From Coordinator's Desk:-

To meet the challenge of ensuring excellence in engineering education, the issue of quality needs to be addressed, debated taken forward in a systematic manner. Accreditation is the principal means of quality assurance in higher education. The major emphasis of accreditation process is to measure the outcomes of the program that is being accredited. In line with this Faculty of Technology of University of Mumbai has taken a lead in incorporating philosophy of outcome based education in the process of curriculum development.

Faculty of Technology, University of Mumbai, in one of its meetings unanimously resolved that, each Board of Studies shall prepare some Program Educational Objectives (PEO's), give freedom to affiliated Institutes to add few (PEO's) course objectives course outcomes to be clearly defined for each course, so that all faculty members in affiliated institutes understand the depth approach of course to be taught, which will enhance learner's learning process. It was also resolved that, maximum senior faculty from colleges and experts from industry should to be involved while revising the curriculum. I am happy to state that, each Board of studies has adhered to the resolutions passed by Faculty of Technology, developed curriculum accordingly. In addition to outcome based education, **Choice Based Credit and Grading System** is also introduced to ensure quality of engineering education.

Choice Based Credit and Grading System enables a much-required shift in focus from teacher-centric to learner-centric education since the workload estimated is based on the investment of time in learning not in teaching. It also focuses on continuous evaluation which will enhance the quality of education. University of Mumbai has taken a lead in implementing the system through its affiliated Institutes. Faculty of Technology has devised a transparent credit assignment policy adopted ten points scale to grade learner's performance. Credit grading based system was implemented for First Year of B. Pharmacy from the academic year 2016-2017. Subsequently this system is being carried forward for Second Year B. Pharmacy in the academic year 2017-2018, and will be carried forward for Third Year and Final Year B. Pharmacy in the academic years 2018-2019, 2019-2020, respectively.

Dr. S. K. Ukarande
Faculty of Technology,
Member - Academic Council
University of Mumbai, Mumbai

B. Pharm. Choice Based Credit and Grading System (CBCS) [2016-17]

Scheme Examination Semesters I to VIII
&
Syllabus Semesters I to IV

[REVISED 2016]

EXAMINATION SCHEME FOR THE
CHOICE BASED CREDIT AND GRADING SYSTEM (CBCS) (2016-17)

SEMESTER I

Course Code	Name	Credits	Hr/Wk	Weightage Internal	Weightage End Semester Exam	Total Marks
BPH_C_101_T	General Chemistry	4	4	20	80	100
BPH_C_102_T	Dispensing and Community Pharmacy	4	4	20	80	100
BPH_C_103_T	Anatomy, Physiology & Pathophysiology I	4	4	20	80	100
BPH_C_104_T	Biochemistry I	4	4	20	80	100
BPH_C_105_T	Communication Skills and Ethics (NUES)	3	3	20	80	100
	TOTAL Theory	**19**	**19**	**100**	**400**	**500**
BPH_C_106_L	General Chemistry Lab	2	4	10	40	50
BPH_C_107_L	Dispensing and Community Pharmacy Lab	2	4	10	40	50
BPH_C_108_L	Anatomy, Physiology & Pathophysiology Lab	2	4	10	40	50
	TOTAL Lab	**6**	**12**	**30**	**120**	**150**
	TOTAL SEM I	**25**	**31**	**130**	**520**	**650**

SEMESTER II

Course Code	Name	Credits	Hr/Wk	Weightage Internal	Weightage End Semester Exam	Total Marks
BPH_C_201_T	Anatomy, Physiology & Pathophysiology II	4	4	20	80	100
BPH_C_202_T	Biochemistry II	4	4	20	80	100
BPH_C_203_T	Pharmacognosy I	4	4	20	80	100
BPH_C_204_T	Hospital Pharmacy and Drug Store Management	4	4	20	80	100
BPH_C_205_T	Environmental Science	3	3	20	80	100
	TOTAL Theory	**19**	**19**	**100**	**400**	**500**
BPH_C_206_L	Pharmacognosy Lab I	2	4	10	40	50
BPH_C_207_L	Biochemistry Lab	2	4	10	40	50
BPH_C_208_L	Computer Lab	2	4	10	40	50
	TOTAL Lab	**6**	**12**	**30**	**120**	**150**
	TOTAL SEM II	**25**	**31**	**130**	**520**	**650**

NO REMEDIAL FOR LATERAL ENTRY AS SEM I AND II SUBJECTS ARE COVERED IN DIPLOMA SYLLABUS

SEMESTER III

Course Code	Name	Credits	Hr/Wk	Weightage Internal	Weightage End Semester Exam	Total Marks
BPH_C_301_T	Organic Chemistry I	4	4	20	80	100
BPH_C_302_T	Physical Pharmacy I	4	4	20	80	100
BPH_C_303_T	Anatomy, Physiology & Pathophysiology III	4	4	20	80	100
BPH_C_304_T	Pharmaceutical Analysis I	3	3	20	80	100
BPH_C_305_T	Pharmaceutical Engineering	3	3	20	80	100
	TOTAL Theory	**18**	**18**	**100**	**400**	**500**
BPH_C_306_L	Organic Chemistry Lab I	2	4	10	40	50
BPH_C_307_L	Physical Pharmacy Lab I	2	4	10	40	50
BPH_C_308_L	Pharmaceutical Analysis Lab I	2	4	10	40	50
	TOTAL Lab	**6**	**12**	**30**	**120**	**150**
	TOTAL SEM III	**24**	**30**	**130**	**520**	**650**

SEMESTER IV

Course Code	Name	Credits	Hr/Wk	Weightage Internal	Weightage End Semester Exam	Total Marks
BPH_C_401_T	Organic Chemistry II	4	4	20	80	100
BPH_C_402_T	Physical Pharmacy II	4	4	20	80	100
BPH_C_403_T	Pharmaceutics I	3	3	20	80	100
BPH_C_404_T	Pharmacology I	4	4	20	80	100
BPH_C_405_T	Microbiology	3	3	20	80	100
BPH_C_406_T	Mathematics and Statistics	3	3	20	80	100
	TOTAL Theory	**21**	**21**	**120**	**480**	**600**
BPH_C_407_L	Physical Pharmacy Lab II	2	4	10	40	50
BPH_C_408_L	Pharmaceutics Lab I	2	4	10	40	50
BPH_C_409_L	Pharmacology Lab I	2	4	10	40	50
	TOTAL Lab	**6**	**12**	**30**	**120**	**150**
	TOTAL SEM IV	**27**	**33**	**150**	**600**	**750**

SEMESTER V

Course Code	Name	Credits	Hr/Wk	Weightage Internal	Weightage End Semester Exam	Total Marks
BPH_C_501_T	Organic Chemistry III	4	4	20	80	100
BPH_C_502_T	Pharmaceutics II	4	4	20	80	100
BPH_C_503_T	Pharmaceutical Biotechnology	4	4	20	80	100
BPH_C_504_T	Pharmacology II	4	4	20	80	100
BPH_E_5xx_T	Choice Based Course I	2	2	10	40	50
BPH_E_5xx_T	Choice Based Course II	2	2	10	40	50
	TOTAL Theory	**20**	**20**	**100**	**400**	**500**
BPH_C_505_L	Organic Chemistry Lab II	2	4	10	40	50
BPH_C_506_L	Pharmaceutics Lab II	2	4	10	40	50
BPH_C_507_L	Experimental Techniques in Microbiology and Biotechnology Lab	2	4	10	40	50
	TOTAL Lab	**6**	**12**	**30**	**120**	**150**
	TOTAL SEM V	**26**	**32**	**130**	**520**	**650**

SEMESTER VI

Course Code	Name	Credits	Hr/Wk	Weightage Internal	Weightage End Semester Exam	Total Marks
BPH_C_601_T	Pharmaceutical Chemistry I	4	4	20	80	100
BPH_C_602_T	Pharmaceutics III	4	4	20	80	100
BPH_C_603_T	Pharmaceutical Analysis II	4	4	20	80	100
BPH_C_604_T	Pharmacognosy II	4	4	20	80	100
BPH_E_6xx_T	Choice Based Course III	4	4	20	80	100
BPH_E_6xx_T	Choice Based Course IV	2	2	10	40	50
	TOTAL Theory	**22**	**22**	**110**	**440**	**550**
BPH_C_605_L	Pharmaceutical Chemistry Lab I	2	4	10	40	50
BPH_C_606_L	Pharmaceutics Lab III	2	4	10	40	50
BPH_C_607_L	Pharmaceutical Analysis Lab II	2	4	10	40	50
	TOTAL Lab	**6**	**12**	**30**	**120**	**150**
	TOTAL SEM VI	**28**	**34**	**140**	**560**	**700**

