burgess Publishing Company, Minneapolis,1971
- 4. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, 6<sup>th</sup> edition, CBS Publications, New Delhi, 2005.





- 5. Stocklosa M. J. Pharmaceutical Calculations, 6<sup>th</sup> edition, Lea & Febiger, Philadelphia, 1974
- Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms—tablets, Vol.1,2,3 edited by Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz, 2<sup>nd</sup> edition, Marcel Dekker Inc., Newyork,1990.
- Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3/edited by Herbert A. Lieberman, Martin, M., and Gilbert S. Banker, 2<sup>nd</sup> edition, Marcel Dekker Inc. New York,1998.
- 8. Ramasamy C, and Manavalan R, Physical Pharmaceutics, 1st edition, PharmaMed Press, 2017.
- 9. Bahl A, Bahl B. S, Tuli G. D, Essentials of Physical Chemistry, 28<sup>th</sup> edition, S Chand Publications, New Delhi, 2000.
- C.V.S. Subrahmanyam, Textbook of Physical Pharmaceutics, 3<sup>rd</sup> edition, Vallabh Prakashan, Delhi, 2015
- 11. C.V.S. Subrahmanyam, Essentials of Physical Pharmaceutics, 2<sup>nd</sup> edition, Vallabh Prakashan, Delhi, 2017

#### <u>BP408P</u> <u>PHARMACOLOGY I (Practical)</u>

#### **Course Objectives**:

The course will impart training in basic laboratory techniques, instruments, and regulatory and ethical guidelines applicable in experimental pharmacology. The students will be appraised on animal handling techniques, routes of administration, anaesthesia and pharmacological effects of various drugs using simulated audio-visual techniques.

#### **Course Outcomes:**

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

- 1. Possess the knowledge of animals and instruments used pharmacology.
- 2. Relate to and apply the regulatory and ethical guidelines in drug/lead testing using preclinical animals.
- 3. Describe the animal handling techniques and procedures used in animal experimentation.

4. Observe the effect of drugs on animals by simulated experiments and interpret the pharmacological actions.

#### **LIST OF EXPERIMENTS**

- 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.
- 5. 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.
- 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.



Syllabus B.Pharm (Choice Based Credit System)



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

#### **Reference Books (Latest Editions to be adopted):**

- 1. Ritter J. M., Flower R. J., Henderson G, Loke Y, MacEwan D, Rang H., Rang and Dale's Pharmacology, 9<sup>th</sup> edition, Elsevier Health, London 2019.
- 2. Katzung B. G., Masters S. B., Trevor A. J., Basic and Clinical Pharmacology, 14<sup>th</sup> edition, Tata Mc Graw-Hill Education, Pvt. Ltd, 2017
- 3. Brunton, L.L., Hilal-Dandan R, Knollman, B., Goodman and Gilman's The Pharmacological Basis of Therapeutics; 13th edition, McGraw-Hill Education, New York, 2017.
- 4. 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
- 5. Zeind C.S., Carvahlo M.G., Applied Therapeutics: The Clinical Use of Drugs, 11<sup>th</sup> edition, Wolters Kluwer, Philadelphia,2018
- 6. Harvey R, Clark MA, Finkel R., Rey, J.A., Whalen, K., Lippincott's Illustrated Reviews-Pharmacology, 5<sup>th</sup> edition, Wolter's Kruwer, 2011.
- 7. Tripathi K.D., Essentials of Medical Pharmacology, 8<sup>th</sup> edition, Jaypee Brothers Medical Publishers (P) Ltd, New Delhi, 2019.
- 8. Sharma H. L., Sharma K. K., Principles of Pharmacology, 1<sup>st</sup> edition, Paras Medical Publisher, 2017.
- 9. Craig C.R., Stitzel, R.E, Modern Pharmacology with clinical Applications, 1<sup>st</sup> edition, Lippincott Williams and Wilkins, Philadelphia, 2004
- 10. Ghosh MN. Fundamentals of Experimental Pharmacology, 6<sup>th</sup> edition, Hilton & Company, Kolkata, 2015.
- 11. Kulkarni SK. Handbook of experimental pharmacology, 4<sup>th</sup> edition, Vallabh Prakashan, 2012.
- 12. Satoskar R.S. Bhandarkar S.D., Tripathi, R.K., Rege N. N., 25<sup>th</sup> edition, Pharmacology & Therapeutics, Elsevier co-published with Popular Prakashan, 2017.
- 13. Kasture, S. B., A handbook of Experiments in Pre-Clinical Pharmacology, 1<sup>st</sup> edition, Career Publications, Nasik, 2009.
- 14. Perry W. L. M., Pharmacological Experiments on isolated preparations, 1<sup>st</sup> edition, E & S Livingstone, Edinburg & London, 1968.

#### <u>BP409P</u> PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

#### **Course Objectives:**

The subject involves identification and evaluation of crude drugs, phytochemicals present in them and their medicinal properties.

#### **Course Outcomes:**

Upon completion of the course, the student shall be able:

- 1. To know the crude drugs, their uses and chemical nature
- 2. Know the evaluation techniques for the herbal drugs
- 3. To carry out the microscopic and morphological evaluation of crude drugs





#### **LIST OF EXPERIMENTS**

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

- 1. Evans W.C, Trease and Evans, Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
- 2. Tyler, V.E, Brady, L.R. and Robbers, J.E., Pharmacognosy, 9<sup>th</sup> Edn., Lea and Febiger, Philadelphia, 1988.
- 3. Wallis T.E, Textbook of Pharmacognosy, 5<sup>th</sup> edition, J & A Churchill Ltd, London, 2005.
- 4. Mohammad Ali, Pharmacognosy and Phytochemistry, 1<sup>st</sup> edition, CBS Publishers & Distributors, New Delhi. 2018 reprint.
- 5. Kokate C.K., Purohit A. P., Gokhale S.B., Textbook of Pharmacognosy, 37<sup>th</sup> Edition, Nirali Prakashan, New Delhi, 2007
- 6. Choudhary R.D, Herbal Drug Industry, 1<sup>st</sup> edition, Eastern Publishers, New Delhi. 1996
- 7. Ansari S. H., Essentials of Pharmacognosy, 2<sup>nd</sup> edition, Birla Publications, New Delhi, 2007
- 8. Kokate C.K., Purohit A. P., Gokhale S.B, Practical Pharmacognosy, 13<sup>th</sup> edition, Nirali Prakashan, New Delhi, 2009.
- 9. Iyengar M.A and Nayak S.G.K, Anatomy of Crude Drugs, 12<sup>th</sup> edition, PharmaMed Press, A unit of BSP books Pvt. Ltd, Hyderabad, 2011.
- 10. Khandelwal K. R. and Vrunda Sethi, Practical Pharmacognosy: Techniques and Experiments, 24<sup>th</sup> edition, Nirali Prakashan, 2014.
- 11. Vasudevan T. N. Laddha K. S, Practical Pharmacognosy, New Vrinda Publishing House, Jalgaon, 1987
- 12. Shah B.A., Seth A, Textbook of Pharmacognosy and Phytochemistry, 1st edition, Elsevier Publications, A division of Reed Elsevier India Pvt. Ltd, New Delhi, 2010.





#### SEMESTER V BP501T

#### MEDICINAL CHEMISTRY – II (Theory) 45 Hours

#### **Course Objectives:**

This course is designed to impart fundamental knowledge on the structure, chemistry, and therapeutic value of drugs. The course is designed to include the structure activity relationships of drugs, importance of physicochemical properties of drugs, metabolism of drugs, and chemical synthesis of important drugs under each class.

#### **Course Outcomes:**

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

- 1. Understand the chemistry of drugs and the relation to their pharmacological activity.
- 2. Understand the drug metabolic pathways, adverse effect, and therapeutic value of drugs.
- 3. Appreciate the Structural Activity Relationship of different class of drugs.
- 4. Outline the chemical synthesis of selected drugs.

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 (*).         1       UNIT - I       10         1.1       Antihistaminic agents: Histamine, receptors, and their distribution in the human body.       4         H <sub>1</sub> -antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelennamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorcyclizine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine, Cromolyn sodium H2-antagonists: Cimetidine*, Famotidine, Ranitidine.       1         1.2       Gastric proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole       5         Alkylating agents: Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Cisplatin       5         Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.       5	Unit	Details	Hours
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 (*).         1       UNIT - I       10         1.1       Antihistaminic agents: Histamine, receptors, and their distribution in the human body.       4         H <sub>1</sub> -antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelennamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorcyclizine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine, Cromolyn sodium H2-antagonists: Cimetidine*, Famotidine, Ranitidine.       1         1.2       Gastric proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole       1         1.3       Anti-neoplastic agents: Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Cisplatin Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.		Study of the development of the following classes of drugs. Classification	
Imeritation of action, uses of utigs metholicit in the course, structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*).       1       UNIT - I       10         1.1       Antihistaminic agents: Histamine, receptors, and their distribution in the human body.       4       4         H1-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelennamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorcyclizine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine, Cromolyn sodium         H2-antagonists: Cimetidine*, Famotidine, Ranitidine.       5         1.2       Gastric proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole       5         1.3       Anti-neoplastic agents: Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Cisplatin       5         Alkylating agents: Mechlorethamine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.       5		Study of the development of the following classes of drugs, Classification,	
1       UNIT - I       10         1.1       Antihistaminic agents: Histamine, receptors, and their distribution in the human body.       4         H1-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelennamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride*, Buclizine hydrochloride, Chlorcyclizine hydrochloride*, Meclizine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine, Cromolyn sodium H2-antagonists: Cimetidine*, Famotidine, Ranitidine.         1.2       Gastric proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole       5         1.3       Anti-neoplastic agents: Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Cisplatin       5         Alkylating agents: Mechlorethamine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.       5		relationship of colority close of druge of specified in the course, Structure activity	
1       UNIT - I       10         1.1       Antihistaminic agents: Histamine, receptors, and their distribution in the human body.       4         H <sub>1</sub> -antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelennamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorcyclizine hydrochloride*, Meclizine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine, Cromolyn sodium H <sub>2</sub> -antagonists: Cimetidine*, Famotidine, Ranitidine.       1         1.2       Gastric proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole       5         1.3       Anti-neoplastic agents: Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Cisplatin       5         Alkylating agents: Mechlorethamine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.       5		drugs superscripted (*)	
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<ul> <li>body.</li> <li>H<sub>1</sub>-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelennamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine, Cromolyn sodium</li> <li>H<sub>2</sub>-antagonists: Cimetidine*, Famotidine, Ranitidine.</li> <li><b>1.2</b> Gastric proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole</li> <li><b>1.3</b> Anti-neoplastic agents: Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Cisplatin</li> <li>Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.</li> </ul>	1.1	Antinistaminic agents: Histamine, receptors, and their distribution in the human	4
<ul> <li>H<sub>1</sub>-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelennamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine, Cromolyn sodium H<sub>2</sub>-antagonists: Cimetidine*, Famotidine, Ranitidine.</li> <li>1.2 Gastric proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole</li> <li>Anti-neoplastic agents: Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Cisplatin Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.</li> </ul>		body.	
<ul> <li>succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelennamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine, Cromolyn sodium H2-antagonists: Cimetidine*, Famotidine, Ranitidine.</li> <li>1.2 Gastric proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole</li> <li>1.3 Anti-neoplastic agents: Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Cisplatin Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.</li> </ul>		$H_1$ -antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamine	
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Cyproheptadine       hydrochloride, Azatidine       maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine, Cromolyn sodium         H2-antagonists:       Cimetidine*, Famotidine, Ranitidine.         1.2       Gastric proton pump inhibitors:       Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole         1.3       Anti-neoplastic agents:       5         Alkylating agents:       Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Cisplatin       5         Antimetabolites:       Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.       5		Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate,	
Cetirizine, Levocetirizine, Cromolyn sodium         H2-antagonists: Cimetidine*, Famotidine, Ranitidine.         1.2       Gastric proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole         1.3       Anti-neoplastic agents: Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Cisplatin         Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.		Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine,	
H2-antagonists: Cimetidine*, Famotidine, Ranitidine.         1.2       Gastric proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole         1.3       Anti-neoplastic agents: Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Cisplatin         Antimetabolites:       Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.		Cetirizine, Levocetirizine, Cromolyn sodium	
1.2       Gastric proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole       1         1.3       Anti-neoplastic agents: Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Cisplatin       5         Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.       5		H <sub>2</sub> -antagonists: Cimetidine*, Famotidine, Kanitidine.	
Pantoprazole       5         1.3       Anti-neoplastic agents:       5         Alkylating agents:       Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Cisplatin       5         Antimetabolites:       Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.       5	1.2	Gastric proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole,	1
1.3       Anti-neoplastic agents:       5         Alkylating agents:       Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Cisplatin       5         Antimetabolites:       Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.       5		Pantoprazole	
Alkylating agents:Mechlorethamine*,Cyclophosphamide,Melphalan,Chlorambucil, Busulfan, Thiotepa, CisplatinAntimetabolites:Mercaptopurine*,Thioguanine,Fluorouracil,Floxuridine,Cytarabine,Methotrexate*,Azathioprine.	1.3	Anti-neoplastic agents:	5
Chlorambucil, Busulfan, Thiotepa, Cisplatin <b>Antimetabolites:</b> Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.		Alkylating agents: Mechlorethamine*, Cyclophosphamide, Melphalan,	
Antimetabolites: Mercaptopurine <sup>*</sup> , Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate <sup>*</sup> , Azathioprine.		Chlorambucil, Busulfan, Thiotepa, Cisplatin	
Cytarabine, Methotrexate <sup>*</sup> , Azathioprine.		Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine,	
		Cytarabine, Methotrexate*, Azathioprine.	
Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Mitoxantrone,		Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Mitoxantrone,	
Bleomycin.		Bleomycin.	
Plant products: Etoposide, Vinblastine sulphate, Vincristine sulphate, Taxol,		Plant products: Etoposide, Vinblastine sulphate, Vincristine sulphate, Taxol,	
Camptothecin.		Camptothecin.	
Tyrosine Kinase Inhibitors and HDAC inhibitors		Tyrosine Kinase Inhibitors and HDAC inhibitors	




2	UNIT - II	10
2.1	Anti-anginal:	7
	<b>Vasodilators:</b> Amyl nitrite. Nitroglycerine*. Pentaerythritol tetranitrate.	
	Isosorbide dinitrate*. Dipyridamole.	
	<b>Calcium channel blockers:</b> Verapamil, Bepridil hydrochloride, Diltiazem	
	hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine,	
	Diuretics:	
	Carbonic anhydrase inhibitors Acetazolamide* Methazolamide	
	Dichlornhenamide	
	Thiazides: Chlorthiazide* Hydrochlorothiazide Hydroflumethiazide	
	Cyclothiazide	
	Loop diuretics: Eurosemide* Bumetanide Ethacrynic acid	
	Potassium sparing diuretics: Spironolactone Triamterene Amiloride	
	Osmotic Diuretics: Mannitol.	
2.2	Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril	3
	hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine	-
	hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium	
	nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.	
3	UNIT - III	10
3.1	Anti-arrhythmic Drugs: Ouinidine sulphate. Procainamide hydrochloride.	4
	Disopyramide phosphate*. Phenytoin sodium, Lidocaine hydrochloride, Tocainide	-
	hydrochloride. Mexiletine hydrochloride. Lorcainide hydrochloride. Amiodarone.	
	Sotalol.	
3.2	Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholestyramine and	2
0.2	Colestipol.	-
3.3	Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*,	2
	Anisindione, Clopidogrel.	
3.4	Drugs used in Congestive Heart Failure: Digoxin	2
	Digitoxin, Nesiritide, Bosentan, Tezosentan.	
4	UNIT - IV	08
4.1	Drugs acting on Endocrine system	2
	Nomenclature, Stereochemistry, and metabolism of steroids.	_
4.2	Sex hormones: Testosterone, Nandralone, Progesterone, Estriol, Estradiol,	1
-	Estrione, Diethyl stilbestrol.	
4.3	Drugs for erectile dysfunction: Sildenafil, Tadalafil.	1
4.4	Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrel.	1
4.5	Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone,	2
	Dexamethasone.	
4.6	Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil,	1
	Methimazole.	
5	UNIT - V	07
5.1	Antidiabetic agents:	2
	Insulin and its preparations.	
	Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride.	
	Biguanides: Metformin.	
	Thiazolidinediones: Pioglitazone, Rosiglitazone.	
	Meglitinides: Repaglinide, Nateglinide.	
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	Glucosidase inhibitors: Acarbose, Voglibose.	
	GLP agonists, DPPIV inhibitors	
5.2	Local Anaesthetics:	5
	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.*	
	TOTAL	45

- 1. Beale J. M., Block J. H., Wilson and Gisvold's Textbook of Organic medicinal and Pharmaceutical Chemistry, 20<sup>th</sup> edition, Lippincott Williams & Wilkins Publishers, 2004.
- 2. Lemke T. L., Williams D. A., Roche V. F., Zito., S. W., Foye's Principles of Medicinal Chemistry, 7<sup>th</sup> edition, Lippincott Williams and Wilkins Publishers, 2001.
- 3. Abraham D. J., Burger's Medicinal Chemistry and Drug Discovery, Vol I to IV, 6<sup>th</sup> edition, John Wiley and Sons, Inc., Publication, 2003.
- 4. Smith H. J., Smith and Williams' Introduction to Principles of Drug Design and Action, 4<sup>th</sup> edition, Taylor and Francis Publications, CRC Press, 2005.
- 5. Remington, The Science and Practice of Pharmacy, 21<sup>st</sup> edition, Lippincott Williams and Wilkins Publication, 2005.
- 6. Robert Buckingham, Martindale: The Extra Pharmacopoeia, 40<sup>th</sup> edition, Pharmaceutical Press, 2020.
- 7. Finar I. L., Organic Chemistry, Vol. II, 4<sup>th</sup> edition, Pearson Publishing House, Longman, 1963.
- 8. Lednicer D., The Organic Chemistry of Drug Synthesis, Vol. 1-7, Wiley-Blackwell, 2007.
- 9. Indian Pharmacopoeia.
- 10. Vogel A.I., Vogel's textbook of Practical Organic Chemistry, 5<sup>th</sup> edition, Pearson Publishing House, India, 1989.

### BP502TINDUSTRIAL PHARMACY I (Theory)45 Hours

#### **Course Objectives**:

This course is designed to enable the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

#### **Course Outcomes:**

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

- 1. Know the various pharmaceutical dosage forms and their manufacturing techniques.
- 2. Know various considerations in development of pharmaceutical dosage forms.
- 3. Formulate solid, liquid, and semisolid dosage forms and evaluate them for their quality.





Unit	Details	Hours
1	UNIT - I - Preformulation Studies	7
1.1	Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.	1
1.2	<i>Physical properties:</i> Solid state properties – crystalline and amorphous, polymorphism, particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), lipophilicity.	2
1.3	<ul> <li>Stability – Chemical :</li> <li>a) Hydrolysis, oxidation, reduction, decarboxylation, racemisation, polymerization, Hygroscopicity, Loss of moisture, Loss of volatile components, Excipient compatibility, Package (container &amp; closure) compatibility.</li> <li>b) Biopharmaceutical considerations- Dissolution &amp; Permeation; BCS classification of drugs.</li> </ul>	2
1.4	Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.	2
2	UNIT - II	10
2.1	Tabletsa. Introduction, ideal characteristics of tablets, classification of tablets. Excipients,Formulation of tablets, granulation methods, compression, and processingproblems. Equipment and tablet tooling. Packaging of tablets.b. Tablet coating: Types of coating, coating materials, formulation of coatingcomposition, methods of coating, equipment employed and defects in coating.c. Quality control tests: In process and finished product tests.d. Layout of tablet section.	8
2.2	<b>Liquid orals:</b> Formulation and large-scale manufacturing consideration of solutions, suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia. Layout of liquid section	2
3	UNIT - III	8
3.1	<i>Hard gelatin capsules:</i> Introduction, Extraction of gelatin and production of hard gelatin capsule shells. size of capsules, Types of Capsule fill formulations; Filling operation, finishing and special techniques of formulation of hard gelatin capsules. Other polymers used for Hard Capsule shells - like HPMC, Carageenan and Alginates Packagin, Storage and In process and final product quality control tests for raw materials and capsules. Layout of capsule section.	3
3.2	<i>Soft gelatin capsules:</i> Definition and uses. Nature of shell and capsule content, size of capsules, formulation considerations and importance of base adsorption and minimum/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules.	3
3.3	<b>Pellets:</b> Introduction, formulation requirements, pelletization process, equipment for manufacture of pellets.	2
4	UNIT - IV	10
4.1	<b>Parenteral Preparations</b> : Definition, types, routes of administration, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity. Preparation of water for injection and pyrogen control.	2

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4.2	Large-scale Production procedure, production facilities and controls. Layout and controls; HVAC; Classification of Clean Rooms and aseptic processing	1
4.3	Formulation of injections, sterile powders, emulsions, suspensions, large volume parenterals and lyophilized products, Sterilization methods (revision).	3
4.4	Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. In process and Quality control tests for injectables.	1
4.5	<b>Ophthalmic Preparations:</b> Introduction, formulation considerations; formulation of eyedrops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations.	3
5	UNIT - V	10
5.1	<b>Cosmetics:</b> Formulation and preparation of the following cosmetic preparations: Lipsticks, nail lacquers, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.	3
5.2	<b>Pharmaceutical Aerosols:</b> Definition, propellants, containers, valves, actuators, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.	3
5.3	<b>Packaging Materials Science:</b> 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.	4
	TOTAL	45

- Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms—tablets, Vol.1,2,3/edited by Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz, 2<sup>nd</sup> edition, Marcel Dekker Inc., New York, 1990.
- Liberman H.A, Lachman L, Pharmaceutical dosage forms. Parenteral Medications, volume 1, 2,3/edited by Avis K, Herbert A. Lieberman H. A. and Lachman L, Martin, M., 3<sup>nd</sup> edition, Marcel Dekker Inc. New York. 1993.
- 3. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3/edited by Herbert A. Lieberman, Martin, M., and Gilbert S. Banker, 2<sup>nd</sup> edition, Marcel Dekker Inc. New York,1998.
- 4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 4<sup>rd</sup> Edition. Marcel Dekker, 2002.
- 5. Remington, The Science and Practice of Pharmacy, 21<sup>st</sup> edition, Lippincott Williams and Wilkins Publication, 2005.
- 6. Lachman, L, Lieberman H.A., Kanig, J.L., The Theory and Practice of Industrial Pharmacy, 1<sup>st</sup> edition, Lea & Febiger, Philadelphia,1986.
- 7. Taylor, K., Aulton M.E., Pharmaceutics: The Science of Dosage Form Design, 2<sup>nd</sup> edition, Churchill Livingstone, Edinburgh, 2001.
- 8. Ansel H.C., Allen L.V., Pharmaceutical Dosage Forms and Drug Delivery Systems, 10<sup>th</sup> edition, Lippincott Williams and Walkins, USA, 2014.
- 9. Drug stability Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.
- 10. Salvatore J. Turco, Sterile dosage forms: their preparation and clinical applications, 4<sup>th</sup> edition, Wolters Kluwer India Pvt. Ltd, 2011.
- R.G. Harry , J. B. Wilkinson and R. J. Moore, Harry's Cosmeticology, 7<sup>th</sup> edition, Longman Scientific & Technical Publishers, 1994.
- 12. M. S. Balsam, E. Sagarin, S. D. Gerhon, S. J. Strianse and M. M. Rieger, Cosmetics Science and Technology, , Volumes 1,2 and 3. Wiley-Interscience, Wiley India Pvt. Ltd.





- 13. Hilda Butler, Poucher's Perfumes, cosmetics & Soaps, 10<sup>th</sup> edition, Klewer Academic Publishers, Netherlands, 2000.
- 14. BIS Guidelines for different cosmetic products.
- 15. Hanlon J., Robert J. Kelsey, "Handbook of Package Engineering" 2<sup>nd</sup> Edition, McGraw-Hill, New York. 1984.
- 16. Paine A., Packaging User's Handbook, 1<sup>st</sup> edition, Springer, 2019.

# BP503TPHARMACOLOGY-II (Theory)45 Hours

#### **Course Objectives:**

This course is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition explain the basic concepts of bioassay.

#### **Course Outcomes:**

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

- 1. Understand the mechanism of drug action and its relevance in the treatment of different diseases.
- 2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments.
- 3. Demonstrate the various receptor actions using isolated tissue preparation.
- 4. Appreciate correlation of pharmacology with related medical sciences.

Unit	Details	Hours
1	UNIT – I	10
	Pharmacology of drugs acting on cardiovascular 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.	
2	UNIT - II	10
2.1	Pharmacology of drugs acting on cardiovascular system	6
	a. Drug used in the therapy of shock.	
	b. Haematinics, coagulants and anticoagulants.	
	c. Fibrinolytics and anti-platelet drugs.	
	d. Plasma volume expanders.	
2.2	Pharmacology of drugs acting on urinary system	4
	a. Diuretics.	
	b. Anti-diuretics.	
3	UNIT - III	10
	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.	

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	e. Non-steroidal anti-inflammatory agents.	
	f. Anti-gout drugs.	
	g. Cytokines	
	h. Histamine, 5-HT and their antagonists.	
	i. Prostaglandins, Thromboxanes and Leukotrienes.	
	j. Angiotensin, Bradykinin and Substance P.	
	k. Non-steroidal anti-inflammatory agents.	
	1. Antirheumatic drugs.	
4	UNIT - IV	08
	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.	
5	UNIT - V	07
5.1	Pharmacology of drugs acting on endocrine system	4
	a. Androgens and Anabolic steroids.	
	b. Estrogens, progesterone and oral contraceptives.	
	c. Drugs acting on the uterus.	
5.2	Bioassays	3
	a. Principles and applications of bioassays.	
	b. Types of bioassays.	
	c. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis,	
	histamine and 5-HT.	
	TOTAL	45

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, 9<sup>th</sup> edition, Churchill Livingstone Elsevier., 2019.
- 2. Ritter J. M., Flower R. J., Henderson G, Loke Y, MacEwan D, Rang H., Rang and Dale's Pharmacology, 9<sup>th</sup> edition, Elsevier Health, London 2019.
- 3. Katzung B. G., Masters S. B., Trevor A. J., Basic and Clinical Pharmacology, 14<sup>th</sup> edition, Tata Mc Graw-Hill Education, Pvt. Ltd, 2017
- 4. Brunton, L.L., Hilal-Dandan R, Knollman, B., Goodman and Gilman's The Pharmacological Basis of Therapeutics; 13th edition, McGraw-Hill Education, New York, 2017.
- 5. 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
- 6. Zeind C.S., Carvahlo M.G., Applied Therapeutics: The Clinical Use of Drugs, 11<sup>th</sup> edition, Wolters Kluwer, Philadelphia,2018
- 7. Harvey R, Clark MA, Finkel R., Rey, J.A., Whalen, K., Lippincott's Illustrated Reviews-Pharmacology, 5<sup>th</sup> edition, Wolter's Kruwer, 2011.
- 8. Tripathi K.D., Essentials of Medical Pharmacology, 8<sup>th</sup> edition, Jaypee Brothers Medical Publishers (P) Ltd, New Delhi, 2019.
- 9. Sharma H. L., Sharma K. K., Principles of Pharmacology, 1<sup>st</sup> edition, Paras Medical Publisher, 2017.





- 10. Craig C.R., Stitzel, R.E, Modern Pharmacology with clinical Applications, 1<sup>st</sup> edition, Lippincott Williams and Wilkins, Philadelphia, 2004
- 11. Ghosh MN. Fundamentals of Experimental Pharmacology, 6<sup>th</sup> edition, Hilton & Company, Kolkata, 2015.
- 12. Kulkarni SK. Handbook of experimental pharmacology, 4<sup>th</sup> edition, Vallabh Prakashan, 2012.
- 13. Satoskar R.S. Bhandarkar S.D., Tripathi, R.K., Rege N. N., 25<sup>th</sup> edition, Pharmacology & Therapeutics, Elsevier co-published with Popular Prakashan, 2017.
- 14. Kasture, S. B., A handbook of Experiments in Pre-Clinical Pharmacology, 1<sup>st</sup> edition, Career Publications, Nasik, 2009.

#### <u>BP504T</u>

#### PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory) 45 Hours

#### **Course Objectives:**

The aim of this course is to impart the students the knowledge of how secondary metabolites are produced in plants, how to isolate them, identify them, and produce them industrially. The course will also impart knowledge of growth and cultivation of plants, production of phytochemicals through plant tissue culture, drug herb interactions and basic principles of traditional system of medicine.

#### **Course Outcomes:**

Upon completion of the course, the student shall be able:

1. To know the modern extraction techniques, Characterization, and identification of the herbal drugs and phytoconstituents.

- 2. To understand the preparation and development of herbal formulation.
- 3. To understand the herbal drug interactions.

4. To carryout isolation and identification of phytoconstituents.

Unit	Details	Hours
1	UNIT - I - Metabolic pathways in higher plants and their determination.	7
1.1	Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathway and Amino acid pathways.	4
1.2	Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.	3
2	UNIT - II – General introduction, composition, chemistry & chemical classes,	14
	general methods of extraction & analysis, biosources, therapeutic uses and	
	commercial applications of following secondary metabolites.	
2.1	Alkaloids: Vinca, Rauwolfia, Belladonna, Opium, Cinchona	2
2.2	Phenylpropanoids and Flavonoids: Lignans-Podophyllum, Tea, Ruta.	2
2.3	Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis.	2
2.4	Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander.	2
2.5	Tannins: Catechu, Pterocarpus, Galls	1
2.6	Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony.	2

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2.7	Glycosides: Senna, Aloes, Cascara, Rhubarb, Bitter Almond, Mustard	1
2.8	Iridoids- Gentian, Other terpenoids - Diterpenes: Taxus, Sesquiterpenes:	2
	Artemesia, Tetraterpenes - carotenoids- Carotene, Lutein & Naphthaquinones:	
	Plumbago, Henna	
3	UNIT - III	6
	Isolation, identification, and analysis of phytoconstituents	
	1. Terpenoids: Menthol, Citral, Artemisinin.	
	2. Glycosides: Glycyrrhetinic acid and Rutin.	
	3. Alkaloids: Atropine, Quinine, reserpine, Caffeine.	
	4. Resins: Podophyllotoxin, curcumin.	
4	UNIT - IV	6
	Industrial production, estimation, and utilization of the following phytoconstituents:	
	Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin,	
	Caffeine, Taxol, Vincristine and Vinblastine.	
5	UNIT - V - Basics of Phytochemistry	10
	Modern methods of extraction, application of latest techniques like Spectroscopy,	
	chromatography and electrophoresis in the isolation, purification and identification	
	of crude drugs.	
	TOTAL	45

- 1. Evans W.C, Trease and Evans, Pharmacognosy, 16<sup>th</sup> edition, W.B. Sounders & Co., London, 2009.
- 2. Tyler, V.E, Brady, L.R. and Robbers, J.E., Pharmacognosy, 9<sup>th</sup> Edn., Lea and Febiger, Philadelphia, 1988.
- 3. Wallis T.E, Textbook of Pharmacognosy, 5<sup>th</sup> edition, J & A Churchill Ltd, London, 2005.
- 4. Mohammad Ali, Pharmacognosy and Phytochemistry, 1<sup>st</sup> edition, CBS Publishers & Distributors, New Delhi, 2018 reprint
- 5. Kokate C.K., Purohit A. P., Gokhale S.B., Textbook of Pharmacognosy, 37<sup>th</sup> Edition, Nirali Prakashan, New Delhi, 2007.
- 6. Choudhary R.D, Herbal Drug Industry, 1<sup>st</sup> edition, Eastern Publishers, New Delhi. 1996.
- 7. Ansari S. H., Essentials of Pharmacognosy, 2<sup>nd</sup> edition, Birla Publications, New Delhi, 2007.
- 8. Kokate C.K., Purohit A. P., Gokhale S.B, Practical Pharmacognosy, 13<sup>th</sup> edition, Nirali Prakashan, New Delhi, 2009.
- 9. Iyengar M.A and Nayak S.G.K, Anatomy of Crude Drugs, 12<sup>th</sup> edition, PharmaMed Press, A unit of BSP books Pvt. Ltd, Hyderabad, 2011.
- 10. Khandelwal K. R. and Vrunda Sethi, Practical Pharmacognosy: Techniques and Experiments, 24<sup>th</sup> edition, Nirali Prakashan, 2014.
- 11. Vasudevan T. N. Laddha K. S, Practical Pharmacognosy, New Vrinda Publishing House, Jalgaon, 1987.
- 12. Shah B.A., Seth A, Textbook of Pharmacognosy and Phytochemistry, 1st edition, Elsevier Publications, A division of Reed Elsevier India Pvt. Ltd, New Delhi, 2010.
- 13. Remington, The Science and Practice of Pharmacy, 21<sup>st</sup> edition, Lippincott Williams and Wilkins Publication, 2005.
- 14. Pharmacognosy & Pharmacobiotechnology. Eds. Bobbers JE, Speedie MK, and Tyler VE, Williams and Wikins, 1996.
- 15. Vyas SP and Dixit VK, Text Book of Biotechnology, 1<sup>st</sup> edition, CBS Publishers, 2012.
- 16. Dubey RC, A Textbook of Biotechnology, 5<sup>th</sup> edition, S Chand Publishers, 2014.
- 17. Appel L, The formulation and preparation of cosmetic, fragrances and flavours, 2<sup>nd</sup> edition, Micelle Press, 1994.





- 18. Panda H, Herbal Cosmetics, 3<sup>rd</sup> revised edition, Asia Pacific Business Press, 2015.
- 19. R Endress, Plant cell Biotechnology, 1<sup>st</sup> edition, Springer-Verlag Berlin Heidelberg, 1994.

# BP505T PHARMACEUTICAL JURISPRUDENCE (Theory) 45 hours

#### **Course Objectives:**

This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India.

#### **Course Outcomes**:

Upon completion of the course, the student shall have knowledge of:

- 1. Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
- 2. Various Indian pharmaceutical Acts and Laws
- 3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.
- 4. The code of ethics for pharmaceutical practice.

Unit	Details	Hours
1	UNIT - I - Drugs and Cosmetics Act, 1940 and its rules 1945	10
1.1	Objectives, Definitions, Legal definitions of schedules to the act and rules.	3
1.2	Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.	2
1.3	Manufacture of drugs – Prohibition of manufacture and sale of certain drugs. Regulations pertaining to manufacture, Sale, Labelling and Packaging of <b>Allopathic</b> , Avurvedic and Homeopathic drugs	2
1.4	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.	3
2	UNIT - II - Drugs and Cosmetics Act, 1940 and its rules 1945.	10
2.1	Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Schedule F & DMR (OA).	4
2.2	Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties.	1
2.3	Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colours. Offences and penalties.	2
2.4	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.	3
3	UNIT - III	10
3.1	<b>Pharmacy Act –1948</b> : 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.	3
3.2	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.	3





	Offences and Penalties.	
3.3	Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives,	4
	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.	
4	UNIT - IV	08
4.1	Study of Salient Features of Drugs and magic remedies Act and its rules:	2
	Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted	
	advertisements, Offences and Penalties.	
4.2	Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional	3
	Animal Ethics Committee, Breeding and Stocking of Animals, Performance of	
	Experiments, Transfer and acquisition of animals for experiment, Records, Power to	
	suspend or revoke registration, Offences and Penalties.	
4.3	National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)-	3
	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).	
5	UNIT - V	07
5.1	Pharmaceutical Legislations – A brief review, Introduction, Study of drugs	1
	enquiry committee, Health survey and development committee, Hathi committee	
	and Mudaliar committee.	
5.2	Code of Pharmaceutical ethics Definition, Pharmacist in relation to his job, trade,	1
	medical profession and his profession, Pharmacist's oath.	
5.3	Medical Termination of Pregnancy Act	1
5.4	Right to information Act	1
5.5	Introduction to Intellectual Property Rights (IPR)	3
	TOTAL	45

- 1. Suresh B, A textbook of Forensic Pharmacy,1<sup>st</sup> edition, Birla Publications Pvt Ltd, 2010.
- 2. Mithal BM, Textbook of Forensic Pharmacy, 10<sup>th</sup> edition, Vallabh Prakashan, 1999.
- 3. Mehra ML, Handbook of drug law, 9<sup>th</sup> edition, Universal Book Agency, 1997.
- 4. Jain NK, A textbook of Forensic Pharmacy, Vallabh Prakashan, 2017.
- 5. Drugs and Cosmetics Act 1940 and Rules 1945 by Govt. of India Publications.
- 6. Medicinal and Toiletries 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 1954 by Govt. of India Publications.
- 9. Bare Acts of the said laws published by Government of India.





#### BP506P INDUSTRIAL PHARMACY(Practical)

#### **Course Objectives:**

This course is designed to impart the student skills to understand and apply the formulation principles and techniques of solid, parenteral, ophthalmic, and cosmetic formulations. The course also aims at providing the students knowledge of various quality control tests of these dosage forms.

#### **Course Outcomes:**

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

- 1. Know the formulation and preparation techniques of solid oral dosage forms.
- 2. Know formulation considerations in development of sterile dosage forms.
- 3. Formulate solid, liquid, and semisolid dosage forms and evaluate them for their quality.

#### LIST OF EXPERIMENTS

- 1. Preformulation studies on 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. (Demonstration)
- 5. Preparation and evaluation of Tetracycline capsules/Ampicillin trihydrate 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 and rubbers (as per IP).
- 12. Evaluation of water for injection as per IP

#### **Recommended Books: (Latest Editions to be adopted):**

- Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms—tablets, Vol.1,2,3/edited by Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz, 2<sup>nd</sup> edition, Marcel Dekker Inc., New York, 1990.
- 2. Liberman H.A, Lachman L, Pharmaceutical dosage forms. Parenteral Medications, volume 1, 2,3/edited by Avis K, Herbert A. Lieberman H. A. and Lachman L, Martin, M., 3<sup>nd</sup> edition, Marcel Dekker Inc. New York. 1993.
- 3. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3/edited by Herbert A. Lieberman, Martin, M., and Gilbert S. Banker, 2<sup>nd</sup> edition, Marcel Dekker Inc. New York,1998.
- 4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 4rd Edition. Marcel Dekker, 2002.
- 5. Remington, The Science and Practice of Pharmacy, 21<sup>st</sup> edition, Lippincott Williams and Wilkins Publication, 2005.
- Lachman, L, Lieberman H.A., Kanig, J.L., The Theory and Practice of Industrial Pharmacy, 1<sup>st</sup> edition, Lea & Febiger, Philadelphia,1986
- 7. Taylor, K., Aulton M.E., Pharmaceutics: The Science of Dosage Form Design, 2<sup>nd</sup> edition, Churchill Livingstone, Edinburgh, 2001.





- 8. Ansel H.C., Allen L.V., Pharmaceutical Dosage Forms and Drug Delivery Systems, 10<sup>th</sup> edition, Lippincott Williams and Walkins, USA, 2014.
- 9. Drug stability Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

#### <u>BP507P</u>

#### PHARMACOLOGY-II (Practical)

#### **Course Objectives:**

This course will impart training to understand the concept of bioassay in experimental pharmacology. Students will also gain knowledge about the conduct of pharmacological activities like anti-inflammatory, analgesic and also determination of PD<sub>2</sub> and PA<sub>2</sub> values of various drugs using simulated audio-visual aids.

#### **Course Outcomes:**

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

1. Explain the various bioassays and their significance.

2. Differentiate between the different types of bioassays.

3. Describe the determination of PA2 and PD2 values along with the significance.

4. Observe the effect of drugs on animals by simulated experiments and interpret the pharmacological actions.

#### **LIST OF EXPERIMENTS**

- 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.
- 6. 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.
- 11. Determination of PA<sub>2</sub> value of prazosin using rat anococcygeus muscle (by Schild's plot method).
- 12. Determination of PD<sub>2</sub> 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 using softwares and videos

#### **Recommended Books (Latest Editions to be adopted):**

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, 9<sup>th</sup> edition, Churchill Livingstone Elsevier., 2019.
- 2. Ritter J. M., Flower R. J., Henderson G, Loke Y, MacEwan D, Rang H., Rang and Dale's Pharmacology, 9<sup>th</sup> edition, Elsevier Health, London 2019.