SEMESTER VII

Course Code	Name	Credits	Hr/Wk	Weightage Internal	Weightage End Semester Exam	Total Marks
BPH_C_701_T	Pharmaceutical Chemistry II	4	4	20	80	100
BPH_C_702_T	Pharmacognosy III	4	4	20	80	100
BPH_C_703_T	Pharmaceutical Analysis III	4	4	20	80	100
BPH_C_704_T	Pharmacology III	4	4	20	80	100
BPH_C_705_T	Pharmaceutical Jurisprudence	3	3	20	80	100
BPH_E_7xx_T	Choice Based Course V	2	2	10	40	50
	TOTAL Theory	**21**	**21**	**110**	**440**	**550**
BPH_C_706_L	Pharmacognosy Lab II	2	4	10	40	50
BPH_C_707_L	Pharmaceutical Analysis Lab III	2	4	10	40	50
BPH_C_708_L	Pharmacology Lab II	2	4	10	40	50
	TOTAL Lab	**6**	**12**	**30**	**120**	**150**
	TOTAL SEM VII	**27**	**33**	**140**	**560**	**700**

SEMESTER VIII

Course Code	Name	Credits	Hr/Wk	Weightage Internal	Weightage End Semester Exam	Total Marks
BPH_C_801_T	Pharmaceutical Chemistry III	4	4	20	80	100
BPH_C_802_T	Pharmaceutics IV	4	4	20	80	100
BPH_E_8xx_T	Choice Based Course VI	4	4	20	80	100
BPH_E_8xx_T	Choice Based Course VII	4	4	20	80	100
	TOTAL Theory	**16**	**16**	**80**	**320**	**400**
BPH_C_803_L	Pharmaceutical Chemistry Lab II	2	4	10	40	50
BPH_C_804_L	Pharmaceutics Lab IV	2	4	10	40	50
BPH_E_805_D	Project	6	12	-	200	200
	TOTAL Lab	**10**	**20**	**20**	**280**	**300**
	TOTAL SEM VIII	**26**	**36**	**100**	**600**	**700**

SYLLABUS FOR F. Y. B. Pharm.

SEMESTER-I

BPH_C_101_T – General Chemistry - (4 Hr/Wk)

Course Objectives

On completion of following theory topics, learner should be able to understand basic concepts of bonding, principles of chemical reaction and catalytic reaction, role of inorganic reagents as medicinal compounds.

Course Outcomes

The learner should be able to:

1) Draw and explain the structures of various molecules or ions based on the concept of ionic and covalent bonding
2) Explain the Rate Law of a Chemical Reaction and Apply the knowledge of principles like Hammonds postulate, Reactivity and Selectivity Microscopic reversibility to predict the nature of reaction and product formation rate
3) Differentiate the types of catalytic reactions and explain the role of catalyst
4) Classify Gastrointestinal Agents, Topical Agents, Saline Cathartics, Expectorants, Emetics, Antidotes and explain their mode of action. Describe sclerosing agents and complexing agents
5) Classify electrolytes/ elements and elaborate their physiological role. Explain use of physiological ions in replacement therapy, acid-base balance and combination therapy.
6) Explain the basic concepts of radiochemistry and biological effects of radiation; describe diagnostics and therapeutic uses of radiopharmaceuticals.

No.	Details	Hours
1	**Review of basic bonding concepts**	**10**
1.1	Quantum numbers, atomic orbitals, electron configuration, electronic diagrams, polar covalent bonds, electronegativity group, electronegativities, electrostatic potential surfaces, inductive effects, bond dipoles, molecular dipoles.	4
1.2	Lewis structures, formal charge.	3
1.3	VSEPR, hybridization involving s, p and d orbitals, hybridization effects	3
2	**Kinetics and reaction mechanism**	**7**
2.1	Energy surfaces, reaction coordinate diagrams, activated complex/transition state rate and rate constants, reaction order and rate laws	2
2.2	Kinetic isotope effects	2
2.3	Hammond Postulate, reactivity vs selectivity, Curtin-Hammett Principle, microscopic reversibility, kinetic vs thermodynamic control	3
3	**Catalysis:**	**7**
3.1	General principles of catalysis, Forms of catalysis – electrophilic catalysis, acid- base catalysis, nucleophilic catalysis, covalent catalysis, phase transfer catalysis.	4
3.2	Bronsted Acid-base catalysis, correlation of reaction rates with acidity functions.	3
4	**Gastrointestinal Agents**	**4**
4.1	Acidifying agents	1
4.2	Antacids:Sodium bicarbonate, aluminum hydroxide, calcium carbonate, tribasic calcium phosphate, magnesium hydroxide, magnesium trisilicate and combination antacid preparations.	1
4.3	Protectives and Adsorbents:Introduction; bismuth subnitrate, bismuth subcarbonate, kaolin, attapulgite and activated charcoal	1
4.4	Cathartics	1
5	**Topical Agents**	**4**
5.1	Protective Topical Agents: Definition; talc, insoluble zinc compounds (zinc oxide, calamine, zinc stearate), titanium dioxide.	1
5.2	Antimicrobials and Astringents: Antimicrobial terminology, mechanism of action Antimicrobial Astringent Products: Oxidative antimicrobial agents; (hydrogen peroxide, zinc peroxide, sodium carbonate, potassium permanganate, sodium hypochlorite, iodine preparation and compounds)	1
5.3	Protein Precipitant Antimicrobial Agents: Silver nitrate, mild silver protein and related products, ammoniated mercury, mercuric chloride, sulphur and sulphur compounds, sublimed sulphur and precipitated sulphur, boric acid and sodium borate, antimony potassium tartrate.	1

5.4	Astringents: Official compounds of aluminium and zinc	1
6	**Complexing and chelating agents used in therapy, poisons and antidotes**	**2**
7	**Miscellaneous inorganic pharmaceutical agents:**	**2**
7.1	Sclerosing agents, expectorants, emetics.	1
7.2	Antioxidants: Theory and principle, selection of antioxidants, official antioxidants (hypophosphorous acid, sodium bisulphite, sodium thiosulphate, sodium nitrite and nitrogen).	1
8	**Inorganic Radio Pharmaceuticals:** Properties of α,β and γ radiation, biological effect of radiation, half-life, clinical application of radiopharmaceuticals (Chromium-51, Iodine-125 and 131, Technetium-99, Iron-59, Cobalt-57 and 60 and Gold-198)	**4**
9	**Major Intra & Extracellular Electrolytes**	**5**
9.1	Major physiological ions (Role and condition related to change in concentration of following ions: chloride, phosphate, bicarbonate, sodium, potassium, calcium, magnesium)	2
9.2	Electrolytes used in replacement therapy: Sodium replacement (sodium chloride), potassium replacement (potassium chloride), calcium replacement (calcium chloride, calcium gluconate)	1
9.3	Physiological acid base balance: Acids and Bases: Buffers (Pharmaceutical and Physiological) Electrolytes used in acid base therapy (sodium acetate, sodium bicarbonate, sodium biphosphate, sodium citrate, sodium lactate, ammonium chloride). Electrolyte combination therapy.	2
10	**Essential and Trace Elements:** Iron and haematinics Copper, zinc, molybdenum, selenium and sulphur. Official iodine products (iodine,potassium iodide, sodium iodide).	**3**
	TOTAL	**48**

Note: Only Uses of pharmaceutical agents mentioned to be covered. Monographs not to be discussed.

Books:

Latest Edition of all books to be referred.

1) Eric V Ansyln and Dennis A Dougherty, Modern Physical Organic Chemistry, John Wiley.
2) Inorganic medicinal and pharmaceutical chemistry, J. H. Block, E. B. Roche, T. O. Soine, and C. O. Wilson. Lea &Febiger, Philadelphia, PA.
3) Modern Inorganic Pharmaceutical Chemistry, Clarence A. Discher. Wiley, New York.
4) Remington: the science and practice of pharmacy, Beringer, P. Lippincott Williams & Wilkins.
5) Inorganic Pharmaceutical Chemistry, Bothara, K. G., Nirali Prakashan.
6) Inorganic Pharmaceutical Chemistry, A. S. Dhake, H. P. Tipnis, Career Publication.