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- Katzung B. G., Masters S. B., Trevor A. J., Basic and Clinical Pharmacology, 14<sup>th</sup> edition, Tata Mc Graw-Hill Education, Pvt. Ltd, 2017
- 4. Brunton, L.L., Hilal-Dandan R, Knollman, B., Goodman and Gilman's The Pharmacological Basis of Therapeutics; 13th edition, McGraw-Hill Education, New York, 2017.
- 5. 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
- 6. Zeind C.S., Carvahlo M.G., Applied Therapeutics: The Clinical Use of Drugs, 11<sup>th</sup> edition, Wolters Kluwer, Philadelphia,2018
- 7. Harvey R, Clark MA, Finkel R., Rey, J.A., Whalen, K., Lippincott's Illustrated Reviews-Pharmacology, 5<sup>th</sup> edition, Wolter's Kruwer, 2011.
- 8. Tripathi K.D., Essentials of Medical Pharmacology, 8<sup>th</sup> edition, Jaypee Brothers Medical Publishers (P) Ltd, New Delhi, 2019.
- 9. Sharma H. L., Sharma K. K., Principles of Pharmacology, 1<sup>st</sup> edition, Paras Medical Publisher, 2017.
- 10. Craig C.R., Stitzel, R.E, Modern Pharmacology with clinical Applications, 1<sup>st</sup> edition, Lippincott Williams and Wilkins, Philadelphia, 2004
- 11. Ghosh MN. Fundamentals of Experimental Pharmacology, 6<sup>th</sup> edition, Hilton & Company, Kolkata, 2015.
- Kulkarni SK. Handbook of experimental pharmacology, 4<sup>th</sup> edition, Vallabh Prakashan, 2012.
- 13. Satoskar R.S. Bhandarkar S.D., Tripathi, R.K., Rege N. N., 25<sup>th</sup> edition, Pharmacology & Therapeutics, Elsevier co-published with Popular Prakashan, 2017.
- 14. Kasture, S. B., A handbook of Experiments in Pre-Clinical Pharmacology, 1<sup>st</sup> edition, Career Publications, Nasik, 2009.

#### <u>BP508P</u> PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

#### **Course Objectives:**

The course is designed to impart basic skills of crude drug identification, extraction, isolation and evaluation by techniques including chromatography.

#### **Course Outcomes:**

Upon completion of the course, the student shall be able to:

- 1. Perform microscopic evaluation of crude drugs.
- 2. Carry out extraction of crude drugs and isolate selected phytoconstituents.
- 3. Detect presence of specific phytoconstituents by chemical tests
- 4. Perform evaluation of crude drug extracts and isolates by chromatographic techniques.

#### **LIST OF EXPERIMENTS**

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander.

2. Exercise involving isolation & detection of active principles. Caffeine - from tea dust.





Diosgenin from Dioscorea Atropine from Belladonna Sennosides from Senna

- 3. Separation of sugars by Paper chromatography.
- 4. TLC of herbal extract.
- 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.

#### **Recommended Books:** (Latest Editions to be adopted):

- 1. Evans W.C, Trease and Evans, Pharmacognosy, 16<sup>th</sup> edition, W.B. Sounders & Co., London, 2009.
- 2. Tyler, V.E, Brady, L.R. and Robbers, J.E., Pharmacognosy, 9<sup>th</sup> Edn., Lea and Febiger, Philadelphia, 1988.
- 3. Wallis T.E, Textbook of Pharmacognosy,5<sup>th</sup> edition, J & A Churchill Ltd, London, 2005.
- 4. Mohammad Ali, Pharmacognosy and Phytochemistry, 1<sup>st</sup> edition, CBS Publishers & Distributors, New Delhi.2018 reprint.
- 5. Kokate C.K., Purohit A. P., Gokhale S.B., Textbook of Pharmacognosy, 37<sup>th</sup> Edition, Nirali Prakashan, New Delhi, 2007
- 6. Choudhary R.D, Herbal Drug Industry, 1<sup>st</sup> edition, Eastern Publishers, New Delhi. 1996
- 7. Ansari S. H., Essentials of Pharmacognosy, 2<sup>nd</sup> edition, Birla Publications, New Delhi, 2007
- 8. Kokate C.K., Purohit A. P., Gokhale S.B, Practical Pharmacognosy, 13<sup>th</sup> edition, Nirali Prakashan, New Delhi, 2009.
- 9. Iyengar M.A and Nayak S.G.K, Anatomy of Crude Drugs, 12<sup>th</sup> edition, PharmaMed Press, A unit of BSP books Pvt. Ltd, Hyderabad, 2011.
- 10. Vasudevan T. N. and Laddha K. S, Practical Pharmacognosy, New Vrinda Publishing House, Jalgaon, 1987.
- 11. Shah B.A., Seth A, Textbook of Pharmacognosy and Phytochemistry, 1st edition, Elsevier Publications, A division of Reed Elsevier India Pvt. Ltd, New Delhi, 2010.
- 12. Remington, The Science and Practice of Pharmacy, 21<sup>st</sup> edition, Lippincott Williams and Wilkins Publication, 2005.
- 13. Pharmacognosy & Pharmacobiotechnology. Eds. Bobbers JE, Speedie MK, and Tyler VE, Williams and Wikins, 1996.
- 14. Vyas SP and Dixit VK, Textbook of Biotechnology, 1<sup>st</sup> edition, 2012, CBS Publishers.
- 15. Dubey RC, A Textbook of Biotechnology, 5<sup>th</sup> edition, S Chand Publishers, 2014.
- 16. Appel L, The formulation and preparation of cosmetic, fragrances and flavours, 2<sup>nd</sup> edition, Micelle Press, 1994.
- 17. Panda H, Herbal Cosmetics, 3<sup>rd</sup> revised edition, Asia Pacific Business Press, 2015
- 18. R Endress, Plant cell Biotechnology, 1<sup>st</sup> edition, Springer-Verlag Berlin Heidelberg, 1994.





# SEMESTER VIBP601TMEDICINAL CHEMISTRY – III (Theory)45 Hours

#### **Course Objectives:**

This course is designed to impart fundamental knowledge on the structure, chemistry, and therapeutic value of drugs. Modern techniques of rational drug design like quantitative structure activity relationship (QSAR), prodrug concept, combinatorial chemistry and computer aided drug design (CADD) are part of the scope of the course. The course also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

#### **Course Outcomes:**

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

- 1. Understand the importance of drug design and different techniques of drug design.
- 2. Understand the chemistry of drugs with respect to their biological activity.
- 3. Know the metabolism, adverse effects and therapeutic value of drugs.
- 4. Appreciate and understand the importance of SAR of drugs.

Unit	Details	Hours
	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 (*).	
1	UNIT - I	12
	<ul> <li>Antibiotics</li> <li>Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.</li> <li>(a) β-Lactam antibiotics: Penicillin, Cephalosporins, β Lactamase inhibitors, Monobactams, Carbapenams, Imipenam.</li> <li>(b) Aminoglycosides: Streptomycin, Neomycin, Kanamycin.</li> <li>(c) Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline.</li> <li>(d) Macrolide: Erythromycin Clarithromycin, Azithromycin.</li> <li>(e) Miscellaneous: Chloramphenicol*, Clindamycin.</li> </ul>	
2	UNIT - II	08
	Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes. <b>Antimalarials:</b> Etiology of malaria. <b>Quinolines:</b> SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine. <b>Biguanides and dihydro triazines:</b> Cycloguanil pamoate, Proguanil. <b>Miscellaneous:</b> Pyrimethamine, Artesunete, Artemether, Atovoquone.	





3	UNIT - III	10
3.1	Anti-tubercular Agents:	3
	(a) Synthetic anti tubercular agents: Isoniazid*, Ethionamide, Ethambutol,	
	Pyrazinamide, Para amino salicylic acid.*	
	(b) Anti-tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine,	
	Streptomycin, Capreomycin sulphate.	-
3.2	Urinary tract anti-infective agents:	3
	<ul> <li>(a) Quinolones: SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin.</li> </ul>	
	(b) <b>Miscellaneous:</b> Furazolidine, Nitrofurantoin <sup>*</sup> , Methanamine.	
3.3	Antiviral agents:	4
	Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride,	
	Acyclovir <sup>*</sup> , Ganciclovir, Zidovudine, Didanosine, Zaicitabine, Lamivudine,	
4	Lovinde, Delavindine, Eravitenz, Kioavinin, Saquinavin, Indinavin, Kitonavin.	08
- <del>-</del> - <u>4</u> 1	Antifungal agants:	2
4.1	(a) Antifungal antibiotics: Amphotericin-B Nystatin Natamycin Griseofulvin	4
	(b) <b>Synthetic Antifungal agents:</b> Clotrimazole, Econazole, Butoconazole,	
	Oxiconazole Tioconozole. Miconazole*. Ketoconazole. Terconazole.	
	Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.	
4.2	Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide,	1
	Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.	
4.3	Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*,	1
	Albendazole, Niclosamide, Oxamniquine, Praziquantel, Ivermectin	
4.4	Sulfonamides and Sulfones:	4
	Historical development, chemistry, classification, and SAR of Sulfonamides:	
	Sulfamethizole, Sulfisoxazole, Sulfamethazine, Sulfacetamide*, Sulphapyridine,	
	Sulfamethoxaole*, Sulfadiazine, Mefenide acetate, Sulfasalazine.	
	Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole	
_	Suitones: Dapsone*.	07
5	UNII - V Introduction to Dung Decign	<u> </u>
5.1	Various approaches used in drug design	3
	<b>Prodrugs:</b> Basic concepts and application of prodrugs design	
	Physicochemical parameters used in quantitative structure activity relationship	
	(OSAR) such as partition coefficient Hammet's electronic parameter. Taft's steric	
	parameter and Hansch analysis.	
	Pharmacophore modeling and docking techniques	
5.2	<b>Combinatorial Chemistry:</b> Concept and applications of	2
	Combinatorial chemistry: Solid phase and solution phase synthesis.	_
	TOTAL	45

- 1. Beale J. M., Block J. H., Wilson and Gisvold's Textbook of Organic medicinal and Pharmaceutical Chemistry, 20<sup>th</sup> edition, Lippincott Williams & Wilkins Publishers, 2004.
- 2. Lemke T. L., Williams D. A., Roche V. F., Zito., S. W., Foye's Principles of Medicinal Chemistry, 7<sup>th</sup> edition, Lippincott Williams and Wilkins Publishers, 2001.





- 3. Abraham D. J., Burger's Medicinal Chemistry and Drug Discovery, Vol I to IV, 6<sup>th</sup> edition, John Wiley and Sons, Inc., Publication, 2003.
- 4. Smith H. J., Smith and Williams' Introduction to Principles of Drug Design and Action, 4<sup>th</sup> edition, Taylor and Francis Publications, CRC Press, 2005.
- 5. Remington, The Science and Practice of Pharmacy, 21<sup>st</sup> edition, Lippincott Williams and Wilkins Publication, 2005.
- 6. Robert Buckingham, Martindale: The Extra Pharmacopoeia, 40<sup>th</sup> edition, Pharmaceutical Press, 2020.
- 7. Finar I. L., Organic Chemistry, Vol. II, 4th edition, Pearson Publishing House, Longman, 1963
- 8. Lednicer D., The Organic Chemistry of Drug Synthesis, Vol. 1-7, Wiley-Blackwell, 2007
- 9. Indian Pharmacopoeia.
- Vogel A.I., Vogel's textbook of Practical Organic Chemistry, 5<sup>th</sup> edition, Pearson Publishing House, India, 1989.

### BP602TPHARMACOLOGY-III (Theory)45 Hours

#### **Course Objectives:**

This course is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs used for respiratory and gastrointestinal diseases, infectious diseases, as part of immuno-pharmacology with emphasis on the principles of toxicology and Chronopharmacology.

#### **Course Outcomes:**

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

- 1. Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases.
- 2. Comprehend the principles of toxicology and treatment of various poisonings.
- 3. Appreciate correlation of pharmacology with related medical sciences.

Unit	Details	Hours
1	UNIT - I	10
1.1	Pharmacology of drugs acting on Respiratory system	5
	a. Anti - asthmatic drugs.	
	b. Drugs used in the management of COPD.	
	c. Expectorants and antitussives.	
	d. Nasal decongestants.	
	e. Respiratory stimulants.	
1.2	Pharmacology of drugs acting on the Gastrointestinal Tract	5
	a. Antiulcer agents.	
	b. Drugs for constipation and diarrhoea.	
	c. Appetite stimulants and suppressants.	
	d. Digestants and carminatives.	
	e. Emetics and anti-emetics.	
2	UNIT - II	10
	Chemotherapy	

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	a. General principles of chemotherapy.	
	b. Sulfonamides and cotrimoxazole.	
	c. Antibiotics - Penicillins, cephalosporins, chloramphenicol, macrolides,	
	quinolones and fluoroquinolones, tetracyclines and aminoglycosides,	
	Linezolid, fusidic acid, Clindamycin.	
3	UNIT - III	10
	Chemotherapy	
	a. Antitubercular agents.	
	b. Antileprotic agents.	
	c. Antifungal agents.	
	d. Antiviral drugs.	
	e. Anthelmintics.	
	f. Antimalarial drugs.	
	g. Antiamoebic agents.	
4	UNIT - IV	08
4.1	Chemotherapy	3
	a. Urinary tract infections and sexually transmitted diseases.	
	b. Chemotherapy of malignancy.	
4.2	Immunopharmacology	5
	a. Immunostimulants.	
	b. Immunosuppressant.	
	c. Protein drugs, monoclonal antibodies.	
	d. Antigen, biosimilars.	
5	UNIT - V	07
5.1	Principles of toxicology	6
	a. Definition and basic knowledge of acute, subacute and chronic toxicity.	
	b. Definition and basic knowledge of genotoxicity, hepatotoxicity,	
	nephrotoxicity, carcinogenicity, teratogenicity and mutagenicity.	
	c. General principles of treatment of poisoning.	
	d. Clinical symptoms and management of barbiturates, morphine,	
	organophosphorus compound and lead, mercury and arsenic poisoning.	
5.2	Chronopharmacology	1
	a. Definition of rhythm and cycles.	
	b. Biological clock and their significance leading to chronotherapy.	
	TOTAL	45

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, 9<sup>th</sup> edition, Churchill Livingstone Elsevier., 2019.
- 2. Ritter J. M., Flower R. J., Henderson G, Loke Y, MacEwan D, Rang H., Rang and Dale's Pharmacology, 9<sup>th</sup> edition, Elsevier Health, London 2019.
- 3. Katzung B. G., Masters S. B., Trevor A. J., Basic and Clinical Pharmacology, 14<sup>th</sup> edition, Tata Mc Graw-Hill Education, Pvt. Ltd, 2017
- 4. Brunton, L.L., Hilal-Dandan R, Knollman, B., Goodman and Gilman's The Pharmacological Basis of Therapeutics; 13th edition, McGraw-Hill Education, New York, 2017.
- 5. 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





- 6. Zeind C.S., Carvahlo M.G., Applied Therapeutics: The Clinical Use of Drugs, 11<sup>th</sup> edition, Wolters Kluwer, Philadelphia,2018
- 7. Harvey R, Clark MA, Finkel R., Rey, J.A., Whalen, K., Lippincott's Illustrated Reviews-Pharmacology, 5<sup>th</sup> edition, Wolter's Kruwer, 2011.
- 8. Tripathi K.D., Essentials of Medical Pharmacology, 8<sup>th</sup> edition, Jaypee Brothers Medical Publishers (P) Ltd, New Delhi, 2019.
- 9. Sharma H. L., Sharma K. K., Principles of Pharmacology, 1<sup>st</sup> edition, Paras Medical Publisher, 2017.
- 10. Craig C.R., Stitzel, R.E, Modern Pharmacology with clinical Applications, 1<sup>st</sup> edition, Lippincott Williams and Wilkins, Philadelphia, 2004
- 11. Ghosh MN. Fundamentals of Experimental Pharmacology, 6<sup>th</sup> edition, Hilton & Company, Kolkata, 2015.
- Kulkarni SK. Handbook of experimental pharmacology, 4<sup>th</sup> edition, Vallabh Prakashan, 2012.
- 13. Satoskar R.S. Bhandarkar S.D., Tripathi, R.K., Rege N. N., 25<sup>th</sup> edition, Pharmacology & Therapeutics, Elsevier co-published with Popular Prakashan, 2017.
- 14. Kasture, S. B., A handbook of Experiments in Pre-Clinical Pharmacology, 1<sup>st</sup> edition, Career Publications, Nasik, 2009.
- 15. Udupa N and Gupta PD, Concepts in Chronopharmacology, 1<sup>st</sup> edition, Shyam Prakashan, 2009.

#### <u>BP603T</u>

#### HERBAL DRUG TECHNOLOGY (Theory) 45 Hours

#### **Course Objectives:**

This course gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The course also emphasizes Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs.

#### **Course Outcomes:**

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

- 1. Understand raw material as source of herbal drugs from cultivation to herbal drug product.
- 2. Know the WHO and ICH guidelines for evaluation of herbal drugs.
- 3. Know the herbal cosmetics, natural sweeteners, nutraceuticals.
- 4. Appreciate patenting of herbal drugs, GMP.

Unit	Details	Hours
1	UNIT - I	11
1.1	Herbs as raw materials	3
	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.	
1.2	Biodynamic Agriculture	3
	Good agricultural practices in cultivation of medicinal plants including Organic	
	farming.	
	Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.	
1.3	Indian Systems of Medicine	5

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	Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy	
	Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas,	
	Gjutika, Churna, Lehya and Bhasma.	
2	UNIT - II	07
2.1	Neutraceuticals	2
	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.	
2.2	Study of following herbs as health food: Alfa alfa, Chicory, Ginger, Fenugreek,	2
	Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina.	_
2.3	Herbal-Drug and Herb-Food Interactions: General introduction to interaction	3
	and classification. Study of following drugs and their possible side effects and	
	interactions: Hypercium, kaya-kaya, Ginko biloba, Ginseng, Garlic, Pepper &	
	Ephedra.	
3	UNIT - III	10
3.1	Herbal Cosmetics	4
	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.	
3.2	Herbal excipients:	3
	Herbal Excipients – Significance of substances of natural origin as excipients –	-
	colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors &	
	perfumes.	
3.3	Herbal formulations:	3
	Conventional herbal formulations like syrups, mixtures and tablets and Novel	-
	dosage forms like phytosomes.	
4	UNIT - IV	10
4.1	<b>Evaluation of Drugs</b> WHO & ICH guidelines for the assessment of herbal drugs.	2
-	Stability testing of herbal drugs.	
4.2	Patenting and Regulatory requirements of natural products:	5
	1. Definition of the terms: Patent, IPR, Farmers right, Breeder's right,	
	Bioprospecting and Biopiracy	
	2. Patenting aspects of Traditional Knowledge and Natural Products. Case study of	
	Curcuma & Neem.	
4.3	Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of	3
	manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs	
5	UNIT - V	07
5.1	General Introduction to Herbal Industry	3
	Herbal drugs 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.	
5.2	Schedule T-Good Manufacturing Practice of Indian systems of medicine	4
	Components of GMP (Schedule $-T$ ) and its objectives.	
	Infrastructural requirements, working space, storage area, machinery and	
	equipment, standard operating procedures, health and hygiene, documentation and	
	records.	
	TOTAL	45

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- 1. Evans W.C, Trease and Evans, Pharmacognosy, 16<sup>th</sup> edition, W.B. Sounders & Co., London, 2009.
- 2. Tyler, V.E, Brady, L.R. and Robbers, J.E., Pharmacognosy, 9<sup>th</sup> Edn., Lea and Febiger, Philadelphia, 1988.
- 3. Wallis T.E, Textbook of Pharmacognosy, 5<sup>th</sup> edition, J & A Churchill Ltd, London, 2005.
- 4. Mohammad Ali, Pharmacognosy and Phytochemistry, 1<sup>st</sup> edition, CBS Publishers & Distributors, New Delhi, 2018 reprint.
- 5. Kokate C.K., Purohit A. P., Gokhale S.B., Textbook of Pharmacognosy, 37<sup>th</sup> Edition, Nirali Prakashan, New Delhi, 2007
- 6. Choudhary R.D, Herbal Drug Industry, 1<sup>st</sup> edition, Eastern Publishers, New Delhi. 1996
- Ansari S. H., Essentials of Pharmacognosy, 2<sup>nd</sup> edition, Birla Publications, New Delhi, 2007
- 8. Kokate C.K., Purohit A. P., Gokhale S.B, Practical Pharmacognosy, 13<sup>th</sup> edition, Nirali Prakashan, New Delhi, 2009.
- 9. Iyengar M.A and Nayak S.G.K, Anatomy of Crude Drugs, 12<sup>th</sup> edition, PharmaMed Press, A unit of BSP books Pvt. Ltd, Hyderabad, 2011.
- 10. Khandelwal K. R. and Vrunda Sethi, Practical Pharmacognosy: Techniques and Experiments, 24<sup>th</sup> edition, Nirali Prakashan, 2014.
- 11. Vasudevan T. N. Laddha K. S, Practical Pharmacognosy, New Vrinda Publishing House, Jalgaon, 1987.
- 12. Shah B.A., Seth A, Textbook of Pharmacognosy and Phytochemistry, 1st edition, Elsevier Publications, A division of Reed Elsevier India Pvt. Ltd, New Delhi, 2010.
- 13. Remington, The Science and Practice of Pharmacy, 21<sup>st</sup> edition, Lippincott Williams and Wilkins Publication, 2005.
- 14. Pharmacognosy & Pharmacobiotechnology. Eds. Bobbers JE, Speedie MK, and Tyler VE, Williams and Wikins, 1996.
- 15. Vyas SP and Dixit VK, Textbook of Biotechnology, 1st edition, 2012, CBS Publishers
- 16. Dubey RC, A Textbook of Biotechnology, 5<sup>th</sup> edition, S Chand Publishers, 2014.
- 17. Appel L, The formulation and preparation of cosmetic, fragrances and flavours, 2<sup>nd</sup> edition, Micelle Press, 1994.
- 18. Panda H, Herbal Cosmetics, 3<sup>rd</sup> revised edition, Asia Pacific Business Press, 2015.
- 19. R Endress, Plant cell Biotechnology1<sup>st</sup> edition, Springer-Verlag Berlin Heidelberg, 1994.
- 19. Pharmacopeial standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy).
- 20. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals, 1<sup>st</sup> edition, Business Horizons Publishers, New Delhi, India, 2012.