BPH_C_102_T – Dispensing and Community Pharmacy – (4 Hr/Wk)

Course Objectives

On completion of the theory topics, the learner should have had an understanding of the concept of drug versus dosage forms, basic calculations relating to the practice of dispensing, prescriptions and their types and their compounding and the role of a community pharmacy in healthcare

Course Outcomes

The learner should be able to:

1. Define and identify various dosage forms
2. Solve problems relating to pharmaceutical calculations
3. Have knowledge of different prescription types
4. Identify and comprehend different steps involved in dispensing of formulations
5. Understand principles involved in compounding of different dosage forms
6. Identify physical and chemical incompatibilities among different active ingredients and formulations
7. Understand the organization of community pharmacy, provide optimal patient care under the direct personal interaction/ counseling

No.	Details	Hours
1	**Concept of formulation:** Definition of drug and dosage form Introduction to routes of administration Classification of dosage form and their applications	4
2	Introduction to compounding and dispensing.	1
3	**Prescription:** Prescription and its parts. Types of prescriptions. Pricing and recording of prescriptions.	2
4	**General dispensing:** Fundamentals of compounding and dispensing including good practices. Containers and closures/packaging for dispensed products. Storage and stability of dispensed products. Labeling of dispensed preparations. Dispensing of proprietary medicines.	5
5	**Pharmaceutical Calculations:** Reduction and enlargement of formulae, formula by weight(w/v, w/w, v/v), in parts Calculations based on expressions of concentration and dilution (percentage, parts, alligation), proof strength. Posology.	4
6	**General compounding of Products (includes excipients used and compounding procedure):** Solutions, suspensions, emulsions and creams, ointments and pastes, gels, suppository and pessaries, powders, granules. and capsules	10
	Self-Study: Compounding of dosage forms such as lozenges, pastilles, pills, tablet triturates.	*5*
7	**Incompatibilities:** Physical Incompatibilities, Chemical Incompatibilities.	3
8	**Community Pharmacy:** Definition and scope Pharmacy and heath care system in India Roles and responsibilities of community pharmacist	2
9	**Health education:** WHO Definition of health, and health promotion Health screening services- definition, importance, methods for screening	3
	Self-Study: Commonly occurring Communicable Diseases, causative agents, Balance diet, treatment & prevention of deficiency disorders, Family planning – role of pharmacist	*3*
10	**Pharmaceutical care:** Definition and Principles of Pharmaceutical care, definition and outcomes of patient counseling	2
11	OTC Medication	2
12	**Pharmaceutical ethics:** Principle and Significance of professional ethics, code of ethics for a pharmacist	2
	TOTAL	**48**

Books:

1. Cooper and Gunn's Dispensing for Pharmaceutical Students, Edns. 11 and 12; Edited by S.J.Carter, IndianEdition, CBS Publishers, Delhi.
2. Pharmaceutical Practice; Edited by D.M.Collet and M.E.Aulton; Churchill Livingstone, ELBS Edition, 1991.
3. Pharmaceutical Practice Edited by A.J.Winfield and R.M.E. Richards, Second Edition, Churchill Livingstone, 1998.]
4. Pharmaceutical Practice; Edited by A.J. Winfild and R.M.E. Richards, Third Edition, Churchill Livingstone,2004.
5. Husa's Pharmaceutical Dispensing, Edited by Eric Martin, Sixth Edition, Mack Publishing Company, 1996.
6. Pharmaceutical Calculations, A.C. Ansel and M.J.Stoklosa, Lippincott Williams and Wilkins, 2006.
7. Pharmaceutical Calculations – Bradley, Gustafson and Stoklosa, Third Edition, Lea and Febiger, 1957.
8. Parmar N.S. Health Education and Community Pharmacy, 18th ed. India: CBSPublishers & Distributers; 2008.
9. Merchant S.H. and Dr. J.S.Quadry. A Textbook of Hospital Pharmacy, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001

10. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A Textbook of Clinical Pharmacy Practice- essential concepts and skills, 1 st ed. Chennai: Orient Longman Private Limited; 2004

BPH_C_103_T - Anatomy, Physiology and Pathophysiology – I (4 Hr/Wk)

Course Objectives

To familiarize the learner with the anatomical organization and physiology of the human body and the pathophysiology of some disease states

Course Outcomes

The learner should be able to:

1. Outline and categorize the various body structural levels (cells, tissues, organs, and systems) and recall the structure, composition and functions of plasma membrane and methods of movement of substances across plasma membrane.
2. Explain anatomy, physiology of lymphatic system, recall & interpret the types of hypersensitivity reactions, and make use of the knowledge of the pathophysiology of AIDS and autoimmune diseases.
3. Tell the composition and functions of blood, explain the process of hemostasis and blood coagulation as well as recall & apply the knowledge of pathophysiology of common haematological disorders.
4. Comprehend the mechanisms of inflammation and repair.
5. Recall the anatomy of skeletal, cardiac and smooth muscle, explain the transmission at the neuromuscular junction and energy metabolism in the muscle as well as the mechanism of skeletal muscle contraction and demonstrate various types of skeletal muscle contractions.

No.	Details	Hours
1.	Brief introduction to human body and organization of human body	1
2.	Structural and functional characteristics of following tissues 1) Epithelial 2) Connective 3) Nervous 4) Muscle	2
3.	Detailed structure of cell membrane and trans-membrane movement of substances	2
4.	Components and functions of lymphatic system • Lymphatic organs and tissues • Organization of lymph vessels • Formation and flow of lymph	4
5.	Pathophysiology of following diseases • AIDS • Autoimmune diseases (Rheumatoid arthritis, Grave's disease, Myasthenia Gravis, Rheumatic fever) • Hypersensitivity and types of hypersensitivity reactions.	6
7.	Haematology • Composition of blood • Functions of blood elements • Erythropoiesis and life cycle of RBC. • Synthesis of Haemoglobin • Leucopoiesis • Immunity: Basics and Types • Coagulation of blood • Blood groups	10
8.	Pathophysiology of following diseases • Anaemias – Types of anaemias • Polycythemia : Physiological and polycythemia vera • Leucopenia • Leukocytosis • Thrombocytopenia • Leukemia	5
6.	Basic mechanism involved in the process of inflammation and repair. • Alteration in vascular permeability and blood flow. • Migration of WBC • Acute and chronic inflammation • Brief outline of the process of repair.	7

9.	Structure and properties of following muscles • Cardiac muscles • Smooth muscles • Skeletal muscles • Neuromuscular transmission and contraction of skeletal muscle • Energy metabolism in the muscle • Types of muscle contractions • Muscle tone	11
	TOTAL	**48**

Books:

Latest editions of the following books can be referred

1. Ross & Wilson, Anatomy & Physiology in Health & Illness by Anne Waugh and Allison Grant, Published by Churchill Livingstone
2. Gerard J. Tortora & Bryan Derrickson, Principals of Anatomy & Physiology, Published by John Wiley and Sons, Inc.
3. A. C. Guyton & J. E. Hall, Textbook of Medical Physiology, Published in India by Prism Books Ltd. on arrangement with W. B. Saunders Company, USA.
4. McNaught & Callander, Illustrated Physiology by B. R. Mackenna & R. Callander, Published by Churchill Livingstone
5. Kaplan, Jack, Opheim, Toivola, Lyon, Clinical Chemistry: Interpretation & Techniques
6. Praful B. Godkar, Textbook of Medical Laboratory Technology, Published by Bhalani Publishing House, Mumbai, India
8. Harsh Mohan, Textbook of Pathology, Published by Jaypee Brothers Medical Publishers Pvt. Ltd., New Delhi

BPH_C_104_T - Biochemistry I - (4 Hr/Wk)

Course Objectives

At the end of the theory lectures, the learner should be familiar with the basic building blocks of the biomolecules and the biomacromolecules themselves in a biological system, understand the role of vitamins as cofactors in enzyme reactions and be aware of the principles of thermodynamics as they apply to biosystems.

Course Outcomes

The learner should be able to:

1. List and identify the commonly occurring carbohydrates, amino acids and fatty acids
2. Describe higher order structures like oligo- and poly-saccharides/peptides and membrane lipids
3. Classify the different vitamins in terms of their aqueous solubility and the biochemical reactions/role they are involved in.
4. Define the laws of thermodynamics and explain the concepts of Gibbs free energy, favorable and unfavorable reactions and role of ATP and NADH as energy carriers
5. Describe the process of digestion, absorption, storage and retrieval of different cellular nutrients

No.	Details	Hours
1.	**Introduction to Carbohydrates:** Introduction to common monosaccharides ranging from trioses to hexoses Introduction to common disaccharides sucrose, cellobiose, maltose, lactose Introduction to common polysaccharides starch and glycogen **Introduction to Proteins:** Introduction to amino acids, their classification, three letter and one letter codes Introduction to hierarchy of protein structures **Introduction to Lipids:** Introduction to common saturated and unsaturated fatty acids Introduction to triacyl glycerol, phospholipids, sphingolipids **Introduction to Nucleic acids:** Introduction to nitrogen bases, nucleosides and nucleotides Introduction to the structure of DNA (helices), melting and annealing of DNA, melting temperature and introduction to higher order packaging of DNA Introduction to the concept of glycoproteins, proteoglycans, lipopolysaccharides, glycolipids, lipoproteins, proteolipids, nucleoproteins, with examples.	22
2.	**Vitamins** Vitamins as co-enzymes and their significance. Biochemical roles of all the vitamins with details of the mechanisms of their functions. (riboflavin, thiamine, pyridoxal, nicotinamide, biotin, folic acid, ascorbic acid, pantothenic acid,	15

	cyanocobolamine, inositol, vitamins A, D, E, K)	
3.	**Biochemical Energetics** Introduction to the concept of free energy, standard free energy, transformed free energy. Thermodynamically favorable or unfavorable reactions. Spontaneous versus thermodynamically favorable reactions. Oxidations as a source of energy in biological systems. ATP, NADH and FADH2 as energy carriers. Introduction to the concepts of anabolism and catabolism. Convergence of metabolic pathways and divergence of anabolic pathways	8
4.	**Digestion** Digestion of food and absorption of food (carbohydrates, lipids and carbohydrates). Fate of absorbed nutrients and the relationship with regard to immediate use, storage, release and interconversion. Role of liver, muscle, adipose tissue, brain and special features of rbcs.	3
	TOTAL	**48**

Books:

1. Lehninger, Principles of Biochemistry, Replika Press.
2. Stryer L, Biochemistry, W. H. Freeman & Co.
3. Harper's Biochemistry, Appleton and Lange, USA.
4. Conn E, Stumpf PK, Brueing G and Doi Roy H, Outlines of Biochemistry, Wiley Liss, USA.
5. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Willliams and Wilkins, USA
6. Foye's Principles of Medicinal Chemistry, Lippincott Williams and Wilkins, USA.

BPH_C_105_T - Communication Skills and Ethics - (3 Hr/Wk)

Course Objectives

To teach the learner the importance of English language, the vocabulary and grammar for effective scientific and non-scientific communication and inculcate the importance of Life Skills and Ethics in fulfilling the role as a pharmacist, healthcare provider and a world citizen.

Course Outcomes

The leaner should be able to:

1. List and identify verbs and the passive voice
2. Apply skills learnt to confidently stand in a group discussion
3. Apply skills learnt to communicate effectively – technically/businesswise
4. Appreciate and imbibe the importance of ethics, human values, honesty and integrity

No.	Details	Hours
1.	**Introduction on language and communication:** Review of grammar and vocabulary, Effective use of dictionary, Phonetics, Meaning and importance of communication, Objectives of Communication. Need for Communication. Types of communication. Written & Verbal communication. Formal and informal communication, upward and downward communication. Non-Verbal, Body Language and Graphic Language. Barriers to effective communication and how to overcome them; brevity, clarity and appropriateness in communication.	**5**
2.	**Technical Communication:** Nature, Origin and Development, Factors involved in Technical Communication (Audience, Purpose, Format & Style), Forms of Technical Communication, Five C's of Technical Communication (Clear, Correct, Concise, Consistent, Comprehensive), Difference between Technical Communication & General Communication	**2**
3.	**Business communication:** Objectives & Functions of Business Communication, Importance of written business correspondence, Types of Business correspondence: Enquiry, Order letter, Complaint letter, Adjustment letter, Official letters, electronic communication, Routine Letters and Goodwill Messages, Office Drafting: Circular, Notice, and Memo. Telephone Communication and Cell Phone etiquettes **Assignment:** Drafting of the above types of business correspondence	**3**
4.	**Career Skills:** Interview skills, Applying for job, Cover letters, Resume and Effective	**4**

	Profiling, group discussion, letter writing, e-mail writing and Netiquettes, Academic Application Drafting, Report writing–preparing rough draft, editing and preparing final report, Presentation Skills: (i) How to make a Power Point presentation (ii) Body language during presentation **Assignment:** Oral presentations by the students, followed by discussion **Mock Interview:** Each student to face an interview and to demonstrate the above taught skills	
5	**Life Skills–** Goal-setting; Self-esteem and Self-Confidence; Problem Solving; Decision Making; Time Management; Stress Management; Positive Thinking; Assertiveness; Teamwork; Interpersonal Relationships; Coping with Life Stresses; Suicidal Tendencies; Peer Pressure; Substance Abuse and Addiction. **Basic Listening Skills:**Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations	**4**
6.	**Effective and Ethical Communication at work:** Flow of communication in organizations, Communication Skills & Success at work, How to overcome typical barriers of Communication and ethical response to office gossip	**2**
7.	**Introduction to Ethics and Human Values**: Definition – Good Behaviour, Conduct and Character; Importance, Respects for Elders, Use and Relevance in Present-day Society, Individual and Society – Desirable Basic Human Characters - Honesty, Truthfulness, Respect, Punctuality, Responsibility, Courtesy, Discipline, Kindness, courage, Character, Forgiveness, Friendship, Compassion, Consideration, Contentedness, Simplicity, Empathy, Avoiding Greed; Family responsibilities, The 3 Cs of ethics – clarity, courage and creativity,	**3**
8.	**Professional Ethics**: Need and Importance – Goals, Dignity of Labour dimensions of ethics; ethics in private and public relationships,Ethical Values in Different Professions – Management, Business, Teaching, Civil Services, Politics, Medicine, Policing, Judiciary.	**2**
9.	**Ethical Practice in Pharmaceutical Industry:** Safety norms, quality norms, clinical trials, packaging, labelling, pricing, distribution, disposal of past-expiry products, advertising, use of medical channels for promotional activities, IPR, Role of R&D, profitability and its linkage to R&D	**2**
10.	**Ethics in Media and Technology**– Impact on Youth; Cyber Ethics and Etiquette;Mobile Phones, Social Networking; Correct and Judicious Use	**1**
11.	**Leadership and Ethics:** What is Ethical Leadership? Principles &commandments of ethical leadership, Characteristics of Ethical leader, Ethical decision making	**2**
12	**Group Projects/ Field Work**	**6**
	Total	**36**

Group Projects: (6 Hrs)
Students could go on a local field trip and submit an account in about 5 pages. Students can be divided into groups of 5 and one written account can be submitted per group. Different groups can undertake different projects so that the logistics are manageable and there is also sharing of experiences/ideas. Students are advised to prepare a list of questions before hand so that they are more focused.
Some suggestions of locations include: Government hospital or dispensary , **old age home**, **Pension Office, Local wholesale market**, **Industry, Cancer care centre, Orphange, Homes for mentally challenged, etc**

Books:

1. The right word at the right time A guide to the English language and how to use it, Elison John, The reader's Digest
2. Study writing, Hamplyons Liz & Ben Heasley, Cambridge University Press.
3. Basic Business Communication, Lesiker Raymond.V and Maire E Hatley, New York, Tata McGraw Hill
4. Business Ethics- A Global and Managerial Perspective, David J. Fritzsche, Tata McGraw Hill
5. Values and Ethics in Organizations – Theory and Practice, S.K.Chakraborty, Oxford University Press (OUP)
6. Ethics Omnibus, S.K.Chakraborty, Oxford University Press (OUP)
7. KK Ramchandran Business communication (Macmilan)
8. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
9. Communication skills, Sanjay Kumar, Pushpalata, 1st Edition, Oxford Press, 2011

10. Organizational Behaviour, Stephen .P. Robbins, 1st Edition, Pearson,2013
11. Brilliant- Communication skills, Gill Hasson, 1st Edition, Pearson Life.
12. Personality development and soft skills, Barun K Mitra, 1st Edition,Oxford Press, 2011

BPH_C_106_L – General Chemistry – Lab - (4 Hr/Wk)

Course Objective

On completion of general chemistry Lab, learner should be able to prepare, purify and examine inorganic pharmaceutical agents.