#### <u>BP604T</u>

#### BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory) 45 Hours

#### **Course Objectives:**

This course is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the mathematical problems therein.

#### **Course Outcomes:**

Upon completion of the course student shall be able to:





- 1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
- 2. Use plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- 3. Understand the concepts of bioavailability and bioequivalence of drug products and their significance.

4. Understand various pharmacokinetic parameters, their significance & applications.

Unit	Details	Hours
1	UNIT - I	10
1.1	Introduction to Biopharmaceutics	1
1.2	<b>Absorption</b> : Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes.	5
1.3	<b>Distribution</b> : Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs.	4
2	UNIT - II	10
2.1	<b>Drug Elimination:</b> Metabolism of drugs and factors affecting metabolism, hepatic clearance, Renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non-renal routes of drug excretion of drugs.	3
2.2	<b>Bioavailability and Bioequivalence:</b> Definition and Objectives of bioavailability studies, absolute and relative bioavailability, measurement of bioavailability, methods of dissolution measurement, factors affecting dissolution, comparison of dissolution profiles, in-vitro drug dissolution models, in-vitro, in-vivo correlations, bioequivalence studies, methods to enhance the bioavailability of poorly soluble drugs. BCS classification.	7
3	UNIT - III - Pharmacokinetics	22
	<ul> <li>Definition and introduction of pharmacokinetics, compartment models, Non-compartmental models, physiological models.</li> <li>One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion. c. Extra vascular administrations. Calculations of Ka, K<sub>E</sub>, t1/2, Vd, AUC, CLt, CLr, F abs, F rel and other parameters.</li> <li>Methods of elimination, understanding of their significance and application (Urine Data – Rate method and Sigma Minus Method).</li> <li>Kinetics of Multiple dosing, steady state drug level, calculation of loading and maintenance dose and their significance in clinical setting.</li> <li>Two compartment open model (IV bolus).</li> </ul>	
4	UNIT - IV	03
	<b>Nonlinear Pharmacokinetics:</b> a. Introduction, b. Factors causing Nonlinearity. c. Michaelis-Menten method of estimating parameters.	
	TOTAL	45

- 1. Gibaldi Milo, Biopharmaceutics and Clinical Pharmacokinetics. 4<sup>th</sup> Edition, 2005, Pharma Book Syndicate, Hyderabad.
- 2. Biopharmaceutics and Pharmacokinetics, Robert F Notari Eds, 1975, Marcel Dekker.





- 3. Applied Biopharmaceutics and Pharmacokinetics, Leon Shargel and Andrew B.C.Yu, 7th edition, 2016, McGraw Hill Education. USA.
- 4. Biopharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B. Jaiswal, 2015, Vallabh Prakashan, Pitampura, Delhi.
- 5. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercel Dekker Inc.
- 6. Handbook of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- 7. Rowland and Tozer's Clinical Pharmacokinetics and Pharmacodynamics-Concepts and Applications, Derendorf H and Schmidt S eds., 5<sup>th</sup> edition, 2019, Walters Kluver.
- 8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozer, Lea and Feibeger, Philadelphia, 1995.
- 9. Abdou H.M, Dissolution, Bioavailability and Bioequivalence, Mack, Publishing Company, Pennsylvania 1989.
- 10. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari, Marcel Dekker Inn, New York and Basel, 1987.
- 11. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania
- 12. Handbook of Basic Pharmacokinetics including clinical applications, Ritschel WA and Kearns GL, 7<sup>th</sup> edition, APhA, 2009,
- 13. Basic Pharmacokinetics, Jambhekar SS and Breen PJ, 2<sup>nd</sup> edition, Pharmaceutical Press, 2012.
- 14. Biopharmaceutics and Pharmacokinetics, Venkateshwarlu V, Pharma Book Syndicate, 2010.
- 15. Drug Bioavailability- Estimation of solubility, permeability, absorption and bioavailability, van der Waterbeemd H, Lennernas H and Artursson P, 2<sup>nd</sup> completely revised edition, Wiley VCH verlag, GmBH and Co, 2009.

#### <u>BP605T</u>

#### PHARMACEUTICAL BIOTECHNOLOGY (Theory) 45 Hours

#### **Course Objectives:**

This course is designed to introduce to the student the application of biotechnology in the field of genetic engineering, fermentation technology, diagnosis/prevention/cure of diseases, and for production of newer pharmaceutical drugs. The course will also introduce transgenic crops/animals and the contribution to healthcare.

#### **Objectives:**

Upon completion of the student shall be able to.

- 1. Understand the importance of rDNA technology in healthcare and drug development.
- 2. Importance of fermentations and immobilised cells/enzymes in production of pharmaceuticals.
- 3. Importance of Monoclonal antibodies in Industries.
- 4. Appreciate the concepts of immunology and vaccine production.

Unit	Details	Hours
1	UNIT - I	08
1.1	Brief introduction to Biotechnology with reference to Pharmaceutical Sciences	1

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1.2	Methods of enzyme/cell immobilization and applications.	2
1.3	Biosensors- Working and applications of biosensors in Pharmaceutical Industries.	1
1.4	Brief introduction to Protein Engineering.	2
1.5	Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.	2
2	UNIT - II - Basic principles of genetic engineering.	12
2.1	Study of cloning vectors, restriction endonucleases and DNA ligase.	2
2.2	Recombinant DNA technology. Application of genetic engineering in medicine.	2
2.3	Application of r DNA technology and genetic engineering in the products:	2
2.4	Interferon b) Vaccines- hepatitis- B c) Hormones- Insulin.	2
2.5	Brief introduction to PCR.	2
3	UNIT - III	10
	<ul> <li>Types of immunity- humoral immunity, cellular immunity</li> <li>a. Structure of Immunoglobulins.</li> <li>b. Structure and Function of MHC.</li> <li>c. Hypersensitivity reactions, Immune stimulation and Immune suppressions.</li> <li>d. General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.</li> <li>e. Storage conditions and stability of official vaccines.</li> <li>f. Hybridoma technology- Production, Purification and Applications.</li> <li>g. Blood products and Plasma Substitutes.</li> </ul>	
4	UNIT - IV	08
4.1	Immunoblotting techniques- ELISA, Western blotting, Southern blotting.	2
4.2	Genetic organization of Eukaryotes and Prokaryotes.	1
4.3	Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.	2
4.4	Introduction to Microbial biotransformation and applications.	2
4.5	Mutation.: Types of mutation/ mutants.	1
5	UNIT - V	07
5.1	Fermentation methods and general requirements, study of media, equipment, sterilization methods, aeration process, stirring.	2
5.2	Large scale production fermenter design and its various controls.	1
5.3	Study of the production of - Penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin.	2
5.4	Blood product collection, Processing and storage of whole volume blood, dried human plasma, plasma substituents.	2
	TOTAL	45

- B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: 5<sup>th</sup> edition, 2017, Taylor and Francis
   Kuby Immunology, Punt J et al eds, 8<sup>th</sup> edition, WH Freeman, 2018.
   J.W. Goding: Monoclonal Antibodies Principles and Practice, 3<sup>rd</sup> edition, Academic Press, 1996.





- 4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology, 4<sup>th</sup> edition, Royal Society of Chemistry, 2000.
- 5. Zaborsky O, Immobilized Enzymes, 1973, CRC Press, Cleveland, Ohio.
- 6. S.B. Primrose: Molecular Biotechnology (2nd Edition), 1992, Wiley Blackwell.
- 7. Stanbury F., P., Whitakar A., and Hall S. J., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi, 1995.

### BP606T PHARMACEUTICAL QUALITY ASSURANCE (Theory) 45 Hours

#### **Course Objectives:**

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

#### **Course Outcomes:**

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

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

Unit	Details	Hours
1	UNIT - I	10
1.1	Quality Assurance and Quality Management concepts: Definition and concept	4
	of Quality control, Quality assurance and cGMP, Quality agreements, Site Master	
	files	
1.2	Total Quality Management (TQM): Definition, elements, philosophies.	2
1.3	ICH Guidelines: purpose, participants, process of harmonization, Brief overview	2
	of QSEM, with special emphasis on Q-series guidelines, ICH stability testing	
	guidelines. Pharmaceutical audit.	
1.4	QbD: Definition, overview, elements of QbD program, tools. Design of	1
	experiments (DOE)	
	ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration.	
1.5	<b>NABL accreditation</b> : Principles and procedure.	1
2	UNIT - II	10
2.1	Organization and personnel: Personnel responsibilities, training, hygiene and	5
	personal records.	
	Premises: Design, construction and plant layout, maintenance, sanitation,	
	environmental control, utilities and maintenance of sterile areas, control of	
	contamination.	
2.2	Equipment and raw materials: Equipment selection, purchase specifications,	5
	maintenance, Purchase specifications and maintenance of stores for raw materials.	
	vendor selection and qualification	
3	UNIT - III	10

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3.1	Quality Control: Quality control test for raw materials, primary (Containers,	5
	closures) and secondary packing materials. Microbiological testing.	
3.2	Good Laboratory Practices: General Provisions, Organization and Personnel,	5
	Facilities, Equipment, Testing Facilities Operation, Test and Control Articles,	
	Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports,	
	Disqualification of Testing Facilities.	
4	UNIT - IV	08
4.1	Complaints: Complaints and evaluation of complaints, Handling of return good,	2
	recalling and waste disposal.	
4.2	Document maintenance in pharmaceutical industry: Batch Formula Record,	6
	Master Formula.	
	Record, SOP, Quality audit, Quality Review and Quality documentation, Reports	
	and documents, distribution records. Data Integrity.	
5	UNIT - V	07
5.1	Calibration and Validation: Introduction, definition and general principles of	6
	calibration, qualification and validation, importance and scope of validation, types	
	of validation, validation master plan. Calibration of pH meter, Qualification of	
	UV-Visible spectrophotometer, General principles of Analytical method	
	Validation., Cleaning validation, Sterilization process validation.	
5.2	Warehousing: Good warehousing practice, materials management.	1
	TOTAL	45

- 1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
- 2. Sandy Weinberg , Good Laboratory Practice Regulations, in Drugs and The Pharmaceutical Sciences, Vol. 69. 3<sup>rd</sup> edition revised and expanded, Marcel Dekker, Inc., 2002.
- 3. Quality Assurance of Pharmaceuticals- A compendium of Guidelines and Related materials Vol I, 1<sup>st</sup> edition, WHO , Geneva, 1997
- 4. Kushik Maitra and Sedhan K Ghosh, A guide to Total Quality Management.
- 5. P. P. Sharma, How to Practice GMP's, 7<sup>th</sup> edition, Vandana Publications, Delhi, 2015.
- 6. Sadhank G Ghosh., Introduction to ISO 9000 and Total Quality Management, 4<sup>th</sup> edition, Oxford Publishing House, 2007
- 7. The International Pharmacopoeia Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms.
- 8. A.F. Hirsch, Good laboratory Practices, Drugs and the Pharmaceutical Sciences, 1<sup>st</sup> edition, Marcel Dekker Inc, 1989
- 9. ICH guidelines, ISO 9000 and 14000 guidelines.
- 10. Cole Graham, Pharmaceutical Production Facilities, Design and Applications, 2<sup>nd</sup> edition, CRC Press, 2019.
- 11. Nash Robert A., Berry Ira R , Pharmaceutical Process Validation, Drugs and The Pharmaceutical Sciences, Volume 129, International 3<sup>rd</sup> edition revised and expanded, Marcel Dekker Inc, New York, 2003.

#### <u>BP607P</u> <u>MEDICINAL CHEMISTRY- III (Practical)</u>

#### **Course Objectives:**

To impart to the Learner the principles and techniques for multistep drug synthesis, purification, and assay

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of the synthesized drugs/ drug intermediates, on a small scale. To teach the Learners the methods to calculate/predict physicochemical parameters using computational tools.

#### **Course Outcomes:**

Upon completion of the laboratory training the learner should be able to:

- a. Set up single and multi-step synthetic reactions
- b. Monitor chemical reactions using TLC
- c. Purify the crude products of reaction workup.
- d. Quantify the purity of the synthesized compounds using Pharmacopoeial assay methods
- e. Apply green procedures via use of microwave reactions

f. Draw and visualize 3D structures of the drugs/ API and their interactions with proteins / peptides using Chemdraw software

g. Calculate physicochemical parameters of the drugs/ API using computational tools

#### **LIST OF EXPERIMENTS**

#### I. Preparation of drugs and intermediates

- Sulphanilamide
- 7-Hydroxy, 4-methyl coumarin
- Chlorobutanol
- Triphenyl imidazole
- Tolbutamide
- Hexamine

#### II. Assay of drugs

- Isonicotinic acid hydrazide
- Chloroquine
- Metronidazole

#### Dapsone

Chlorpheniramine maleate

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 (Lipinski's RO5).

#### **Recommended Books (Latest Editions to be adopted):**

- 1. Beale J. M., Block J. H., Wilson and Gisvold's Textbook of Organic medicinal and Pharmaceutical Chemistry, 20<sup>th</sup> edition, Lippincott Williams & Wilkins Publishers, 2004.
- 2. Lemke T. L., Williams D. A., Roche V. F., Zito., S. W., Foye's Principles of Medicinal Chemistry, 7<sup>th</sup> edition, Lippincott Williams and Wilkins Publishers, 2001.
- 3. Abraham D. J., Burger's Medicinal Chemistry and Drug Discovery, Vol I to IV, 6<sup>th</sup> edition, John Wiley and Sons, Inc., Publication, 2003.
- 4. Smith H. J., Smith and Williams' Introduction to Principles of Drug Design and Action, 4<sup>th</sup> edition, Taylor and Francis Publications, CRC Press, 2005.
- 5. Remington, The Science and Practice of Pharmacy, 21<sup>st</sup> edition, Lippincott Williams and Wilkins Publication, 2005. .
- 6. Robert Buckingham, Martindale: The Extra Pharmacopoeia, 40<sup>th</sup> edition, Pharmaceutical Press, 2020.

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- 7. Finar I. L., Organic Chemistry, Vol. II, 4<sup>th</sup> edition, Pearson Publishing House, Longman, 1963
- 8. Lednicer D., The Organic Chemistry of Drug Synthesis, , Vol. 1-7, Wiley-Blackwell, 2007
- 9. Indian Pharmacopoeia.
- 10. Vogel A.I., Vogel's textbook of Practical Organic Chemistry, 5<sup>th</sup> edition, Pearson Publishing House, India, 1989.

#### BP608P PHARMACOLOGY-III (Practical)

#### **Course Objectives:**

This course will impart training to learn the toxicity studies in experimental pharmacology. Students will also understand different animal models (preclinical studies) and biostatistical methods using simulated audio-visual aids.

#### **Course Outcomes:**

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

- 1. Describe dose calculations in pharmacological experiments.
- 2. Explain the types of toxicity studies.
- 3. Elaborate on different animal models.
- 4. Possess knowledge of biostatistical methods in experimental pharmacology.
- 5. Observe the effect of drugs on animals by simulated experiments and interpret the pharmacological actions.

#### LIST OF EXPERIMENTS

- 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).

\*Experiments are demonstrated by simulated experiments/videos





#### **Recommended Books (Latest Editions to be adopted):**

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, 9<sup>th</sup> edition, Churchill Livingstone Elsevier., 2019.
- 2. Ritter J. M., Flower R. J., Henderson G, Loke Y, MacEwan D, Rang H., Rang and Dale's Pharmacology, 9<sup>th</sup> edition, Elsevier Health, London 2019.
- 3. Katzung B. G., Masters S. B., Trevor A. J., Basic and Clinical Pharmacology, 14<sup>th</sup> edition, Tata Mc Graw-Hill Education, Pvt. Ltd, 2017
- 4. Brunton, L.L., Hilal-Dandan R, Knollman, B., Goodman and Gilman's The Pharmacological Basis of Therapeutics; 13th edition, McGraw-Hill Education, New York, 2017.
- 5. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, 9<sup>th</sup> edition, Lippincott Williams & Wilkins, 2009.
- 6. Zeind C.S., Carvahlo M.G., Applied Therapeutics: The Clinical Use of Drugs, 11<sup>th</sup> edition, Wolters Kluwer, Philadelphia, 2018
- 7. Harvey R, Clark MA, Finkel R., Rey, J.A., Whalen, K., Lippincott's Illustrated Reviews-Pharmacology, 5<sup>th</sup> edition, Wolter's Kruwer, 2011.
- 8. Tripathi K.D., Essentials of Medical Pharmacology, 8<sup>th</sup> edition, Jaypee Brothers Medical Publishers (P) Ltd, New Delhi, 2019.
- 9. Sharma H. L., Sharma K. K., Principles of Pharmacology, 1<sup>st</sup> edition, Paras Medical Publisher, 2017.
- 10. Craig C.R., Stitzel, R.E, Modern Pharmacology with clinical Applications, 1<sup>st</sup> edition, Lippincott Williams and Wilkins, Philadelphia, 2004
- 11. Ghosh MN. Fundamentals of Experimental Pharmacology, 6<sup>th</sup> edition, Hilton & Company, Kolkata, 2015.
- 12. Kulkarni SK. Handbook of experimental pharmacology, 4<sup>th</sup> edition, Vallabh Prakashan, 2012.
- 13. Satoskar R.S. Bhandarkar S.D., Tripathi, R.K., Rege N. N., 25<sup>th</sup> edition, Pharmacology & Therapeutics, Elsevier co-published with Popular Prakashan, 2017.
- 14. Kasture, S. B., A handbook of Experiments in Pre-Clinical Pharmacology, 1<sup>st</sup> edition, Career Publications, Nasik, 2009.
- 15. Udupa N and Gupta PD, Concepts in Chronopharmacology, 1<sup>st</sup> edition, Shyam Prakashan, 2009.

#### <u>BP609P</u> HERBAL DRUG TECHNOLOGY (Practical)

#### **Course Objectives:**

The course equips the student with skills to develop herbal formulations and evaluate them as per Pharmacopeial specifications.

#### **Course Outcomes:**

Upon completion of the course, the student shall be able to:

- 1. Perform evaluation of excipients and finished formulations of herbal origin, as per Pharmacopoeial specifications.
- 2. Develop solid and liquid formulations of herbal origin, for oral and topical use
- 3. Perform quantitative estimation of select phytoconstituents in herbal materials

#### LIST OF EXPERIMENTS

- 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
- 4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
- 5. 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

#### **Recommended Books: (Latest Editions to be adopted):**

- 1. Evans W.C, Trease and Evans, Pharmacognosy, 16<sup>th</sup> edition, W.B. Sounders & Co., London, 2009.
- 2. Tyler, V.E, Brady, L.R. and Robbers, J.E., Pharmacognosy, 9<sup>th</sup> Edn., Lea and Febiger, Philadelphia, 1988.
- 3. Wallis T.E, Textbook of Pharmacognosy, 5<sup>th</sup> edition, J & A Churchill Ltd, London, 2005.
- 4. Mohammad Ali, Pharmacognosy and Phytochemistry,1<sup>st</sup> edition, CBS Publishers & Distributors, New Delhi.2018 reprint.
- 5. Kokate C.K., Purohit A. P., Gokhale S.B., Textbook of Pharmacognosy, 37<sup>th</sup> Edition, Nirali Prakashan, New Delhi, 2007
- 6. Choudhary R.D, Herbal Drug Industry, 1<sup>st</sup> edition, Eastern Publishers, New Delhi. 1996
- 7. Ansari S. H., Essentials of Pharmacognosy, 2<sup>nd</sup> edition, Birla Publications, New Delhi, 2007
- 8. Kokate C.K., Purohit A. P., Gokhale S.B, Practical Pharmacognosy, 13<sup>th</sup> edition, Nirali Prakashan, New Delhi, 2009.
- 9. Iyengar M.A and Nayak S.G.K, Anatomy of Crude Drugs, 12<sup>th</sup> edition, PharmaMed Press, A unit of BSP books Pvt. Ltd, Hyderabad, 2011.
- 10. Khandelwal K. R. and Vrunda Sethi, Practical Pharmacognosy: Techniques and Experiments, 24<sup>th</sup> edition, Nirali Prakashan, 2014.
- 11. Vasudevan T. N. and Laddha K. S, Practical Pharmacognosy, New Vrinda Publishing House, Jalgaon, 1987.
- 12. Shah B.A., Seth A, Textbook of Pharmacognosy and Phytochemistry, 1st edition, Elsevier Publications, A division of Reed Elsevier India Pvt. Ltd, New Delhi, 2010.
- 13. Remington, The Science and Practice of Pharmacy, 21<sup>st</sup> edition, Lippincott Williams and Wilkins Publication, 2005.
- 14. Pharmacognosy & Pharmacobiotechnology. Eds. Bobbers JE, Speedie MK, and Tyler VE, Williams and Wikins, 1996.
- 15. Vyas SP and Dixit VK, Textbook of Biotechnology, 1<sup>st</sup> edition, 2012, CBS Publishers.
- 16. Dubey RC, A Textbook of Biotechnology, 5<sup>th</sup> edition, S Chand Publications, 2014.
- 17. Appel L, The formulation and preparation of cosmetic, fragrances and flavours, 2<sup>nd</sup> edition, Micelle Press, 1994.
- 18. Panda H, Herbal Cosmetics, 3<sup>rd</sup> revised edition, Asia Pacific Business Press, 2015.
- 19. R Endress, Plant cell Biotechnology, 1<sup>st</sup> edition, Springer-Verlag Berlin Heidelberg, 1994.
- 20. Pharmacopeial standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy).
- 21. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals, 1<sup>st</sup> edition, Business Horizons Publishers, New Delhi, India, reprint 2012.





#### <u>SEMESTER VII</u> <u>BP701T</u>

#### INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

#### **Course Objectives:**

This course deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This course is designed to impart fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic techniques. Emphasis will be placed on theoretical and practical knowledge of modern analytical instruments that are used for drug testing.

#### **Course Outcomes:**

The students will be able to:

- 1. Comprehend underlying principle, instrumentation, application and limitations in instrumental techniques involving molecular absorption and emission techniques such as UV-Visible, Fluorescence, and Infra-Red spectroscopy.
- 2. Comprehend underlying principle, instrumentation, application and limitations in instrumental techniques involving atomic absorption and emission techniques such as atomic absorption spectroscopy, atomic emission spectroscopy, and nephloturbidimetry technique.
- 3. Describe and evaluate the chromatography techniques and electrophoresis techniques used for the separation, identification, and quantification of analytes.
- 4. Apply knowledge of spectroscopy and chromatographic techniques for qualitative and quantitative analysis and comprehend ICH guidelines for analytical method validation.

Unit	Details	Hours
1.	UNIT – I	10
1.1	UV Visible spectroscopy: Introduction to Electromagnetic radiations and	3
	absorption spectroscopy, Electronic transitions, chromophores, auxochromes,	
	spectral shifts, Wavelength maxima, solvent effect on absorption spectra,	
	Beer and Lambert's law, derivation and deviations, Chemical derivatization techniques	
1.2	Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode, Single and double beam instruments	2
1.3	Pharmaceutical Applications- Spectrometric titrations, Single component and Multicomponent analysis by UV Spectroscopy (Assay as a single component sample, Corrected interference, Assay after solvent extraction, Simultaneous Equation method, Absorbance Ratio method, Difference Spectroscopy method, Derivative Spectroscopy), Calculation of wavelength maxima using Woodward Fieser rules for dienes and $\alpha,\beta$ -unsaturated ketones with alkyl substituents, and determination of pKa.	2
1.4	<b>Fluorimetry:</b> Introduction to Molecular Emission Spectroscopy, Theory of fluorescence, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence and quenching of fluorescence Instrumentation - Filter fluorimeter and Spectrofluorimeter, Sources of radiation, Monochromators (Filters, gratings), Sample cells, Detectors Applications - Chemical derivatization to fluorescent compound, e.g. use of	3





	Dansyl chloride, Fluoresamine, o-phthalaldehyde & Choice of fluorimetry over	
2	UNIT II	10
21	IR Spectroscopy	<u> </u>
	Introduction, requirements for I.R. absorption, vibrational and rotational transitions, dipole changes, potential energy diagrams (harmonic oscillator and anharmonic oscillator), force constants, fundamental modes of vibrations in poly atomic molecules, factors affecting vibrations Sample preparation for I.R spectroscopy -Solids (mulling, pelleting and thin film deposition, and in solution form), Liquids (Neat and in solution form), sample handling techniques (Attenuated Total Reflectance and Diffuse Reflectance) Instrumentation (FTIR) - Sources of radiation, wavelength selectors, detectors - Golay cell,Bolometer, Thermocouple, Thermister, Pyroelectric detector Applications – Pharmaceutical applications including Identification, Polymorph analysis, structure elucidation for alkanes, alkenes, alkynes, alcohols, amines, aldehydes, ketones, carboxylic acids and esters, Nitro and cyano compounds, Benzene derivatives	
2.2	<b>Flame Photometry:</b> Principle, interferences, instrumentation and pharmaceutical applications.	2
2.3	<b>Atomic absorption spectroscopy</b> : Principle, interferences, background correction methods, instrumentation and pharmaceutical applications.	2
2.4	<b>Nepheloturbidometry</b> : Principle, instrumentation and pharmaceutical applications.	2
3	UNIT – III	10
3.1	Classification of chromatographic methods on the basis of- interaction of solute to the stationary phase, chromatographic bed shape and the physical state of the mobile phase, by mechanism- Adsorption, partition, ion-exchange, size exclusion and affinity chromatography, Methodology, advantages, disadvantages and applications of various chromatographic methods. <i>Terminologies / concepts:</i> stationary phase, mobile phase, retention time, gradient and isocratic elution, normal and reverse phase chromatography, retention factor, internal standard, reference standard, working standard, tailing factor (symmetry factor), asymmetry factor, resolution, signal to noise ratio, column chromatography, preparative chromatography, Plate number, HETP, resolution, <i>Quantitative analysis</i> (Peak height, peak areas, calibration curve, internal standard, and area normalization) <i>Optimization of column performance</i> (Column efficiency and band broadening, shape of peak-Gaussian, Plate height, Number of theoretical plates, van Deemter equation, Capacity factor, Selectivity factor, Tailing factor, peak width, and Resolution) Numerical and justification-based problems related to chromatographic methods Adsorption and partition chromatography-Advantages, disadvantages and pharmaceutical applications <b>Thin-layer chromatography-:</b> Introduction, Principle, Methodology-types of	2
3.2	<b>Thin-layer chromatography-:</b> Introduction, Principle, Methodology-types of adsorbents, Developmental techniques, Visualisation techniques, Rf values and factors affecting resolution, advantages, disadvantages, pharmaceutical applications of TLC and Preparative TLC. <b>HPTLC:</b> Instrumentation- Applicator, photodensitometry, photodocumentation,	2

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	Advantages of HPTLC over TLC and HPLC.	
3.3	Paper chromatography: Introduction, Principle, Methodology-Developmental	2
	techniques (Ascending, Descending, Radial and Two-dimensional) and Spray	
	reagents, advantages, disadvantages and pharmaceutical applications.	
3.4	Electrophoresis: Introduction, factors affecting electrophoretic mobility,	2
	Techniques of paper, gel, capillary electrophoresis, applications.	
4	UNIT – IV	8
4.1	Gas chromatography: Introduction, theory, Instrumentation- Carrier gas	4
	supply, Sample injection system including Head space analysis, Columns	
	(Packed, Open tubular columns, Capillary columns) and column ovens, Detectors	
	(Thermal conductivity, Electron capture, Flame ionization), derivatization,	
	temperature programming, advantages, limitations and pharmaceutical	
	applications.	
4.2	High performance liquid chromatography (HPLC): Introduction, theory,	4
	Instrumentation-Mobile phase reservoir, Dual piston reciprocating Pumps,	
	Sample injection systems (Rheodyne injector and autosampler), Column types	
	(analytical, guard and preparative columns) and column packing ( porous,	
	pellicular and monolithic), Detectors (Concept of solute and bulk property	
	detector-Refractive index ,UV-Vis, Photodiode array, fluorescence, ,	
	Electrochemical, Evaporative Light Scattering ), Differences between UPLC and	
	HPLC, Applications, Advantages and Limitations of HPLC.	
	<b>Ion pair chromatography-</b> Introduction, theory, instrumentation and	
	pharmaceutical applications	
5	UNIT – V	7
5.1	Ion exchange chromatography: Introduction, classification, ion exchange	2
	resins, properties, mechanism of ion exchange process, factors affecting ion	
	exchange, methodology and applications.	
5.2	Gel chromatography: Introduction, theory, instrumentation and Pharmaceutical	2
	applications.	
5.3	Affinity chromatography: Introduction, theory, instrumentation and	2
	applications.	
5.4	Analytical method Validation-ICH guidelines.	1
	TOTAL	45

- 1. Skoog, D. A., F. J. Holler and S. R. Crouch. Principles of Instrumental Analysis, 6<sup>th</sup> edition, Brooks Cole, 2006
- Connors, K. A., A Textbook of Pharmaceutical Analysis,3<sup>rd</sup> edition, John Wiley and Sons, Canada, 2007.
- 3. A. H. Beckett and J. B. Stenlake, Practical Pharmaceutical Chemistry, Part I and II, 4<sup>th</sup> edition, CBS Publishers and Distributors, India, 1997.
- 4. D. A. Skoog, D. M. West, F. J. Holler and S. R. Crouch, Fundamentals of Analytical Chemistry, 9<sup>th</sup> edition, Saunders College Publishing, USA, 2013.
- 5. G. D. Christian, Analytical Chemistry, 6<sup>th</sup> edition, John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd, 2003.





- 6. H.H. Willard, L. L. Merrit and J. A. Dean, Instrumental Method of Analysis, 7<sup>th</sup> edition, CBS Publishers & Distributors, New Delhi, 1988.
- 7. Indian Pharmacopoeia, The Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India.
- 8. United States Pharmacopeia
- 9. J. Mendham, R. C. Denney, J. D. Barnes, M. J. K. Thomas, B. Sivasankar, Vogel's Textbook of Quantitative Chemical Analysis, 6<sup>th</sup> edition, Pearson Education, New Delhi, 2009.
- 10. D. G. Watson, Pharmaceutical Analysis –A textbook for pharmacy students and pharmaceutical chemists. 5<sup>th</sup> edition, Elsevier, 2020.
- 11. J. W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, 7<sup>th</sup> edition, Marcel Dekker, CRC Press, Taylor & Francis group, New York, USA, 2014.
- 12. R. Kellnar, J. M. Mermet, M. Otto, M. Valcarcel and, H. M. Widmer, Analytical Chemistry: A modern approach to analytical science, 2<sup>nd</sup> edition, Wiley-VCH, USA, 2004.
- 13. J. W. Munson, Pharmaceutical Analysis: Modern methods (in two parts), 1<sup>st</sup> edition, Marcel Dekker Inc., USA, 1981.
- 14. W. Kemp, Organic Spectroscopy, Palgrave Publishers Ltd., 3<sup>rd</sup> edition, New York, USA, 1991(reprint 2002).
- 15. R. M. Silverstein, F. X. Webster and D. J. Kiemle, Spectrometric identification of organic compounds, 8<sup>th</sup> edition, John Wiley & Sons, Inc. (Indian edition), New Delhi (Reference book), 2014.
- 16. J. R. Dyer, Applications of Absorption Spectroscopy Of Organic Compounds, Eastern Economy Edition, Prentice- Hall of India Pvt Ltd, New Delhi, India, 2011.
- 17. D. L. Pavia, G. M. Lampman, G. S. Kriz and J. R. Vyvyan, Introduction to Spectroscopy, 3<sup>rd</sup> edition, Brooks/Cole Cengage Learning, Australia, 2011
- 18. L. R. Snyder, J. J. Kirkland, J. L. Glajch, Practical HPLC Method Development, 2<sup>nd</sup> edition, Wiley-Interscience publication, John Wiley & Sons, Inc., Canada (Reference book), 1997
- 19. S. Ahuja and M. W. Dong, Handbook of Pharmaceutical Analysis by HPLC, Volume 6 of Separation Science and Technology, 1<sup>st</sup> edition, Elsevier Academic Press, Indian edition (Reference book), 2005.

#### **BP702T**

#### INDUSTRIAL PHARMACY II (Theory) 45 Hours

#### **Course Objectives:**

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

#### **Course Outcomes:**

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

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





Unit	Details	Hours
1.	UNIT – I	10
	<b>Pilot plant scale up techniques:</b> 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	
2	UNIT – II	10
	<b>Technology development and transfer:</b> WHO guidelines for Technology Transfer: Terminologies, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packing materials) Documentation, Premises and equipment, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TOT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; Technology of Transfer (TOT) related documentation - confidentiality agreements, licensing, MoUs, legal issues.	
3	UNIT – III	10
3.1	<b>Regulatory affairs:</b> Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals.	2
3.2	<b>Regulatory requirements for drug approval:</b> 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.	8
4	UNIT – IV	8
	<b>Quality management systems:</b> Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP.	
5	UNIT – V	7
	Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Common Technical Document (CTD), Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs. ANDA	
	TOTAL	45

#### **Recommended Books: (Latest Editions to be adopted):**

- 1. <u>https://en.wikipedia.org/wiki/Regulatory affairs</u>. (Regulatory Affairs from Wikipedia, the free encyclopedia, last edited July 2021)
- 2. <u>http://www.iraup.com/about.php</u>.(International Regulatory Affairs Updates, 2005)
  - 3. Douglas J. Pisano, David Mantus, FDA Regulatory Affairs: A Guide for Prescription drugs,





Medical Devices, and Biologics, 2<sup>nd</sup> edition, Informa Health care., Inc, 2008.
http://www.cgmp.com/ra.htm.(Regulatory Affairs brought by learning plus, inc.)

# BP703T PHARMACY PRACTICE (Theory) 45 Hours

#### **Course Objectives:**

The course introduces several aspects of Hospital Pharmacy like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. The courses also introduces different aspects of community pharmacy like dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

#### **Course Outcomes:**

Upon completion of the course, the student shall be able to

1. Know various drug distribution methods in a hospital, pharmacy store management and inventory control.

2. Understand the monitoring of drug therapy of patient through medication chart review and clinical review.

3. Obtain medication history interview, counsel the patients identify drug related problems, detect and assess adverse drug reactions.

- 4. Interpret selected laboratory results of specific disease states.
- 5. Know pharmaceutical care services, do patient counseling in community pharmacy.
- 6. Appreciate the concept of Rational drug therapy.

Unit	Details	Hours
1.	UNIT – I	10
1.1	Hospital and its organization	2
	Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals,	
	Classification based on clinical and non- clinical basis, Organization Structure of	
	a Hospital, and Medical staff involved in the hospital and their functions.	
1.2	Hospital pharmacy and its organization	2
	Definition, functions of hospital pharmacy, Organization structure, Location,	
	Layout and staff requirements, and Responsibilities and functions of hospital	
	pharmacists.	
1.3	Adverse drug reaction	3
	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,	
	pharmacodynamic drug interactions. Methods for detecting drug interactions,	
	spontaneous case reports and record linkage studies, and Adverse drug reaction	
	reporting and management.	
1.4	Community Pharmacy	3
	Organization and structure of retail and wholesale drug store, types and design,	

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	Legal requirements for establishment and maintenance of a drug store, Dispensing	
	of proprietary products, maintenance of records of retail and wholesale drug store.	
	Role of pharmacist.	
2	UNIT – II	10
2.1	Drug distribution system in a hospital	2
	Dispensing of drugs to inpatients, types of drug distribution systems, charging	
	policy and labelling. Dispensing of drugs to ambulatory patients and dispensing of	
	controlled drugs.	
2.2	Hospital formulary	2
	Definition, contents of hospital formulary, Differentiation of hospital formulary	
	and Drug list, preparation and revision, and addition and deletion of drug from	
	hospital formulary.	
2.3	Therapeutic drug monitoring	2
	Need for Therapeutic Drug Monitoring, Factors to be considered during the	
	Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug	
	Monitoring. Role of pharmacist.	
2.4	Medication adherence	l
	Causes of medication non-adherence, pharmacist role in the medication	
2.5	Potient medication history interview	1
2.3	Need for the nation medication history interview medication interview forms	1
2.6	Community pharmacy management	2
2.0	Financial, materials, staff, and infrastructure requirements.	4
3	IINIT - III	10
		10
3.1	Pharmacy and therapeutic committee	2
3.1	Pharmacy and therapeutic committee Organization, functions, Policies of the pharmacy and therapeutic committee in	2
3.1	Pharmacy and therapeutic committee Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic	2
3.1	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.	2
3.1	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> </ul>	2
3.1	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised</li> </ul>	2
3.1	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> </ul>	2
3.1 3.2 3.3	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> <li>Patient counselling</li> </ul>	10 2 1 2
3.1 3.2 3.3	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> <li>Patient counselling</li> <li>Definition of patient counselling, factors affecting counselling, steps</li> </ul>	10 2 1 2
3.1 3.2 3.3	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> <li>Patient counselling</li> <li>Definition of patient counselling, factors affecting counselling, steps involved in patient counselling, and special cases. Role of pharmacist.</li> </ul>	10 2 1 2 2
3.1 3.2 3.3 3.4	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> <li>Patient counselling</li> <li>Definition of patient counselling, factors affecting counselling, steps involved in patient counselling, and special cases. Role of pharmacist.</li> <li>Education and training program in the hospital</li> </ul>	10 2 1 2 2 3
3.1 3.2 3.3 3.4	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> <li>Patient counselling</li> <li>Definition of patient counselling, factors affecting counselling, steps involved in patient counselling, and special cases. Role of pharmacist.</li> <li>Education and training program in the hospital</li> <li>Role of pharmacist in the education and training program, Internal and</li> </ul>	10 2 1 2 2 3
3.1 3.2 3.3 3.4	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> <li>Patient counselling</li> <li>Definition of patient counselling, factors affecting counselling, steps involved in patient counselling, and special cases. Role of pharmacist.</li> <li>Education and training program in the hospital</li> <li>Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of</li> </ul>	10 2 1 2 3
3.1 3.2 3.3 3.4	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> <li>Patient counselling</li> <li>Definition of patient counselling, factors affecting counselling, steps involved in patient counselling, and special cases. Role of pharmacist.</li> <li>Education and training program in the hospital</li> <li>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 interdementary accommunity health education</li> </ul>	10 2 1 2 3
3.1 3.2 3.3 3.4	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> <li>Patient counselling</li> <li>Definition of patient counselling, factors affecting counselling, steps involved in patient counselling, and special cases. Role of pharmacist.</li> <li>Education and training program in the hospital</li> <li>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.</li> </ul>	10 2 1 2 3
3.1 3.2 3.3 3.4 3.5	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> <li>Patient counselling</li> <li>Definition of patient counselling, factors affecting counselling, steps involved in patient counselling, and special cases. Role of pharmacist.</li> <li>Education and training program in the hospital</li> <li>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.</li> <li>Prescribed medication order and communication skills</li> </ul>	10 2 1 2 3 3
3.1 3.2 3.3 3.4 3.5	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> <li>Patient counselling</li> <li>Definition of patient counselling, factors affecting counselling, steps involved in patient counselling, and special cases. Role of pharmacist.</li> <li>Education and training program in the hospital</li> <li>Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for communication and community health education.</li> <li>Prescribed medication order and communication skills</li> <li>Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients</li> </ul>	2 1 2 3 3
3.1 3.2 3.3 3.4 3.5 4	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> <li>Patient counselling</li> <li>Definition of patient counselling, factors affecting counselling, steps involved in patient counselling, and special cases. Role of pharmacist.</li> <li>Education and training program in the hospital</li> <li>Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for communication and communication skills</li> <li>Prescribed medication order and communication skills</li> <li>Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.</li> </ul>	10 2 1 2 3 3 2 8
3.1 3.2 3.3 3.4 3.5 4 4.1	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> <li>Patient counselling</li> <li>Definition of patient counselling, factors affecting counselling, steps involved in patient counselling, and special cases. Role of pharmacist.</li> <li>Education and training program in the hospital</li> <li>Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for communication and communication skills</li> <li>Prescribed medication order and communication skills</li> <li>Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.</li> <li>UNIT – IV</li> </ul>	$     \begin{array}{r}       10 \\       2 \\       1 \\       2 \\       3 \\       2 \\       \hline       8 \\       2 \\       \hline       8 \\       2   \end{array} $
$     \begin{array}{r}       3.1 \\       3.2 \\       3.3 \\       3.4 \\       3.5 \\       4 \\       4.1 \\     \end{array} $	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> <li>Patient counselling</li> <li>Definition of patient counselling, factors affecting counselling, steps involved in patient counselling, and special cases. Role of pharmacist.</li> <li>Education and training program in the hospital</li> <li>Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for communication and communication skills</li> <li>Prescribed medication order and communication skills</li> <li>Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.</li> <li>UNIT – IV</li> <li>Budget preparation and implementation.</li> </ul>	10       2       1       2       3       2       8       2
$   \begin{array}{c}     3.1 \\     3.2 \\     3.3 \\     3.3 \\     3.4 \\     \overline{} \\     3.5 \\     4 \\     4.1 \\     4.2 \\   \end{array} $	<ul> <li>Pharmacy and therapeutic committee</li> <li>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.</li> <li>Drug information services</li> <li>Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</li> <li>Patient counselling</li> <li>Definition of patient counselling, factors affecting counselling, steps involved in patient counselling, and special cases. Role of pharmacist.</li> <li>Education and training program in the hospital</li> <li>Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for communication and communication skills</li> <li>Prescribed medication order and communication skills</li> <li>Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.</li> <li>UNIT – IV</li> <li>Budget preparation and implementation</li> <li>Budget preparation and implementation.</li> </ul>	
$     \begin{array}{r}       3.1 \\       3.2 \\       3.3 \\       3.4 \\       3.5 \\       4 \\       4.1 \\       4.2 \\     \end{array} $	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, factors affecting counselling, steps         involved in patient counselling, and special cases. Role of 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- interpretation and legal requirements, and         Communication skills- communication with prescribers and patients.         UNIT – IV         Budget preparation and implementation.         Budget preparation and implementation.         Clinical Pharmacy         Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and	10       2       1       2       3       2       3       2       8       2       5

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	responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart	
	review, clinical review, pharmacist intervention, Ward round participation,	
	Medication history and pharmaceutical care.	
4.3	Over the counter (OTC) sales	1
	Introduction and sale of over the counter, and Rational use of common over the	
	counter medications.	
5	UNIT – V	7
5.1	Drug store management and inventory control	3
	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.	
5.2	Investigational use of drugs	2
	Description, principles involved, classification, control, identification, role of	
	hospital pharmacist, advisory committee.	
5.3	Interpretation of Clinical Laboratory Tests	2
	Blood chemistry, haematology, and urinalysis.	
	TOTAL	45

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

#### Journals:

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

## BP704T NOVEL DRUG DELIVERY SYSTEMS (Theory) 45 Hours

#### **Course Objectives:**

This course is designed to impart basic knowledge on the principles and methods for development of novel drug delivery systems.