Course Outcomes

The learner should be able to:

1) Analyze inorganic mixtures qualitatively by semi-micro methods.
2) Identify different inorganic impurities in inorganic medicinal agents by performing Pharmacopoeial test. .
3) Prepare and purify inorganic pharmaceuticals

Practicals:

1) The background and systematic qualitative analysis of inorganic mixtures of up to four radicals. Six mixtures to be analyzed, preferably by semi-micro methods.
2) Identification tests for pharmacopoeial inorganic pharmaceuticals and qualitative tests for cations and anions should be covered (any two)
3) Limit Test for Impurities in Pharmaceutical Compounds: Chloride, Sulphate and Iron
4) Preparation of Selected Inorganic Pharmaceuticals: Potash alum and ferrous oxalate.
5) Purification of Selected Inorganic Pharmaceuticals: Copper sulphate and ferrous sulphate.

References

1) Svehla G. Vogel's Textbook of Micro and Semimicro-Qualitative Inorganic Analysis. Orient Longman, Hyderabad. Latest Edition.
2) Indian Pharmacopoeia. The Indian Pharmacopeia Commission, Central Indian Pharmacopeia Laboratory,Govt. of India. Ministry of Health and Family Welfare, Ghaziabad. Latest Edition.

BPH_C_107_L - Dispensing and Community Pharmacy – (4 Hr/Wk)

Course Objectives

The train the learner in the requirements of a dispensing pharmacist and teach pharmacist-patient interactions at the professional level.

Course Outcomes

The learner should be able to:
1. Read prescriptions, identify commonly used Latin terms in Pharmacy practice
2. Calculate the quantities of active ingredients and excipients required for compounding the required quantity of formulation (expansion and reduction of formula)
3. Compound, label and dispense extemporaneous formulations
4. Understand patient counseling and patient education methods

No.	Details
1	**Solutions:** 1. Potassium Permanganate Solution 2. Paediatric Ferrous Sulphate Oral Solution BP 1988
2	**Suspensions:** 1. Paediatric Chalk Mixture BP 1988 2. Kaolin Mixture BP 1988
3	**Emulsions:** 1. Arachis Oil Emulsion 2. Calciferol Emulsion 3. Medicated cream
4	**Ointment/paste:** 1. Zinc and Castor Oil Ointment BP 1988 / Calamine Ointment IP 2010/Compound Zinc Paste BP 1988
5	**Jelly:** 1. Lubricating jelly
6	**Powders:** 1. Bulk Powder: Compound Magnesium trisilicate Oral Powder BP 1988 /Zinc, Starch and Talc Dusting Powder BPC 1973 2. Divided Powder : Hyoscine Hydrobromide Powder

7	**Granules:** 1. Isaphgol Granules 2. Effervescent Granules
8	**Capsules:** 1. Chlordiazepoxide capsules BP
9	**Suppositories:** 1. Compound Bismuth Subgallate Suppositories BP 1980
10	**Incompatibility:** 1. Eutectic mixture
11	**Community Pharmacy project1:** Disease state education flip charts, Video library development, Patient Education
12	**Community Pharmacy project2:** Presentations on patient counseling with reference to indications, mechanism of action, contraindications and drug interactions of a particular drug.

Patient Education: Training for blood glucose meters • Inhaler and other device use (placebo inhaler cartridge) • Smoking cessation products • Have students offer BP readings to patients picking up anti-hypertensive medications • Have students offer blood glucose logs and a review of medications to patients picking up diabetes medications

Video library development: Have the student develop a video library from which patients could check out videos. The student could gather videos, organize them, and create marketing for the library to advertise it to patients.

Disease state education flip charts: Have the student develop a flip chart (that fits into a standard 3-ring binder) that can be used to educate a patient on a disease state. This standardizes the education that is given to each patient

Books:

1. Cooper and Gunns Dispensing for Pharmaceutical Students, Edns. 11 and 12; Edited by S.J.Carter, IndianEdition, CBS Publishers, Delhi.
2. Pharmaceutical Practice; Edited by D.M.Collet and M.E.Aulton; Churchill Livingstone, ELBS Edition, 1991.
3. Pharmaceutical Practice Edited by A.J.Winfield and R.M.E. Richards, Second Edition, Churchill Livingstone, 1998.]
4. Pharmaceutical Practice; Edited by A.J. Winfild and R.M.E. Richards, Third Edition, Churchill Livingstone,2004.
5. Husa's Pharmaceutical Dispensing, Edited by Eric Martin, Sixth Edition, Mack Publishing Company, 1996.
6. Pharmaceutical Calculations, A.C. Ansel and M.J.Stoklosa, Lippincott Williams and Wilkins, 2006.
7. Pharmaceutical Calculations – Bradley, Gustafson and Stoklosa, Third Edition, Lea and Febiger, 1957.
8. Parmar N.S. Health Education and Community Pharmacy, 18th ed. India: CBSPublishers & Distributers; 2008.
9. Merchant S.H. and Dr. J.S.Quadry. A textbook of hospital pharmacy, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001
10. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1 st ed. Chennai: Orient Longman Private Limited; 2004

BPH_C_108_L - Anatomy, Physiology and Pathophysiology – Lab I (4 Hr/Wk)

Course Objectives

To familiarize the learner with the diagnostic methods for determination of the pathology of some disease states

Course Outcomes

The learner should be able to:

1. Perform RBC count, WBC count, Differential Leukocyte count, ESR, PCV, Bleeding time, clotting time and interpret the results and correlate with clinical conditions and record/measure blood pressure.
2. Identify and locate the bones in human skeleton.
3. Identify and describe the various body tissues and organs based on the structure and organisation of cells.
4. List the common diagnostic and biochemical tests performed in various clinical conditions and make use of it in diagnosis and prognosis of the diseases.

No.	Details
1.	HEMATOLOGY 1. Red Blood Cell (RBC) Count 2. Total Leukocyte Count 3. Differential Leukocyte (WBC) Count 4. Hemoglobin content of blood 5. Bleeding / Clotting Time 6. Blood groups 7. Erythrocyte Sedimentation Rate (ESR) / Hematocrit (Demonstration)

2.	Study of human skeleton
3.	Microscopic study of permanent slides Tissues : - Columnar, Cuboidal, Squamous, Ciliated Epithelium - Cardiac / Skeletal / Smooth muscle - Ovary, Testis, Liver, Pancreas, Thyroid, Tongue, Stomach, Intestine, Kidney, Lung, Spinal Cord, Cerebrum, Artery, Vein
4.	Measurement of blood pressure
5.	Tutorial / Discussion on some common investigational procedures used in diagnosis of diseases with the help of charts / slides Name and Importance of following tests : 1. Electroencephalogram (EEG) in diagnosis of Epilepsy 2. Use of Positron emission tomography (PET) Computed tomography scan (CT Scan), Single photon emission computed tomography (SPECT) in diagnosis. 3. Use of flow cytometry as a diagnostic tool. 4. Electrocardiogram (ECG) in diagnosis of cardiac arrhythmia 5. Liver Function Tests – - Serum Bilirubin, - serum glutamate oxaloacetate transaminase (SGOT) - serum glutamate pyruvate transaminase (SGPT) - Urine Bilirubin, - Urine Urobilinogen, 6. Kidney Function Tests – Serum Creatinine, – Serum Urea, Uric Acid – Blood Urea Nitrogen (BUN) 7. Blood Glucose 8. Serum Cholesterol / Triglycerides 9. Serum Alkaline phosphatase (ALT) 10. Serum Acid phosphatase (APT) 11. Serum Lipase 12. Serum Amylase 13. Serum Calcium 14. Serum lactate dehydrogenase (LDH) 15. Thyroid Function Tests – T_3, T_4 16. Prothrombin time (PT) 17. Partial thromboplastin time (PTT) 18. Activated partial thromboplastin time (APTT) 19. Diagnostic tests for infectious diseases like - Malaria - Tuberculosis - Dengue - H1N1 swine flu -Typhoid

Books:

1. McNaught & Callander, Illustrated Physiology by B. R. Mackenna & R. Callander, Published by by Churchill Livingstone
2. Kaplan, Jack, Opheim, Toivola, Lyon, Clinical Chemistry: Interpretation & Techniques, Published by Elseviers Publications
3. Praful B. Godkar, Textbook of Medical Laboratory Technology, Published by Bhalani Publishing House, Mumbai, India
4. C. L. Ghai, Textbook of Practical Physiology, Published by Jaypee Brothers Medical Publishers Pvt. Ltd., New Delhi

SEMESTER-II

BPH_C_201_T - Anatomy, Physiology and Pathophysiology – II - (4 Hr/Wk)

Course Objectives

To familiarize the learner with the anatomical organization and physiology of the different systems of the human body. To introduce the learner to cancer and the causes of cancer.