#### **Course Outcomes:**

Upon completion of the course student shall be able to:

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

Unit	Details	Hours
1	UNIT - I	10
1.1	<b>Controlled drug delivery systems</b> : Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Oral systems-Matrix & reservoir systems. Approaches to design of controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations. Evaluation of the systems.	7
1.2	<b>Polymers:</b> Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.	3
2	UNIT – II	10
2.1	<b>Microencapsulation:</b> Definition, advantages and disadvantages, microspheres/microcapsules, microparticles, methods of microencapsulation (phase separation coacervation (various techniques), Wurster process, spray drying and related processes, interfacial polymerization, multiorifice centrifugal process, pan coating, solvent evaporation; extrusion & spheronization), applications	4
2.2	<b>Mucosal Drug Delivery system:</b> Introduction, Principles of bioadhesion, mucoadhesion, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems.	3
2.3	<b>Implantable Drug Delivery Systems:</b> Introduction, advantages and disadvantages, concept of implants and osmotic pump (Basic principles of osmotic drug delivery, classification- Implantable osmotic pumps, oral osmotic pumps, applications & evaluation)	3
3	UNIT – III	10
3.1	<b>Transdermal Drug Delivery Systems:</b> Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches.	3
3.2	<b>Gastroretentive drug delivery systems:</b> Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, swelling and expandable, mucoadhesive, inflatable and gastroadhesive systems and their applications.	2
3.3	<b>Nasopulmonary drug delivery system:</b> Introduction to Nasal and Pulmonary routes of drug delivery, Advantages and limitations; Nasal drug delivery-absorption pathways of intranasally administered drugs, permeation enhancers, intranasal formulations, nose-to-brain delivery Pulmonary delivery- Weibel model of Lungs (Pulmonary tree), aerosol deposition mechanisms and pattern in lungs, concepts of mass median aerodynamic diameter (MMAD) and Fine particle fraction (FPF) Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers.	5
4	UNIT – IV	8
	Nanotechnology and its Concepts: Concepts and approaches for targeted drug delivery systems, advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles (polymeric and lipid), monoclonal antibodies and their applications. Concept of Targeting to Brain: Blood brain barrier (BBB), transport through	





	TOTAL	45
	disadvantages, development of intra uterine devices (IUDs).	
5.2	Intrauterine Drug Delivery Systems: Introduction, advantages and	2
	ocuserts (Non-erodible and Erodible inserts).	
	overcomePreliminary study, ocular formulations, in situ gelling systems and	
5.1	Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to	5
5	UNIT – V	7
	two examples	
	Concept of Targeting to tumor – EPR effect, ligand-based active targeting with	
	Concept of Lymphatic targeting-need and approaches-	
	delivery	
	BBB, factors affecting drug permeation through BBB, strategies for brain drug	

- 1. Y W. Chien, Novel Drug Delivery Systems, 2<sup>nd</sup> edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
- 2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, 2<sup>nd</sup> edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
- 3. Edith Mathiowitz, Encyclopedia of Controlled Delivery. Wiley Interscience Publication, 1<sup>st</sup> edition, John Wiley and Sons, Inc, New York, 1999.
- 4. N.K. Jain, Controlled and Novel Drug Delivery, 1<sup>st</sup> edition, CBS Publishers & Distributors, New Delhi, 1997 (reprint in 2001).
- 5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, 1<sup>st</sup> edition, Vallabh Prakashan, New Delhi, 2002.

#### Journals

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

#### <u>BP705P</u> INSTRUMENTAL METHODS OF ANALYSIS (Practical)

#### **Course Objectives:**

To impart to the learner through experiential learning the knowledge to operate the instruments, understand their functioning, prepare solutions accurately, conduct analysis using appropriate instrument, calculate, report and interpret the results of analysis.

#### **Course Outcomes:**

Upon completion of the course the learner should be able to:

Record, calculate and interpret data obtained from UV spectrophotometry, fluorimetry, colorimetry, flame photometry and nephelo turbidometry analysis.

Develop and optimize mobile phase composition for qualitative analysis by TLC and interpret data obtained by TLC and paper chromatography.

Outline working and application of column chromatography, HPLC and GC.

Apply ICH guidelines to validate an analytical method by UV spectroscopy and interpret results obtained.

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### LIST OF EXPERIMENTS

- 1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds.
- 2. Estimation of dextrose by colorimetry.
- 3. Estimation of sulfanilamide/ streptomycin sulphate injection by colorimetry.
- 4. Simultaneous estimation of ibuprofen and paracetamol/ caffeine and sodium benzoate injection by UV spectroscopy-simultaneous equation method and absorbance ratio method
- 5. UV spectrophotometric estimation of formulation by Difference spectroscopy: e.g., Phenylephrine HCl ophthalmic solution.
- 6. Assay of Trimethoprim in cotrimoxazole tablets
- 7. Assay of paracetamol/ paracetamol tablets/ Rifampicin capsules by UV- Spectrophotometry.
- 8. Estimation of quinine sulfate by fluorimetry.
- 9. Study of quenching of fluorescence.
- 10. Determination of sodium by flame photometry.
- 11. Determination of potassium by flame photometry.
- 12. Determination of chlorides and sulphates by nepheloturbidometry.
- 13. Separation of amino acids by paper chromatography.
- 14. Separation of sugars by thin layer chromatography.
- 15. Separation of plant pigments by column chromatography.
- 16. Demonstration experiment on HPLC.
- 17. Demonstration experiment on Gas Chromatography.
- 18. Determination of validation parameters (linearity, precision, accuracy) by UV spectroscopy: e.g., Ibuprofen, Paracetamol.

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

- 1. Beckett A. H., Stenlake J. B., Practical Pharmaceutical Chemistry, Vol. I & II, 2<sup>nd</sup> edition, Athlone Press, University of London, London, 1970.
- G. D. Christian, Analytical Chemistry, 6<sup>th</sup> edition, John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd, 2003.
- 3. Connors, K. A., A Textbook of Pharmaceutical Analysis,3<sup>rd</sup> edition, John Wiley and Sons, Canada, 2007.
- 4. Skoog, D. A., F. J. Holler and S. R. Crouch. Principles of Instrumental Analysis, 6<sup>th</sup> edition, Brooks Cole, 2006
- 5. Skoog, D. A., and D. M. West. Fundamentals of Analytical Chemistry, 7<sup>th</sup> edition, Brooks Cole, USA, 1995.
- 6. Watson, D. G, Pharmaceutical Analysis: A Textbook for Pharmacy Students and Pharmaceutical Chemists, 4<sup>th</sup> edition, Elsevier, 2015.
- 7. J. Mendham, R. C. Denney, J. D. Barnes, M. J. K. Thomas, B. Sivasankar, Vogel's Textbook of Quantitative Chemical Analysis, 6<sup>th</sup> edition, Pearson Education, New Delhi, 2009.
- 8. Indian Pharmacopoeia, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, India.
- 9. Vogel A.I., Textbook of Quantitative Inorganic Analysis, 2<sup>nd</sup> edition, Longman Green and Co., London, 1951.





10. D. C. Garrett., Quantitative Analysis of Drugs, 3<sup>rd</sup> edition, Springer US, 1964.

11. P. D. Sethi, Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3<sup>rd</sup> edition, CBS Publishers and Distributors Pvt. Ltd 2019

#### BP706PS PRACTICE SCHOOL (180 Hours)

Every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time. At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.





### <u>SEMESTER VIII</u> <u>BP801T</u>

#### BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory) 45 Hours

#### **Course Objectives:**

To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphs, Correlation, Regression, logistic regression, Probability theory, Sampling technique, Parametric tests, Non-Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R, MINITAB statistical software's, and analysing the statistical data using Excel.

#### **Course Outcomes:**

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

- 1. Know the operation of MS Excel, SPSS, R and MINITAB®, DoE (Design of Experiment).
- 2. Know the various statistical techniques that apply to analysis of a given data set.
- 3. Appreciate the use of statistical techniques in data analysis.

Unit	Details	Hours
1	UNIT - I	10
1.1	Introduction: Statistics, Biostatistics, Frequency distribution.	2
1.2	Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples.	3
1.3	<b>Measures of dispersion</b> : Dispersion, Range, standard deviation - Pharmaceutical problems.	2
1.4	<b>Correlation</b> : Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples.	3
2	UNIT – II	10
2.1	<b>Regression:</b> 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.	3
2.2	<b>Probability:</b> 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.	4
2.3	<b>Parametric test</b> : t-test (Sample, Pooled or Unpaired and Paired), ANOVA, (One wayand Two way), Least Significance difference.	3
3	UNIT – III	10
3.1	Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallistest, Friedman Test.	2
3.2	<b>Introduction to Research:</b> Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism.	3
3.3	Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph.	2
3.4	<b>Designing the methodology:</b> Sample size determination and Power of a study, Reportwriting and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.	3





4	UNIT – IV	8
4.1	Blocking and confounding system for Two-level factorials	2
4.2	<b>Regression modeling:</b> Hypothesis testing in Simple and Multiple regression models.	2
4.3	<b>Introduction to Practical components of Industrial and Clinical Trials</b> <b>problems</b> : Statistical Analysis Using Excel, SPSS, MINITAB <sup>®</sup> , DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach.	4
5	UNIT – V	7
5.1	<b>Design and Analysis of experiment- Factorial Design:</b> Definition, 2 <sup>2</sup> , 2 <sup>3</sup> design. Advantage of factorial design.	3
5.2	<b>Response Surface methodology</b> : Central composite design, Historical design, Optimization Techniques.	4
	TOTAL	45

- 1. Sanford Bolton, Charles Bon, Pharmaceutical statistics Practical and clinical applications, Drugs and the Pharmaceutical Sciences, Vol. 135, 4<sup>th</sup> edition revised and expanded, Marcel Dekker, New York, 2004.
- 2. S.C. Gupta, Fundamental of Statistics, 7<sup>th</sup> edition, Himalaya Publishing House, 2018.
- 3. R. Pannerselvam, Design and Analysis of Experiments, 1<sup>st</sup> edition, PHI Learning India Pvt Limited, 2012.
- 4. Douglas, and C. Montgomery, Design and Analysis of Experiments , 10<sup>th</sup> edition, John Wiley and Sons, 2019

# BP802TSOCIAL AND PREVENTIVE PHARMACY(Theory)45 Hours

#### **Course Objectives:**

The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduces a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

#### **Course Outcomes:**

After the successful completion of this course the student shall be able to:

1. Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.

- 2. Acquire a critical way of thinking based on current healthcare development.
- 3. Evaluate alternative ways of solving problems related to health and pharmaceutical issues.

Unit	Details	Hours
1	UNIT - I	10
1.1	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.	
1.2	Social and health education: Food in relation to nutrition and health, Balanced	
	diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.	
1.3	Sociology and health: Socio cultural factors related to health and disease, Impact	



### Syllabus B.Pharm (Choice Based Credit System)



	of urbanization on health and disease, Poverty and health.	
1.4	Hygiene and health: personal hygiene and health care; avoidable habits.	
2	UNIT – II	10
2.1	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.	
3	UNIT – III	10
	National health programs, its objectives, functioning and outcome of the	
	following: 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.	
4	UNIT – IV	8
	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.	
5	UNIT – V	7
	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.	
	TOTAL	45

#### **Recommended Books (Latest editions to be adopted):**

- 1. Prabhakara GN, Short Textbook of Preventive and Social Medicine, , 2<sup>nd</sup> Edition, ISBN: 9789380704104, Jaypee Publications, 2010.
- Roy Rabindra Nath, Saha Indranil, Textbook of Preventive and Social Medicine (Mahajan and Gupta), 4<sup>th</sup> Edition, ISBN: 9789350901878, Jaypee Publications, 2013.
- 3. Jain Vivek, Review of Preventive and Social Medicine (Including Biostatistics), 6<sup>th</sup> Edition, ISBN: 9789351522331, Jaypee Publications,2014.
- 4. Hiremath Lalita D, Hiremath Dhananjaya A, Essentials of Community Medicine—A Practical Approach, 2<sup>nd</sup> Edition, ISBN: 9789350250440, Jaypee Publications, 2012.
- 5. Park, Textbook of Preventive and Social Medicine, 21<sup>st</sup> Edition, ISBN-14: 9788190128285, Banaridas Bhanot Publishers, 2011.
- 6. Ramesh Adepu, Community Pharmacy Practice, 1<sup>st</sup> edition, PharmaMed Press, 2017

#### **Recommended Journals:**

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





# BP803ET PHARMACEUTICAL MARKETING MANAGEMENT (Theory) – ELECTIVE 45 Hours

#### **Course Objectives:**

The course will provide the Knowledge and Know-how of marketing management and groom students for taking up challenging roles in Sales and Product management.

#### **Course Outcomes:**

Upon completion of the course the student will be able to:

1. Understand marketing concepts and techniques and their applications in the pharmaceutical industry.

Unit	Details	Hours
1	UNIT - I	10
1.1	Marketing:	
	Definition, general concepts, and scope of marketing; Distinction between	
	marketing & selling; Marketing environment; Industry and competitive analysis;	
	Analyzing consumer buying behaviour; industrial buying behaviour.	
1.2	Pharmaceutical market:	
	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; patients' choice of physician and retail pharmacist.	
	Analyzing the Market; Role of market research.	
2	UNIT – II	10
	Product decision:	
	Meaning, Classification, product line and product mix decisions, product life	
	cycle, product portfolio analysis; product positioning; New product decisions;	
	Product branding, packaging and labelling decisions, Product management in	
	pharmaceutical industry.	
3	UNIT – III	10
	Promotion:	
	Meaning and 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.	
4	UNIT – IV	8
4.1	Pharmaceutical marketing channels:	
	Designing channel, channel members, selecting the appropriate channel, conflict	
	in channels, physical distribution management: Strategic importance, tasks in	
	physical distribution management.	
4.2	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.	





5	UNIT – V	7
5.1	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).	
5.2	Emerging concepts in marketing:	
	Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial	
	Marketing; Global Marketing.	
	TOTAL	45

- 1. Philip Kotler and Kevin Lane Keller: Marketing Management, 15<sup>th</sup> Global edition, Pearson, 2015.
- 2. Walker, Boyd and Larreche, Marketing Strategy- Planning and Implementation, International 3<sup>rd</sup> revised edition, Mc Graw Hill Education, 1999.
- 3. Dhruv Grewal and Michael Levy: Marketing, 8th edition, Mc Graw Hill, 2022
- 4. Arun Kumar and N Menakshi, Marketing Management, 3<sup>rd</sup> edition, Vikas Publishing, India, 2016.
- 5. Rajan Saxena: Marketing Management, 3<sup>rd</sup> edition, Tata MC Graw-Hill Education, India, 2005.
- Ramaswamy, U.S & Namakamari, S: Marketing Management: Global Perspective, Indian Context, 4<sup>th</sup> edition, Om books, 2009
- 7. Ravi Shanker, Service Marketing, 1<sup>st</sup> edition, Excel Books, New Delhi, 2009.
- 8. Subba Rao Changanti, Pharmaceutical Marketing in India, Excel books, New Delhi, 2005.

#### <u>BP804ET</u>

### PHARMACEUTICAL REGULATORY SCIENCE (Theory) – ELECTIVE 45 Hours

#### **Course Objectives:**

This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

#### **Objectives:**

Upon completion of the course student shall be able to;

- 1. Know about the process of drug discovery and development
- 2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- 3. Know the regulatory approval process and their registration in Indian and international markets

Unit	Details	Hours
1	UNIT - I	12
1.1.	New Drug Discovery and development	6
	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, Medical Devices, Biologics,	
1.2.	Biosimilars. Overview of Quality systems & Assurance for Drugs and Biologics, Biologics, Medical Devices.	6

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2	UNIT –II	9
2.1	Regulatory Approval Process	6
	Approval processes and timelines involved in Investigational New Drug	
	(IND), New Drug Application (NDA), Abbreviated New Drug Application	
	(ANDA) in US. Changes to an approved NDA / ANDA.	
2.2	Regulatory authorities and agencies	3
	Overview of regulatory authorities of United States, European Union,	
	Australia, Japan, Canada (Organization structure and types of applications).	
3	UNIT – III	10
3.1.	Regulatory Concepts	2
	Basic terminologies, guidance, guidelines, regulations, laws and acts, Orange	
	book, Federal Register, Code of Federal Regulatory, Purple book.	
3.2.	Registration of Indian drug product in overseas market (USA &	
	European Union)	8
	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.	
4	UNIT – IV	7
	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.	
5	UNIT – V	7
	Overview of Regulation of :	
	-Pharmaceutical & Biologic Products	
	-Medical Devices & Diagnostics	
	-Nutraceuticals & Dietary Supplements	
	TOTAL	45

- 1. Sachin Itkar, N.S. Vyawahare, Drug Regulatory Affairs, 4th edition, Nirali Prakashan, Educational Publishers, 2019.
- 2. Ira R. Berry and Robert P. Martin (Editors), The Pharmaceutical Regulatory Process, Drugs and the Pharmaceutical Sciences, Vol.185, 2nd Edition, Informa Health care, Inc, 2008.
- 3. Richard A Guarino, New Drug Approval Process: Accelerating Global Registrations, Drugs and the Pharmaceutical Sciences, 5<sup>th</sup> edition, Vol. 190, Informa Health care, Inc, 2009.
- 4. Sandy Weinberg, Guidebook for Drug Regulatory Submissions, 1<sup>st</sup> edition, John Wiley & Sons. Inc., 2008.
- 5. Douglas J. Pisano, David Mantus, FDA Regulatory Affairs: A Guide for Prescription drugs, Medical Devices, and Biologics, 2<sup>nd</sup> edition, Informa Health care., Inc, 2008.
- 6. Leon Shargel and Isader Kaufer, Generic Drug Product Development, Solid Oral Dosage forms, Vol. 143, 1<sup>st</sup> edition, Marcel Dekker, New York, 2005.
- 7. Fay A. Rozovsky and Rodney K. Adams, Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance, 1<sup>st</sup> edition, Jossey-Bass, San Francisco, 2003.





- 8. John I. Gallin and Frederick P. Ognibene, Principles and Practices of Clinical Research, 3<sup>rd</sup> Edition, , Academic Press, 2012.
- 9. Rick Ng., Drugs: From Discovery to Approval, 2<sup>nd</sup> Edition, Willey Blackwell, 2012,

#### PHARMACOVIGILANCE (Theory) – ELECTIVE 45 Hours

#### **Course Objectives:**

This course 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. The course will train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data, signal detection, skills of classifying drugs, diseases and adverse drug reactions.

#### **Course Outcomes:**

Upon completion of the course student shall be able to;

- 1. Appreciate drug safety monitoring and History and development of pharmacovigilance
- 2. Understand the National and international scenario of pharmacovigilance and Dictionaries, coding and terminologies used in pharmacovigilance
- 3.Understand the mechanisms for Detection of new adverse drug reactions and their assessment, Adverse drug reaction reporting systems and communication in pharmacovigilance
- 4. Have knowledge of Methods to generate safety data during preclinical, clinical and post approval phases of drugs' life cycle, Drug safety evaluation in paediatrics, geriatrics, pregnancy, and lactation
- 5. Know the Pharmacovigilance Program of India (PvPI), ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning and CIOMS requirements for ADR reporting
- 6. Write case narratives of adverse events and their quality.

Unit	Details	Hours
1	UNIT - I	10
1.1	Introduction to Pharmacovigilance	4
	History and development of Pharmacovigilance. Importance of safety	
	monitoring of Medicine. WHO international drug monitoring programme.	
	Pharmacovigilance Program of India(PvPI).	
1.2	Introduction to adverse drug reactions	4
	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.	
1.3	Basic terminologies used in pharmacovigilance	2
	Terminologies of adverse medication related events. Regulatory terminologies	
2	UNIT – II	10
2.1	Drug and disease classification	3
	Anatomical, therapeutic, and chemical classification of drugs. International	
	classification of diseases. Daily defined doses. International Non-proprietary	
	Names for drugs.	
2.2	Drug dictionaries and coding in pharmacovigilance	3
	WHO adverse reaction terminologies. MedDRA and Standardised MedDRA	
	queries. WHO drug dictionary. Eudravigilance medicinal product dictionary.	
2.3	Information resources in pharmacovigilance	2
	Basic drug information resources. Specialised resources for ADRs	

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## Syllabus B.Pharm (Choice Based Credit System)



2.4	Establishing pharmacovigilance programme	2
	Establishing in a hospital. Establishment & operation of drug safety	
	a pational programme	
2	LINIT III	10
21	Vaccine sefety supervillence	10
3.1	Vaccine Safety Surveinance	3
	immunization	
3.2	Pharmacovigilance methods	5
	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.	
3.3	Communication in pharmacovigilance	2
	Effective communication in Pharmacovigilance. Communication in Drug	
	Safety Crisis management. Communicating with Regulatory Agencies,	
	Business Partners, Healthcare facilities & Media.	-
4	UNIT – IV	8
4.1	Statistical methods for evaluating medication safety data Safety data	3
	generation	
	Preclinical phase. Clinical phase. Post approval phase.	-
4.2	ICH Guidelines for Pharmacovigilance	5
	Organization and objectives of ICH. Expedited reporting. Individual case	
	safety reports. Periodic safety update reports. Post approval expedited	
	pharmacovigilance studies	
5	Jinit - V	7
51	Pharmacogenomics of adverse drug reactions	3
5.1	Genetics related ADR with example focusing PK parameters	5
5.2	Drug safety evaluation in special population	2
0.2	Paediatrics. Pregnancy and lactation. Geriatrics.	-
5.3	CIOMS	1
	CIOMS Working Groups. CIOMS Form.	
5.4	CDSCO (India) and Pharmacovigilance	1
	D&C Act and Schedule Y. Differences in Indian and global pharmacovigilance	
	requirements.	
	TOTAL	45





- 1. S K Gupta, Textbook of Pharmacovigilance, 1<sup>st</sup> edition, Jaypee Brothers Medical Publishers Pvt. Ltd, 2019.
- 2. Barton Cobert, Pierre Biron, Practical Drug Safety from A to Z, 1 edition, Jones and Bartlett Publishers Inc, 2017
- 3. Elizabeth B. Andrews, Nicholas Moore (eds), Mann's Pharmacovigilance, 3<sup>rd</sup> edition, Wiley Blackwell Publishers, 2014.
- 4. John Talbot, Patrick Walle, Stephens' Detection of New Adverse Drug Reactions, Wiley Blackwell Publishers.
- 5. Patrick Waller and Mira Harrison-Woolrych, An Introduction to Pharmacovigilance, 2<sup>nd</sup> edition, Wiley Blackwell Publishers, 2017
- 6. Barton Cobert, William Gregory, Jean-Loup Thomas, Cobert's Manual of Drug Safety and Pharmacovigilance, 3<sup>rd</sup> edition, World Scientific, 2019.
- 7. Brian L. Strom, Stephen E Kimmel, Sean Hennessy (Editors), Textbook of Pharmacoepidemiology, 6<sup>th</sup> edition, Wiley Blackwell Publishers, 2013.
- 8. G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata, A Textbook of Clinical Pharmacy Practice Essential Concepts and Skills, 1<sup>st</sup> edition, Universities Press, 2014.
- 9. National Formulary of India, Ministry of Health, Government of India, 5<sup>th</sup> edition, 2016
- 10. Yashpal Munjal, API Textbook of Medicine, 10<sup>th</sup> edition, Jaypee Brothers Medical Publishers (P) Ltd, 2015.
- 11. GP Mohanta and PK Manna., Textbook of Pharmacovigilance: Concept and Practice, First edition, BSP books, 2015.
- 12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
- 13. <u>http://www.ich.org/</u>
- 14. http://www.cioms.ch/
- 15. http://cdsco.nic.in/
- 16. http://www.who.int/vaccine\_safety/en/
- 17. http://www.ipc.gov.in/PvPI/pv\_home.html

#### BP806ET

### QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory) ELECTIVE 45 Hours

#### **Course Objectives:**

In this course the student will learn about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The course also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

#### **Course Outcomes:**

Upon completion of the subject the student shall be able to;

- 1. Know WHO guidelines for quality control of herbal drugs
- 2. Know Quality assurance in herbal drug industry
- 3. Know the regulatory approval process and their registration in Indian and international markets
- 4. Appreciate EU and ICH guidelines for quality control of herbal drugs



### Syllabus B.Pharm (Choice Based Credit System)



Unit	Details	Hours
1	UNIT - I	10
	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.	
2	UNIT – II	10
2.1	<b>Quality assurance in herbal drug industry</b> of cGMP, GAP, GMP and GLP in traditional system of medicine.	6
2.2	WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.	4
3	UNIT – III	10
	EU and ICH guidelines for quality control of herbal drugs.	
	Research Guidelines for Evaluating the Safety and Efficacy of Herbal	
	Medicines.	
4	UNIT – IV	08
	Stability testing of herbal medicines. Application of various chromatographic	
	techniques in standardization of herbal products.	
	Preparation of documents for new drug application and export registration.	
	GMP requirements and Drugs & Cosmetics Act provisions.	
5	UNIT – V	07
	Regulatory requirements for herbal medicines.	
	WHO guidelines on safety monitoring of herbal medicines in	
	pharmacovigilance systems.	
	Comparison of various Herbal Pharmacopoeias.	
	Role of chemical and biological markers in standardization of herbal	
	products.	
	TOTAL	45

#### **Recommended Books: (Latest Editions to be adopted):**

- 1. Evans W.C, Trease and Evans, Pharmacognosy, 16<sup>th</sup> edition, W.B. Sounders & Co., London, 2009.
- Tyler, V.E, Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 2. 1988.
- 3. Wallis T.E, Textbook of Pharmacognosy, 5<sup>th</sup> edition, J & A Churchill Ltd, London, 1967.
- 4. Mohammad Ali, Pharmacognosy and Phytochemistry,1st edition, CBS Publishers & Distributors, New Delhi, 2018 reprint
- 5. Kokate C.K., Purohit A. P., Gokhale S.B., Textbook of Pharmacognosy, 37<sup>th</sup> Edition, Nirali Prakashan, New Delhi, 2007
- 6. Choudhary R.D, Herbal Drug Industry, 1<sup>st</sup> edition, Eastern Publishers, New Delhi, 1996.
- Ansari S. H., Essentials of Pharmacognosy, 2<sup>nd</sup> edition, Birla Publications, New Delhi, 2007.
   Kokate C.K., Purohit A. P., Gokhale S.B, Practical Pharmacognosy, 13<sup>th</sup> edition, Nirali Prakashan, New Delhi, 2009.
- 9. Ivengar M.A and Navak S.G.K, Anatomy of Crude Drugs, 12<sup>th</sup> edition, PharmaMed Press, A unit of BSP books Pvt. Ltd, Hyderabad, 2011.
- 10. Khandelwal K. R. and Vrunda Sethi, Practical Pharmacognosy: Techniques and Experiments, 24th edition, Nirali Prakashan, 2014.
- 11. Vasudevan T. N. Laddha K. S, Practical Pharmacognosy, 1st edition, New Vrinda Publishing House, Jalgaon, 1987.

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- 12. Shah B.A., Seth A, Textbook of Pharmacognosy and Phytochemistry, 1st edition, Elsevier Publications, A division of Reed Elsevier India Pvt. Ltd, New Delhi, 2010.
- 13. Remington, The Science and Practice of Pharmacy, 21<sup>st</sup> edition, Lippincott Williams and Wilkins, 2005.
- 14. Bobbers JE, Speedie MK, and Tyler VE, Pharmacognosy & Pharmacobiotechnology, Williams and Wilkins, Baltimore, 1996.
- 15. Vyas SP and Dixit VK, Textbook of Biotechnology, 1<sup>st</sup> edition, CBS Publishers, 2012.
- 16. Dubey RC, A Textbook of Biotechnology, 5<sup>th</sup> edition, S Chand Publishing, 2014.
- 17. Appel L, The formulation and preparation of cosmetic, fragrances and flavours, 2<sup>nd</sup> edition, Micelle Press, 1994.
- 18. Panda H, Herbal Cosmetics, 3<sup>rd</sup> revised edition, Asia Pacific Business Press, 2015.
- 19. R Endress, Plant cell Biotechnology, 1<sup>st</sup> edition, Springer-Verlag, Berlin, 1994.
- 20. Pharmacopeial standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy).
- 21. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals,1<sup>st</sup> edition, Business Horizons Publishers, New Delhi, India, reprint 2012.
- 22. Agarwal, S.S., Herbal Drug Technology, 2<sup>nd</sup> edition, Universities Press, 2002.
- 23. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products.
- 24. 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.
- 25. WHO, Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998.
- 26. 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.
- 27. WHO, The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edition, World Health Organization, Geneva, 1981.
- 28. WHO, Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
- 29. 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.
- 30. WHO, Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

## BP807ET COMPUTER AIDED DRUG DESIGN (Theory)- ELECTIVE 45 Hours

#### **Course Objectives:**

This course is designed to provide detailed knowledge of application of computational methods in rational drug design process and various techniques used in rational drug design process.

#### **Course Outcomes:**

Upon completion of the course, the student shall be able to understand:

- 1. Design and discovery of lead molecules
- 2. The role of drug design in drug discovery process
- 3. The concept of QSAR and docking
- 4. Various strategies to develop new drug like molecules.





5. The design of new drug molecules using molecular modelling software

Unit	Details	Hours
1	UNIT - I	10
1.1	Introduction to Drug Discovery and Development	2
	Stages of drug discovery and development.	
1.2	Lead discovery and Analog Based Drug Design	4
	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.	
1.3	Analog Based Drug Design: Bioisosterism, Classification,	4
	Bioisosteric replacement. Any three case studies.	
2	UNIT – II	10
	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,	
	Hammett's substituent constant and Tafts steric constant. Hansch analysis,	
	Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.	10
3	UNIT – III - Molecular Modeling and virtual screening techniques	10
3.1	<b>Virtual Screening techniques:</b> Drug likeness screening, Concept of pharmacophore mapping and pharmacophore - based screening,	6
3.2	Molecular docking: Rigid docking, flexible docking, manual docking,	4
	Docking based screening. De novo drug design.	
4	UNIT – IV	8
	Informatics & Methods in drug design	
	Introduction to Bioinformatics, chemoinformatics. ADME databases,	
	chemical, biochemical and pharmaceutical databases.	
5	UNIT – V	7
	Molecular Modeling: Introduction to molecular mechanics and quantum	
	mechanics. Energy Minimization methods and Conformational Analysis,	
	global conformational minima determination.	
	TOTAL	45

### **Recommended Books (Latest Editions to be adopted)**

- 1. Beale J. M., Block J. H., Wilson and Gisvold's Textbook of Organic medicinal and Pharmaceutical Chemistry, 20<sup>th</sup> edition, Lippincott Williams & Wilkins Publishers, 2004.
- 2. Lemke T. L., Williams D. A., Roche V. F., Zito., S. W., Foye's Principles of Medicinal Chemistry, 7<sup>th</sup> edition, Lippincott Williams, and Wilkins Publishers, 2001.
- 3. Abraham D. J., Burger's Medicinal Chemistry and Drug Discovery, Vol I to IV, 6<sup>th</sup> edition, John Wiley and Sons, Inc., 2003.
- 4. Smith H. J., Smith and Williams' Introduction to Principles of Drug Design and Action, 4<sup>th</sup> edition, Taylor and Francis Publications, CRC Press, 2005.
- 5. Robert GCK, Drug Action at the Molecular Level, 1<sup>st</sup> edition, Palgrave Macmillan UK, 1977.
- 6. Martin YC, Quantitative Drug Design, 2<sup>nd</sup> edition, CRC press, 2010.
- Korolkovas A, Burckhalter JH, Essentials of Medicinal Chemistry, 2<sup>nd</sup> edition, Wiley-Blackwell, 1988.
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New York, 1980

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- 10. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
- 11. Silverman R. B. The Organic Chemistry of Drug Design and Drug Action, 3<sup>rd</sup> edition, Academic Press New York, 2014.

## BP808ET CELL AND MOLECULAR BIOLOGY (Theory)- ELECTIVE 45 Hours

#### **Course Objectives:**

The course will introduce the student to cells, their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function.

#### **Course Outcomes:**

Upon completion of the subject the student shall be able to;

- 1. Summarize cellular functioning and composition.
- 2. Describe the chemical foundations of cell biology.
- 3. Summarize the structure and function of DNA, protein structure and function and cellular membrane structure and function.
- 4. Describe basic molecular genetic mechanisms.
- 5. Summarize the Cell Cycle

Unit	Details	Hours
1	UNIT - I	10
	a) Cell and Molecular Biology: Definition, theory and basics and	
	Applications.	
	b) Cell and Molecular Biology: History and Summation.	
	c) Theory of the Cell. Properties of cells and cell membrane.	
	d) Prokaryotic versus Eukaryotic	
	e) Cellular Reproduction	
	f) Chemical Foundations – an Introduction and Reactions (Types)	
2	UNIT –II	10
	DNA and the Flow of Molecular Structure, DNA Functioning, DNA and	
	RNA, Types of RNA, Transcription and Translation.	
3	UNIT – III	10
	Proteins: Defined and Amino Acids, Protein Structure, Regularities in	
	Protein Pathways, Cellular Processes, Positive Control and significance of	
	Protein Synthesis.	
4	UNIT – IV	8
	Science of Genetics, Transgenics and Genomic Analysis, Cell Cycle analysis, Mitosis and Meiosis, Cellular Activities and Checkpoints.	
5	UNIT – V	7
	a) Cell Signals: Introduction	
	b) Receptors for Cell Signals	
	c) Signaling Pathways: Overview	
	d) Misregulation of Signaling Pathways	
	e) Protein-Kinases: Functioning	
	TOTAL	45

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- 2. Reed G., Prescott and Dunn's, Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi, 2004.
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- 8. Peppler HJ, Microbial Technology, 2<sup>nd</sup> Edition, Academic Press (Elsevier), Massachusetts , 1979.
- 9. I.P., B.P., U.S.P.- latest editions.
- 10. Reba Kanungo, Ananthnarayan and Paniker's Textbook of Microbiology,10<sup>th</sup> Edition, Orient-Longman, Chennai, 2017.
- 11. Pommerville, J.C., Alcamo's Fundamentals of Microbiology, 3rd Edition, Jones and Bartlett, Burlington, Massachusetts, 2014.
- 12. Jain N.K, Pharmaceutical Microbiology, 3<sup>rd</sup> Edition, Vallabh Prakashan, Delhi, 2001.
- 13. Garry G.M., Bergey's Manual of Systematic Bacteriology, 2<sup>nd</sup> Edition, Springer publishing, New York, 2005.
- 14. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: 5<sup>th</sup> edition, 2017, Taylor and Francis
- 15. Kuby Immunology, Punt J et al eds, 8<sup>th</sup> edition, WH Freeman, 2018.
- 16. J.W. Goding: Monoclonal Antibodies Principles and Practice, Academic Press, 1996.
- 17. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology, 4<sup>th</sup> edition, Royal Society of Chemistry, 2000.
- 18. Zaborsky O, Immobilized Enzymes, 2<sup>nd</sup> edition, CRC Press, Cleveland, Ohio, 1973.
- 19. S.B. Primrose: Molecular Biotechnology, 2<sup>nd</sup> edition, Wiley Blackwell, 1992.
- 20. Lehninger AL, Nelson DL, Cox MM. Lehninger Principles of Biochemistry,7<sup>th</sup> edition, Macmillan, New York, 2017.
- 21. Murry RK, Granner DK, Mayes PA, Rodwell VW, Harper's Biochemistry, 23rd edition, Appleton & Lange, Connecticut, 1993.
- 22. Berg JM, Tymoczko JL, Stryer L. Biochemistry, 9<sup>th</sup> edition, WH Freeman, New York, 2019.

## BP809ET COSMETIC SCIENCE (Theory) – ELECTIVE 45 Hours

**Course Objectives:** This course is designed impart the learner with knowledge of Cosmeticology with respect to the types of formulations, evaluation, and regulatory aspects.

Course Outcomes: Upon completion of the course, the learner shall be able to:

- 1. Discuss the various raw materials for cosmetics
- 2. Understand the toxicological aspects and toxicity testing for cosmetics.
- 3. Discuss the various cosmetics products with respect to raw materials, large scale manufacturing and functional and physicochemical evaluation
- 4. Know the regulatory guidelines and sensorial assessment for cosmetics



## Syllabus B.Pharm (Choice Based Credit System)



Unit	Details	Hours
1	UNIT - I	10
1.1	Classification of cosmetic and cosmeceutical products.	2
	Definition of cosmetics as per Indian and EU regulations, Evolution of	
	cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.	
1.2	Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients,	8
	preservatives, perfumes, colours, oils, fats, waxes, antioxidants and water.	
	Classification and applications.	
	Skin: Basic structure and function of skin.	
	Hair: Basic structure of hair. Hair growth cycle.	
	<b>Unit Common problem associated with teeth and gums.</b>	10
2		10
2.1	Principles of formulation and building blocks of skin care products:	5
	Face wash, Moisturizing cream, Cold Cream, Vanishing cream, Barrier	
	creams and colored cosmetics (eye makeup, lipsticks, and nail lacquer) their	
	relative skin sensory, advantages and disadvantages. Application of these	
	products in formulation of cosmeceuticals.	-
	Principles of formulation and building blocks of Hair care products:	5
	Cleansing and Conditioning snampoo, Hair conditioners, antidandruff	
	snampoo.	
	Hair grooming preparations - Hair setting fotions & sprays; brintantines,	
	Tall Olls. Chemistry and formulation of Dara phylona diaming based hair due	
	Dringinlag of formulation and building blocks of oral gars products:	
	toothnowder toothnoste Toothnoste for blooding gums sensitive tooth Tooth	
	whitening denture cleansers mouthwash	
	Shaving products (Wet $Dry \& After shave)$ Depilatory preparations	
3	UNIT – III	10
3.1	Sun protection Classification of Sunscreens and SPF	2
32	Role of herbs in cosmetics:	6
0.2	Skin Care: Aloe and turmeric.	Ū
	Hair care: Henna and amla.	
	Oral care: Neem and clove.	
	Case study of Herbal products (Self Study)	
3.3	Analytical cosmetics: BIS specification and analytical methods for	2
	shampoo, skin-cream and toothpaste.	
4	UNIT – IV	8
	Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer.	
	Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing	
	properties, Soaps and syndet bars. Evolution and skin benefits. Irritation and	
	sensitization reactions to cosmetics, sensitivity testing and safety aspects.	
	Sensorial evaluation of cosmetics- concept and need, sensory perception,	
	requirements for sensory testing, methods used, interpretation and	
	documentation/representation.	
5	UNIT – V	7
	Oily and dry skin causes leading to dry skin, skin moisturisation. Basic	
	understanding of the terms Comedogenic, dermatitis.	