Course Outcomes

The learner should be able to:
1. Explain the types of and mechanisms of cellular injuries and cellular adaptation.
2. Compare and contrast between benign and malignant tumours, Classify malignant tumours and explain the etiology and pathogenesis of cancer.
3. Discuss the biological effects of radiations.
4. Explain the anatomy and physiology of the respiratory system, endocrine system, nervous system and the sensory organs.
5. Comprehend the aetiology, pathogenesis, signs, and symptoms of common diseases/disorders of respiratory system, endocrine system and nervous system.

No.	Details	Hours
1.	Principles of cell injury and adaptation • Causes of cell injury • Pathogenesis and morphology of cell injury. • Cellular adaptation • Cellular atrophy and hypertrophy.	4
2.	- Disturbances of growth of cells • Differences between benign and malignant tumor • Classification of malignant tumors • Etiology and pathogenesis of cancer- Invasion, metastasis and patterns of spread of cancer.	3
3.	Biological effects of radiation • Nuclear radiation • U.V. radiation. • X-ray and other radiations.	3
4.	Anatomy and Physiology of Respiratory System • Exchange of gases • External and internal respiration • Mechanism and regulation of respiration • Lung volumes and lung capacities	4
5.	Pathophysiology of following diseases • Asthma • Pneumonia • Bronchitis • Emphysema • Respiratory Acidosis and Alkalosis	4
6.	Endocrine System Anatomy and physiology of following endocrine glands : • Pituitary • Thyroid & Parathyroid • Adrenal • Pancreas	8
7.	Pathophysiology of hypo and hyper secretion of above endocrine glands and related diseases	4
8.	Nervous System Neurons, Neurotransmitter and neurotransmission Anatomy and physiology of **:** • Central Nervous System (CNS) - Autonomic Nervous System (ANS) - Cranial and spinal nerves	8

	- Sensory and Motor pathways	
9.	Pathophysiology of following diseases • Epilepsy • Parkinsonism • Alzheimer's Disease • Cerebral Hypoxia • Stroke (Cerebrovascular disease) • Anxiety & Depression • Mania and Schizophrenia	4
10.	Structure and Function of following sensory organs • Eye • Ear • Tongue • Nose • Skin	6
	TOTAL	**48**

Books:

Latest editions of the following books can be referred

1. Ross & Wilson, Anatomy & Physiology in Health & Illness by Anne Waugh and Allison Grant, Published by Churchill Livingstone
2. Gerard J. Tortora & Bryan Derrickson, Principals of Anatomy & Physiology, Published by John Wiley and Sons, Inc.
3. A. C. Guyton & J. E. Hall, Textbook of Medical Physiology, Published in India by Prism Books Ltd. On arrangement with W. B. Saunders Company, USA.
4. McNaught & Callander, Illustrated Physiology by B. R. Mackenna & R. Callander, Published by Churchill Livingstone
5. Kaplan, Jack, Opheim, Toivola, Lyon, Clinical Chemistry: Interpretation & Techniques
6. Praful B. Godkar, Textbook of Medical Laboratory Technology, Published by Bhalani Publishing House, Mumbai, India
8. Harsh Mohan, Text book of Pathology, Published by Jaypee Brothers Medical Publishers Pvt. Ltd., New Delhi

BPH_C_202_T – Biochemistry II - (4 Hr/Wk)

Course Objectives

To teach the learner the different pathways of intermediary metabolism, their interplay, metabolism based disorders and drugs to treat the same.

Course Outcomes

The learner should be able to:

1. Discuss carbohydrate metabolism with respect to different pathways, structures of intermediates, enzymes and cofactors involved, energy requirements/yields, regulation and drugs affecting metabolism
2. Discuss lipid metabolism with respect to different pathways, structures of intermediates, enzymes and cofactors involved, energy requirements/yields, regulation and drugs affecting metabolism
3. Discuss nucleic metabolism with respect to different pathways, structures of intermediates, enzymes and cofactors involved, energy requirements/yields, regulation and drugs affecting metabolism

No.	Details	Hours
1	Carbohydrate metabolism discussed with respect to the structures of intermediates, enzymes and cofactors, energy yield/requirements and regulation. Examples of drugs modulating carbohydrate metabolism.	**20**
1.1	Glycolysis (Embden Meyerhoff Pathway), TCA cycle (Kreb's Cycle, Citric acid Cycle) and glyoxalate shunt. Entry of sugars other than glucose into glycolytic pathway. Discussion of shuttle systems to transfer NADH to the mitochondria.	08
1.2	Electron Transport Chain discussed with respect to the components of the ETC, explanation of oxidative phosphorylation vs substrate level phosphorylation. Discussion of proton motive force and generation of ATP using proton gradients. Discussion of uncouplers of oxidative phosphorylation.	04
1.3	Discussion of pentose phosphate pathway, glycogenesis, glycogenolysis, gluconeogenesis and other systems involved in carbohydrate metabolism	08
2	Lipid metabolism discussed with respect to the structures of intermediates, enzymes and cofactors involved, energy yield/requirements and regulation.	**18**
2.1	Beta oxidation pathway for catabolism of saturated and unsaturated even number	08

	fatty acids, catabolism of odd number carbon containing fatty acids, formation of ketone bodies	
2.2	Acetate mevalonate pathway to cholesterol biosynthesis,	04
2.3	Biosynthesis of fatty acids, prostaglandins, leukotrienes and phospholipids.	04
2.4	Examples of drugs modulating lipid/cholesterol metabolism.	02
3	Nucleic Acid Metabolism discussed with respect to the structures of intermediates, enzymes and cofactors, energy yield/requirements and regulation	**10**
3.1	Discussion of biosynthesis of purines.	04
3.2	Discussion of biosynthesis of pyrimidines.	02
3.3	Salvage pathways for nucleic acid metabolism. Examples of drugs modulating purine/pyrimidine biosynthesis.	04
	TOTAL	**48**

Books

1. Lehninger, Principles of Biochemistry, Replika Press.
2. Stryer L, Biochemistry, W. H. Freeman & Co.
3. Harper's Biochemistry, Appleton and Lange, USA.
4. Conn E, Stumpf PK, Brueing G and Doi Roy H, Outlines of Biochemistry, Wiley Liss, USA.
5. Wilson and Gisvolds Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Willliams and Wilkins, USA
6. Foye's Principles of Medicinal Chemistry, Lippincott Williams and Wilkins, USA.

BPH_C_203_T – Pharmacognosy I - (4 Hr/Wk)

Course Objectives

This subject highlights the understanding of natural drugs, their cultivation and preparation, phytochemistry and their derivatives used in Allopathic and Complementary Systems of Medicine.

Course Outcomes

The learner should be able to:

1	Outline the Alternative and complementary systems of medicine, classify drugs of natural origin
2	Describe Primary and secondary plant metabolites their biosynthesis, evaluation and therapeutic application
3	Understand the morphological and Microscopic features of medicinal plants
4	Elaborate commercial production, collection, preparation, storage and factors affecting cultivation of medicinal plants
5	Describe chemistry, source, preparation, evaluation of carbohydrate containing crude drugs and their commercial utility as Pharmaceutical Aids and Medicines
6	Describe the source, composition, preparation and applications of fibers, minerals, important protein and enzymes of natural origin.

No.	Details	Hours
1.	Introduction, development, present status, significance and future scope of pharmacognosy. Alternative and Complementary systems of medicine Ayurveda, Unani, Siddha, Homeopathy, Chinese medicine and Aromatherapy. Self study: Examples of sources of DONO • Examples of drugs used in different traditional systems of medicine.	2 1
2	Classification of drugs: Alphabetical, morphological, taxonomical, pharmacological and chemical	1
3	Techniques in microscopy of powdered drugs covering use of mountants, clearing agents, chemomicroscopic reagents, micrometer, quantitative microscopy	2
4	Plant description, morphology, cell differentiation and ergastic cell contents:Study of plant parts, cell and tissue, underground or subterranean drugs,roots, rhizomes, corms, bulb, tubers, stolen, runners, and suckers; Leaves: Simple and compound, stomata, stomata number, stomatal index, palisade - ratio, hydathodes and water pores, epidermal trichomes, calcium oxalate crystals, vein-islet number,vein termination number; Inflorescence and flowers; Fruits; Seeds; Barks, and wood. Unorganised drugs: Dried latex, dried juices, dried extracts, gums and mucilages, resins.	7