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Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat, and body odor.	
Antiperspirants and Deodorants- Actives and mechanism of action.	
TOTAL	45

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- 4. J. S. Jellinek, Formulation and function of cosmetics, 3<sup>rd</sup> edition, Wiley Interscience, New York, 1970
- 5. Poucher's Perfumes, Cosmetics & Soaps, 10<sup>th</sup> Ed, Editor- Hilda Butler, Kluwer Academic Publishers, Netherlands, 2000.
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- 8. Morten C. Meilgaard, B. Thomas Carr, Gail Vance Civille, Sensory Evaluation Techniques, 4<sup>th</sup> Edition, CRC Press
- 9. ISO 13299:2016 Sensory analysis Methodology General guidance for establishing a sensory profile (<u>https://www.iso.org/standard/58042.html</u>)
- 10. BIS standards for cosmetics preparations (<u>https://www.bis.gov.in/index.php/standards/technical-department/petroleum-coal-and-related-products/indian-standards-referred-in-government-regulations/</u>)

## <u>BP810ET</u>EXPERIMENTAL PHARMACOLOGY- ELECTIVE45 Hours

#### **Course Objectives:**

This course is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

#### **Objectives**:

Upon completion of the course the student shall be able to,

- 1. Appreciate the applications of various commonly used laboratory animals.
- 2. Appreciate and demonstrate the various screening methods used in preclinical research
- 3. Appreciate and demonstrate the importance of biostatistics and research methodology
- 4. Design and execute a research hypothesis independently

Unit	Details	Hours
1	UNIT - I	8
	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.	
	Techniques for collection of blood and common routes of drug	
	administration in laboratory animals Techniques of blood collection and	
	euthanasia.	
2	UNIT – II	13
2.1	Preclinical screening models	6
	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.	
2.2	Preclinical screening models: for CNS activity- analgesic, antipyretic, anti-	7
	inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic,	
	antidepressant, antiepileptic, anti-Parkinsonism, Alzheimer's disease	
3	UNIT $-111$	12
5		12
5	Preclinical screening models: for ANS activity, sympathomimetics,	12
5	<b>Preclinical screening models:</b> for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal	12
5	<b>Preclinical screening models:</b> for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.	12
4	<b>Preclinical screening models:</b> for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics. <b>UNIT – IV</b>	12
4	<ul> <li>Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.</li> <li>UNIT – IV</li> <li>Preclinical screening models: for CVS activity- antihypertensives,</li> </ul>	12 12 6
4 4.1	<ul> <li>Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.</li> <li>UNIT – IV</li> <li>Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, anti-dyslipidemic, anti-aggregatory, coagulants,</li> </ul>	12 12 6
4 4.1	<ul> <li>Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.</li> <li>UNIT – IV</li> <li>Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, anti-dyslipidemic, anti-aggregatory, coagulants, and anticoagulants.</li> </ul>	12 12 6
4 4.1	<ul> <li>Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.</li> <li>UNIT – IV</li> <li>Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, anti-dyslipidemic, anti-aggregatory, coagulants, and anticoagulants.</li> <li>Preclinical screening models for other important drugs like antiulcer,</li> </ul>	12 12 6
4.1	<ul> <li>Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.</li> <li>UNIT – IV</li> <li>Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, anti-dyslipidemic, anti-aggregatory, coagulants, and anticoagulants.</li> <li>Preclinical screening models for other important drugs like antiulcer, antidiabetic, and anticancer.</li> </ul>	<u>12</u> <u>6</u>
4 4.1 4.2	<ul> <li>Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.</li> <li>UNIT – IV</li> <li>Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, anti-dyslipidemic, anti-aggregatory, coagulants, and anticoagulants.</li> <li>Preclinical screening models for other important drugs like antiulcer, antidiabetic, and anticancer.</li> <li>Research methodology and Biostatistics</li> </ul>	12 12 6 6
4.1	<ul> <li>Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.</li> <li>UNIT – IV</li> <li>Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, anti-dyslipidemic, anti-aggregatory, coagulants, and anticoagulants.</li> <li>Preclinical screening models for other important drugs like antiulcer, antidiabetic, and anticancer.</li> <li>Research methodology and Biostatistics</li> <li>Selection of research topic, review of literature, research hypothesis and</li> </ul>	12 12 6 6
4.1	<ul> <li>Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.</li> <li>UNIT – IV</li> <li>Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, anti-dyslipidemic, anti-aggregatory, coagulants, and anticoagulants.</li> <li>Preclinical screening models for other important drugs like antiulcer, antidiabetic, and anticancer.</li> <li>Research methodology and Biostatistics</li> <li>Selection of research topic, review of literature, research hypothesis and study design.</li> </ul>	12 12 6 6
4.1	<ul> <li>Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.</li> <li>UNIT – IV</li> <li>Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, anti-dyslipidemic, anti-aggregatory, coagulants, and anticoagulants.</li> <li>Preclinical screening models for other important drugs like antiulcer, antidiabetic, and anticancer.</li> <li>Research methodology and Biostatistics</li> <li>Selection of research topic, review of literature, research hypothesis and study design.</li> <li>Pre-clinical data analysis and interpretation using Student's 't' test and One-</li> </ul>	12 6 6
4 4.1 4.2	<ul> <li>Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.</li> <li>UNIT – IV</li> <li>Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, anti-dyslipidemic, anti-aggregatory, coagulants, and anticoagulants.</li> <li>Preclinical screening models for other important drugs like antiulcer, antidiabetic, and anticancer.</li> <li>Research methodology and Biostatistics</li> <li>Selection of research topic, review of literature, research hypothesis and study design.</li> <li>Pre-clinical data analysis and interpretation using Student's 't' test and Oneway ANOVA. Graphical representation of data.</li> </ul>	12 6 6

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- 2. Kulkarni SK. Handbook of experimental pharmacology, 4<sup>th</sup> edition, Vallabh Prakashan, 2012.
- 3. CPCSEA guidelines for laboratory animal facility, 2020.
- Vogel H.G, Drug discovery and Evaluation, 3<sup>rd</sup> edition, Springer, 2007.
   Suresh Kumar Gupta and S. K. Gupta, Drug Screening Methods, 3<sup>rd</sup> edition, Jaypee Brothers Medical Publishers, 2016.
- 6. PSS Sundar Rao and J Richard, Introduction to Biostatistics and Research Methods, 5th edition, PHI Learning Pvt Ltd, 2012.



Syllabus B.Pharm (Choice Based Credit System)



# BP811ET ADVANCED INSTRUMENTATION TECHNIQUES (Theory) – ELECTIVE 45 Hours

#### **Course Objectives:**

This course deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This course is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

#### **Course Outcomes:**

Upon completion of the course the students will be able to:

- 1. Describe the principle and working of <sup>1</sup>H NMR and <sup>13</sup>C-NMR spectroscopy, mass spectrometry techniques and hyphenated techniques.
- 2. Analyse and Interpret spectral data to predict structure of a given compound and propose mass fragmentation pathway.
- 3. Explain fundamentals, working principle and applications of X-ray diffraction technique and thermal methods of analysis like TG, DSC and DTA.
- 4. Understand the concepts and quality control aspects related to radiopharmaceuticals and radioimmunoassay.
- 5. Describe calibration procedures for analytical instruments and compare validation parameters for analytical and bioanalytical procedures.

Unit	Details	Hours
1	UNIT - I	19
1.1	<b>Nuclear Magnetic Resonance spectroscopy</b> Principles of <sup>1</sup> H-NMR and <sup>13</sup> C-NMR, spinning nucleus, precessional motion, precessional frequency, gyromagnetic ratio, energy transitions and relaxation processes, NMR Spectra, chemical shift, factors affecting chemical shift (Electronegativity-Shielding and Deshielding, Van der Waal's deshielding, anisotropic effect), shielding and deshielding, Van der Waal's deshielding, Deuterium exchange, Chemical and magnetic equivalence, anisotropic effect (e.g. Alkanes, alkenes, alkynes, carbonyl, aromatic and cyclohexane), Solvents, Reference compounds and internal standards, coupling constant, Spin - spin coupling – Spin-spin splitting (N+1 rule (Pascal's triangle), theory of spin-spin splitting, formation of doublet, triplet and quartet due to possible spin orientations, inverted tree diagram, Coupling constants & values for alkyl, alkenyl, aromatic), relaxation, instrumentation and pharmaceutical applications Structural elucidation of simple organic molecules with molecular formula using <sup>1</sup> H-NMR and/or <sup>13</sup> C-NMR with or without IR spectroscopic and UV spectroscopic data	
1.2	<b>Mass Spectrometry</b> - Principles, Mass spectrum, relative abundance, mass to charge ratio, molecular ion, fragment ion (daughter ion), metastable ion, base peak, isotope peak, mass to charge ratio, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers -Time of flight and Quadrupole, instrumentation, pharmaceutical applications Examples of different Fragmentation pathways - Fissions (homolytic and heterolytic, $\alpha$ and $\beta$ fission), Rearrangement (McLafferty, Retro Diel-Alders, 4	





	membered cyclic rearrangement), Nitrogen rule and Even electron rule	
2	UNIT – II	10
2.1	Thermal Methods of Analysis: Principles, instrumentation, factors affecting	
	analysis and pharmaceutical applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Security Colorimetry (DSC)	
2.2	<b>X Pay Diffraction Methods:</b> Origin of X rays basic aspects of crystals. X ray	
2.2	Crystallography Bragg's Law	
	Rotating crystal technique, single crystal diffraction, nowder diffraction	
	instrumentation structural elucidation and pharmaceutical applications	
3	UNIT – III	6
3.1	Calibration and validation-as per ICH and USEDA guidelines	Ū
32	Calibration of following Instruments- Electronic balance UV-VIS	
0.2	spectrophotometer FTIR spectrophotometer Fluorimeter Flame Photometer	
	HPLC and GC.	
	Comparison of validation of analytical and bioanalytical methods by ICH and	
	USFDA guidelines	
4	UNIT – ĬV	6
4.1	Radiopharmaceuticals and Radioimmuno assay	
	Properties of radionuclide, Radioisotope, Radioactive decay, half-life of	
	radioactivity, specific activity, Becquerel, curie, Sievert and Gray, Relative	
	biological effectiveness, Radionuclidic purity, Radiochemical purity, Safety	
	aspects of radiopharmaceutical laboratory, Measurements of radioactivity- Geiger-	
	Muller Counting, liquid Scintillation Counting	
	Requirements of radiopharmaceuticals- Properties of radionuclides,	
	Pharmaceutical and chemical properties, Radionuclide generator- 99m Tc	
	generator, Quality control of radiopharmaceuticals: Physical, Chemical	
	(Radionuclidic purity, Radiochemical purity)	
	Radioimmuno assay - Importance, various components, Principle, different	
10	The first for the last sector of the first sec	
4.2	EXtraction techniques: Namet Distribution low and partition coefficient. Distribution coefficient	
	Nernst Distribution law and partition coefficient, Distribution coefficient,	
	General principle and procedure involved in the solid phase extraction and	
	liquid-liquid extraction	
5	UNIT- V	4
	<b>Hyphenated techniques-</b> Significance interfaces and applications of -I C-	•
	MS/MS, GC-MS/MS, HPTLC-MS.	
	TOTAL	45
L		

- Sharma, B.K., Instrumental Methods of Chemical Analysis, 24<sup>th</sup> revised and enlarged edition, Goel Publishing House, Meerut, 2005.
- Y. R. Sharma, Elementary Organic spectroscopy, Principles and Chemical Applications, 5<sup>th</sup> Edition, S. Chand Publishing, 2013.
- 3. Beckett A. H., Stenlake J. B., Practical Pharmaceutical Chemistry, Vol. I & II, 2<sup>nd</sup> edition, Athlone Press, University of London, London, 1970
- Connors, K. A., A Textbook of Pharmaceutical Analysis, 3<sup>rd</sup> edition, John Wiley and Sons, Canada., 2007.





- 5. Skoog, D. A., F. J. Holler and S. R. Crouch. Principles of Instrumental Analysis, 6<sup>th</sup> edition, Brooks Cole, 2006.
- 6. J. Mendham, R. C. Denney, J. D. Barnes, M. J. K. Thomas, B. Sivasankar, Vogel's Textbook of Quantitative Chemical Analysis, 6<sup>th</sup> edition, Pearson Education, New Delhi, 2009.
- 7. Silverstein RM and Webster FX, Spectrophotometric identification of Organic Compounds, 6<sup>th</sup> edition, John Wiley and Sons, 1998.
- 8. Finar I. L., Organic Chemistry, Vol. 1, 4<sup>th</sup> edition, Longman, 1963.
- 9. Organic spectroscopy, William Kemp, 3<sup>rd</sup> edition, Macmillan, 2019.
- 10. P. D. Sethi, Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3<sup>rd</sup> edition, CBS Publishers, 2019.
- 11. D. C. Garrett, The quantitative Analysis of Drugs, , 3<sup>rd</sup> edition, Springer, 1976.

#### <u>BP812ET</u> DIETARY SUPPLEMENTS AND NUTRACEUTICALS (Theory) –ELECTIVE 45 Hours

#### **Course Objectives:**

This course covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.

#### **Course Outcomes:**

After completion of the course the student should be able to:

- 1. Understand the need of supplements by the different group of people to maintain healthy life.
- 2. Understand the outcome of deficiencies in dietary supplements.
- 3. Appreciate the components in dietary supplements and the application.
- 4. Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

Unit	Details	Hours
1	UNIT - I	10
	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. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community. 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.	

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2	UNIT –I I	10
	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.	
3	UNIT – III	10
	a) 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.	
4	UNIT – IV	8
	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, a- Lipoic acid, melatonin Synthetic	
	antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.	
	c) Functional foods for chronic disease prevention.	
5	UNIT - V	7
	a) Effect of processing, storage and interactions of various environmental factors	
	on the potential of nutraceuticals.	
	b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs	
	on Food Safety. Adulteration of foods.	
	c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.	
	TOTAL	45

- 1. Sri Lakshmi B, Dietetics, 8<sup>th</sup> edition, New Age Publishers Pvt Ltd, 2014.
- 2. K.T Agusti, P. Faizal and Paul Augustine, Role of dietary fibres and nutraceuticals in preventing diseases, BSP Books Pvt Ltd., 2018.
- 3. Cooper. K.A., Advanced Nutritional Therapies, 1<sup>st</sup> edition, Thomas Nelson Inc, United Kingdom, 1998.
- 4. Jean Carper, The Food Pharmacy, New Edition, Simon & Schuster, London, 2000.
- 5. James F. Balch and Phyllis A Balch, Prescription for Nutritional Healing, 2<sup>nd</sup> Edn, Avery Publishing Group, New York, 1997.
- 6. G. Gibson and C. Williams Editors, Functional foods Woodhead Publishing Company, 1<sup>st</sup> edition, London, 2000.





- Goldberg, I., Functional Foods Designer foods, Pharma foods, Nutraceuticals, Chapman and Hall, 1<sup>st</sup> edition, New York. 1994.
- 8. Labuza, T.P., 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. 1<sup>st</sup> edition, Springer Publications, 2000.
- 9. Widman REC and Bruno RS, Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition), CRC Press, 2019.
- 10. Shils, ME, Olson, JA, Shike, M., Modern Nutrition in Health and Disease. eighth edition. Lea and Febiger. 1994.

# BP813ET PHARMACEUTICAL PRODUCT DEVELOPMENT(Theory) ELECTIVE 45 Hours

#### **Course Objectives:**

This course covers topics that will provide the learner with understanding of essential active and excipient studies required for pharmaceutical product development. The course will enable the learner to understand the step-by-step procedure to be followed towards developing a stable commercially viable product.

#### **Course Outcomes:**

After completing the course the student should be able to:

- 1. Apply different characterization techniques for evaluating API and excipients before the initiation of product development
- 2. Devise strategies in designing stable commercially viable products
- 3. Characterise different dosage forms for essential quality parameters
- 4. Devise protocols for development of products exhibiting regulatory compliance

Unit	Details	Hours
1	UNIT - I	10
1.1	Introduction to pharmaceutical product development:	
	Objectives, concept of product life cycle, regulations related to	
	preformulation, formulation development, Purpose and role of IIG, stability	
	assessment, manufacturing and quality control testing of different types of	
	dosage forms.	
2	UNIT – II	10
2.1	An advanced study of Pharmaceutical Excipients in pharmaceutical product	
	development with a special reference to the following categories	
	i. Solvents and solubilizers.	
	ii. Lipids, 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.	
3	UNIT – III	10
3.1	IPEC role and responsibility, Introduction to EXCIPACT- for excipient	
	regulations. 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.	

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	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.	
4	UNIT – IV	8
	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. Self-study on case studies based on QbD approach in development of solid, semisolid and parenteral dosage forms	
5	UNIT- V	7
	Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations. Regulatory considerations for product development pertaining to FDA guidelines- BCS classification and its importance with relevance to Biowaivers, Q1/Q2 approach in development of oral, dermal and injectable dosage forms.	
	TOTAL	45

- 1. Stanford Bolton and Charles Bon, Pharmaceutical Statistics Practical and Clinical Applications, 5<sup>th</sup> edition, CRC press, 2009.
- 2. Encyclopedia of Pharmaceutical Technology, 6 volume set, edited by James Swarbrick, 3<sup>rd</sup> Edition, Informa Healthcare Publishers, 2006
- 3. Roop K Khar, S P Vyas, Farhan J Ahmad, Gaurav K Jain, The Theory and Practice of Industrial Pharmacy, 4<sup>th</sup> Edition, CBS Publishers and Distributors Pvt. Ltd. 2013.
- Sinko PJ, Singh Y. Martin's Physical Pharmacy and Pharmaceutical Sciences: Physical Chemical and Biopharmaceutical Principles in the Pharmaceutical Sciences, 6<sup>th</sup> edition, Walter Kluer, Philadelphia, 2011.
- 5. S. P. Vyas and R. K. Khar, Targeted and Controlled Drug Delivery, Novel Carrier Systems, CBS Publishers and Distributors Pvt. Ltd, 2019.
- 6. Ansel H.C., Allen L.V., Pharmaceutical Dosage Forms and Drug Delivery Systems, 10<sup>th</sup> edition, Lippincott Williams and Walkins, USA, 2014.
- 7. Michael E. Aulton, Aulton's Pharmaceutics The Design and Manufacture of Medicines, 4th Ed., 2013.
- 8. Gennaro A.R., Remington's: The Science and Practice of Pharmacy, 21st edition, Lippincott Williams and Wilkins, Philadelphia, 2005.
- 9. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms—tablets, Vol.1,2,3 edited by Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz, 2<sup>nd</sup> edition, Marcel Dekker Inc., New York, 1990.
- Liberman H.A, Lachman L, Pharmaceutical dosage forms. Parenteral Medications, volume 1, 2,3 edited by Avis K, Herbert A. Lieberman H. A. and Lachman L, Martin, M., 3<sup>rd</sup> edition, Marcel Dekker Inc. New York. 1993.
- 11. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3 edited by Herbert A. Lieberman, Martin, M., and Gilbert S. Banker, 2<sup>nd</sup> edition, Marcel Dekker Inc. New York,1998.
- 12. <u>https://ipec-federation.org/</u>





13. https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm

14. Advanced Review Articles related to the topics.

### **BP814PW**

### PROJECT WORK 180 Hours

Project is a requirement for the B. Pharm. degree, wherein under the guidance of a faculty member, a group of not more than five learners in the eighth semester, is required to do some innovative work with the application of knowledge gained while learning various courses in the earlier years. The area of the project shall be directly related to any one of the elective courses opted by the student in semester VIII. The learner/s is/are expected to do a survey of literature in the subject, work out a Project plan and carry it out through survey, experimentation and/or modelling / computation. Through the Project work the learner should exhibit skills for both analysis and critical thinking. The complete details of the project have to submitted as a report of not less than 25 pages (A4, 1 inch margin, single line space, font Times Roman, font size 12, excluding count of reference pages) to the College before the prescribed date. The credits assigned for Project is 6 credits.