5	Introduction, classification with examples and important biological activities of following groups of plant constituents: Carbohydrates; Alkaloids, Glycosides, saponins, steroids and triterpenoids Flavonoids, lignans, coumarins, tannins and polyphenolic compounds, Lipids and volatile oils; Gums, mucilages, resins and resin combinations with examples. Details of Phytochemical test for the evaluation of each class	12
6	Cultivation, Collection, Processing and storage of crude drugs: Factors influencing cultivation of medicinal plants. Types of soils and fertilizers of common use. Pest management and natural pest control agents. Plant hormones and their applications. Polyploidy, mutation and hybridization with reference to medicinal plants.	4
7	Study of plant, animal & mineral fibres with respect to their classification, sources, production, chemistry, commercial utility and significance in Pharmaceutical Industry for the following: Absorbent & nonabsorbent cotton, jute, flax, hemp, asbestos, glass wool, silk, wool, rayon, viscose	3
8	Systematic pharmacognostic study of following a) Carbohydrates and derived products: agar, guar gum acacia, Honey, Isabgol, pectin, Starch, sterculia chitin, xanthan gum, tamarind kernel powder (TKP) and Tragacanth. b) Lipids: Bees wax, Castor oil, Arachis oil, Cocoa butter, Shea butter, Cod~liver oil, Hydnocarpus oil, Kokum butter, Lard, Linseed oil, Rice Bran oil, Wheat germ oil, Shark liver oil and Wool fat	7
9	Proteins and Enzymes Study of Proteins and Enzymes with respect to sources, preparation and uses - protein hydrolysates, gelatin, casein, thyroid hormones, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin). Study of plant lectins with respect to sources, composition and applications for Abrin, ricin. Self study: Marketed formulations containing serratiopeptidase and their applications	4 1
10	Biological source, chemical constituents and uses of the following: Chirata, Shatavari, Kalmegh, Karela, Punarnava, Guggul, Tinospora. Self study: Brahmi, Neem,Tulsi, Amla,	2 1
11	Self study: Minerals: Kiselghur, Chalk, Talc, and Bentonite.	1
	TOTAL	**48**

Books

1. Trease D. & Evans W. C.: Text Book of Pharmacognosy: W. B. Saunders.
2. Tyler V.E., Brady L.R. & Robbers J. E.: Pharmacognosy; LeaFeibger, USA.
3. Wallis T. E.;Text Book of Pharmacognosy; CBS Publishers, Delhi.
4. Kokate C.K., Purohit A. P. &Gokhale S. B.: Pharmacognosy; Nirali Publications, Pune.
5. Harbone J. B.: Phytochemical Methods: A guide to modern techniques Analysis: Chapman& Hall, London.
6. Bruneton J.: Pharmacognosy, Phytochemistry, Medicinal Plants: Intercept Limited.
7. Vasudevan T.N. & Laddha K.S.: A Textbook of Pharmacognosy, Vrinda Publication House, Jalgaon.
8. The Indian Pharmacopeia: The Controller of Publication; Delhi.
9. Brain K.R. & Turner T. D.: The Practical Evaluation of Phytopharmaceuticals: Wright, Scientica, Bristol.

BPH_C_204_T – Hospital Pharmacy and Drug Store Management - (4 Hr/Wk)

Course Objectives

To introduce the learner to the organization and functioning of a retail pharmacy and a hospital pharmacy.

Course Outcomes

The learner should be able to:

1. Appreciate the difference in the functions, layout, legal requirements, organization, drug procurement, storage and dispensing of medicines in a retail versus hospital pharmacy setting.
2. Appreciate the importance of documentation in the functioning of a pharmacy
3. Understand the importance of a hospital level formulation and compounding of parenterals.
4. Understand the importance and functioning of the hospital sterile supply services department
5. Appreciate the dangers/detection/reporting of fraudulent pharmacy practices
6. Appreciate the concept of Rational Drug Therapy

Unit No.	Sub-unit	TOPICS	DURATION (HOURS)
1	1.1	Hospitals: Definition, Organization Structure, Classification, Functions	2
	1.2	Hospital Pharmacy: Definition, Organization structure, Location, Layout and staff requirements and responsibilities and functions of hospital pharmacists.	2
	1.3	Budget of Hospital Pharmacy: Preparation and Implementation	2
2.	2.1	Drug Distribution Systems in Hospitals: Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labeling, Dispensing of drugs to ambulatory patients, and Dispensing of Controlled Substances including Hospital Control Procedures	4
3	3.1	Pharmacy and Therapeutics Committee (PTC): Objective, composition, Functions, Role of PTC in Drug Safety, Adverse Drug Reaction Monitoring and Emergency Drug Lists.	3
4	4.1	Hospital formulary: Definition, Advantages and Disadvantages, contents of hospital formulary, Differentiation of hospital formulary and Drug list, Preparation and revision, and addition and deletion of drug from hospital formulary.	3
	4.2	*Medication errors and ASHP Guidelines to prevent errors, Infection control in hospitals (Self Study)*	*2*
5	5.1	*Drug Utilization Review(Self Study)*	*2*
	5.2	*Safe Use of Medications in Hospitals(Self Study)*	*2*
	5.3	Handling of radiopharmaceuticals in hospitals	2
6		Central Sterile Supply Services	
	6.1	Introduction to sterilization, basic techniques used for sterilization of hospital supplies	2
	6.2	Advantages, Plan, Location, Layout	4
	6.3	Sterilization of surgical dressings – methods of packing, loading and prevention of wetting of dressings. Sterilization of rubber gloves, syringes, needles, catheters, tubing, surgical instruments, mattresses, utensils and bedpans and other accessories Manufacturing and Bulk compounding of large volume parenterals, Total Parenteral Nutrition and Intravenous additives.	
	6.4		2
7	7.1	Planning of retail pharmacy and entrepreneurship	2
	7.2	*(Self-study) Forms of Business Organization: Sole Proprietor, Partnership, Hindu Undivided Family, Joint Stock Company and Co-operative Society*	*2*
	7.3	*Channels of Distribution for Pharmaceuticals: Wholesaler, Retailer*	*1*
8		Setting Up and management of a Drug Store-	
	8.1	Legal Aspects and Registrations	2
	8.2	Selection of site, Space layout, Location Analysis and Layout design and staff	2
	8.3	Materials- Coding, stocking, maintenance of various registers,	1
	8.4	Use of Computers: Business and health care soft wares	1
	8.5	Sales promotion and window display	2
9		Purchasing and Inventory control in drug store:	
	9.1	Purchasing procedure in retail trade	1
	9.2	Definition of inventory control, various methods of Inventory Control (Want Book, Systematic Want Book, Open to Buy budgeting, ABC,VED, EOQ analysis),	1
10	10.1	Risk management, Insurance policies and Frauds in retail practice	1
		TOTAL	**48**

Books:

1. Hospital Pharmacy, W. E. Hassan, Edition, Lea and Febiger, Philadelphia.
2. A text – book of Hospital Pharmacy, S.H. Merchant and Dr. J.S. Quadry, B.S. Shah Prakashan, Ahmedabad.
3. Hospital Pharmacy, Dr. H. P. Tipnis and Dr. Amrita Bajaj, Career Publication, Maharashtra.
4. Gennaro Alfonso R, Remington – The Science and Practice of Pharmacy", Lippincott Williams and Wilkins.
5. Principles and methods of Pharmacy Management, Smith, Lea and Febiger, Philadelphia.
6. Drug store management, Nolen and Maynard. McGraw Hill.
7. Drug Store and Business Management, A. P. Battasse, Unique Publication.
8. Text book of Forensic Pharmacy, N. K. Jain, Vallabh Prakashan.

BPH_C_205_T - Environmental Science - (3 Hr/Wk)

Course Objectives

1.	To study the importance of environmental science and environmental studies
2.	To know the importance of key to the future of mankind.
3.	To study continuing problems of pollution, loss of forget, solid waste disposal, degradation of environment, issues like economic productivity and national security
4.	Study of Global warming, the depletion of ozone layer and loss of biodiversity have made everyone aware of environmental issues.

Course Outcomes

The learner should be able to:

1. Describe the basics of Environmental sciences like need and purpose of study the subject, Ecology, food chain and ecological pyramids, sustainable development
2. Outline, Environmental Legislation, role of different ministries and environment control boards
3. Classify and compare different sources of energies
4. Relate technology to control pollution and economic benefits thereof,

infer, the concept of green building, carbon credit and disaster management

Realize the environment related moral responsibilities and identify Legal (environmental) aspects for becoming entrepreneur in future

No.	Details	Hours
1.	**Multidisciplinary Nature of Environmental Studies:** • Scope and Importance • Need for Public Awareness • Depleting Nature of Environmental resources such as Soil, Water, Minerals, and Forests. • Global Environmental Crisis related to Population, Water, Sanitation and Land. • Ecosystem: Concept, Classification, Structure of Ecosystem, overview of Food chain, Food web and Ecological Pyramid	5
2.	**Sustainable Development** • Concept of sustainable development • Social, Economical and Environmental aspect of sustainable development. • Control Measures: 3R (Reuse, Recovery, Recycle), Appropriate Technology, Environmental education, Resource utilization as per the carrying capacity**.**	5
3.	**Environmental Pollution:** • Air Pollution: Sources, Effects of air pollution with respect to Global Warming, Ozone layer Depletion, Acid Rain, Photochemical smog, Two Control Measures, Bag house Filter, Venturi scrubber. Case Study: Bhopal Gas Tragedy • Water Pollution: Sources and Treatment, Concept of waste waters - Domestic &Industrial and treatment. Case Study: Minamata Disease. • Land Pollution: Solid waste, Solid waste Management by Land filling, Composting. • Noise Pollution; Sources and Effects • E-Pollution: Sources and Effects.	11
4.	**Environmental Legislation:** • Overview • Ministry of Environment and Forests (MoE&F). Organizational structure of MoE&F. • Functions and powers of Central Control Pollution Board. • Functions and powers of State Control Pollution Board. • Environmental Clearance, Consent and Authorization Mechanism. • Environmental Protection Act • Any two case studies pertaining to Environmental Legislation.	5
5.	**Renewable sources of Energy:** • Limitations of conventional sources of Energy.	5

	• Various renewable energy sources. • Solar Energy: Principle, Working of Flat plate collector & Photovoltaic cell. • Wind Energy: Principle, Wind Turbines. • Hydel Energy: Principle, Hydropower generation. • Geothermal Energy: Introduction, Steam Power Plant	
6.	**Environment and Technology** • Role of Technology in Environment and health • Concept of Green Buildings, Indoor air pollution • Carbon Credit: Introduction, General concept. • Disaster Management: Two Events: Tsunami, Earthquakes, Techniques of Disaster Management • Case Study: Earthquake in Japan	5
	TOTAL	**36**

Books:

1. Hazardous Waste Incineration, Brunner R.C., McGraw Hill Inc
2. Global Biodiversity Assessment, Heywood V.H and Waston R.T., Cambridge Univ. Press
3. Environmental Science systems & Solutions, Mckinney M.L. and School R.M., Web enhanced edition.
4. Fundamentals of Ecology, Odum E.P., W.B. Saunders Co. USA.
5. Textbook of Environmental studies by Erach Bharucha, University Press.
6. Environmental Studies by R. Rajagopalan, Oxford University Press.
7. Essentials of Environmental Studies by Kurian Joseph & Nagendran, Pearson Education
8. Renewable Energy by Godfrey Boyle, Oxford Publications.
9. Perspective Of Environmental Studies, by Kaushik and Kaushik, New Age International
10. Environmental Studies by. Anandita Basak, Pearson Education
11. Textbook of Environmental Studies by Dave and Katewa, Cengage Learning
12. Environmental Studies by Benny Joseph, Tata McGraw Hill

BPH_C_206_L – Pharmacognosy Lab I - (4 Hr/Wk)

Course Objectives

This subject highlights the morphological, microscopic and phytochemical evaluation of natural drugs used in Allopathic as well as Complementary Systems of Medicine.

Course Outcomes

The learner should be able to:

1	Carry out quantitative microscopy for leaf constants
2	Determine different extractive and ash values as per pharmacopoeial requirements
3	Identify diagnostic features of plants such as calcium-oxalate, starch and trichomes
4	Differentiate between different plant parts based on morphological and microscopic evaluation
5	Identify fibers and carbohydrates based on chemical evaluation

No.	Experiments
1.	Quantitative microscopy (Estimation of Leaf constants i.e. Stomatal Index, Vein islet number and Vein termination number, Palisade ratio)
2	Determination of alcohol soluble and water soluble extractives, Total ash value and acid insoluble ash and water soluble ash value for any one crude drug as per IP.
3	Study of different types of starch grains, calcium oxalate crystals, Trichomes and stomata
4	Identification of Fibres based on chemical tests as covered in theory. Tests for detection of honey, starch, tragacanth, acacia, guar gum, agar
5	Microscopical Studies of basic tissues a) Stem: Ephedra b) Leaves: Vasaka, Senna c) Roots: Rauwolfia d) Bark: Cinchona e) Seed: Nux vomica, Linseed f) Fruits: Fennel

Books:

1. Trease D. & Evans W. C.: Textbook of Pharmacognosy: W. B. Saunders.

2. Tyler V.E., Brady L.R. & Robbers J. E.: Pharmacognosy; Lea Febiger, USA.
3. Wallis T. E.; Textbook of Pharmacognosy; CBS Publishers, Delhi.
4. Kokate C.K., Purohit A. P. &Gokhale S. B.: Pharmacognosy; Nirali Publications, Pune.
5. Harborne J. B.: Phytochemical Methods: A guide to modern techniques Analysis: Chapman& Hall, London.
6. Bruneton J.: Pharmacognosy, Phytochemistry, Medicinal Plants: Intercept Limited.
7. Vasudevan T.N. & Laddha K.S.: A Textbook of Pharmacognosy, Vrinda Publication House, Jalgaon.
8. The Indian Pharmacopeia: The Controller of Publication; Delhi.
9. Brain K.R. & Turner T. D.: The Practical Evaluation of Phytopharmaceuticals: Wright, Scientica, Bristol.

BPH_C_207_L - Biochemistry Lab - (4 Hr/Wk)

Course Objectives

To teach the learner the methods for the detection and estimation of different biomolecules

Course Outcomes

The learners should be able to understand the principles and methods for the estimation of:
1. Carbohydrates
2. Amino acids and proteins
3. Fats and Lipids
4. Nucleic acids
5. Enzyme kinetic parameters
6. Enzyme activity as diagnostic markers

EXPERIMENTS

1. Qualitative tests for carbohydrates and confirmatory tests by ozasone formation
2. Qualitative test and simple color reactions for amino acids and proteins. Precipitation reactions of proteins.
3. Chromatographic separation of amino acids.
4. Quantitative estimation of glucose (Willstaters and Lane & Eynon's methods). Estimation of sucrose. Colorimetric estimation of glucose.
5. Quantitative estimation of proteins by Biuret method and Folin method (one titrimetry and one by colorimetry)
6. Estimation of enzyme activity – Ptyline (amylase) in saliva and alkaline phosphatase (including plotting of data to determine Km and Vmax for any one of these enzymes)
7. Quantitative estimation of properties of lipids – acid value, iodine value, saponification value.
8. Quantitative estimation of RNA and DNA.
9. Demonstrations of estimation of blood glucose, SGOT or SGPT using commercial kits (suggest that students should volunteer for fasting and post prandial glucose determinations)
10. Demonstration of isolation of DNA.

Books:

1. An Introduction to Practical Biochemistry – Plummer D.T., Tata Mcgraw Hill, N Delhi, India
2. Laboratory Manual In Biochemisty, Jayaraman J, Wiley Easter, N Delhi. India

BPH_C_208_L - Computer Lab - (4 Hr/Wk)

Course Objectives

To Introduce the learner to the importance of computers – hardware and software – and their potential applications to the pharmacy profession

Course Outcomes

The learner should be able to:
1. Describe the components of a PC
2. Compare the different operating systems
3. Record simple programs using BASIC and C programming languages
4. Apply knowledge gained for use of computers in pharmacy

No.	Details	Hours
1.	Introduction to Computers.	2
2.	History of Computer development and respective generation: Abacus, Napier's Bones, Slide rule, Pascal's Calculator. General use of computers in everyday life.	5

	Computer Classification: Mainframe, Mini and Micro Computers, comparison of Analog & Digital Computers, Hardware and Software. Calculator and Computer	
3.1	Operating Systems: Introduction to types of operating systems, UNIX, MS-DOS, etc. RAM, ROM, Virtual Memory etc	4
3.2	Students should learn on Windows and Linux OS based systems use of basic Windows and Linux commands	4
4.1	Type of Languages: Conventional languages; their advantages, limitations; C, Pascal, FORTRAN, Programming of these languages	4
4.2	Students should be taught some programming in BASIC and C	4
5.1	Introduction to Computer Networks: Architecture of seven layers of communications	4
5.2	Students should be taken to a computer lab with has a network and shown the basic connections and operation of different types of networks.	3
6.1 6.2	Introduction to Data Structure: Like Queues, list, trees, Binary trees algorithms, Flow chart, Structured Systems, Analysis and development, Ingress-SQL, Gateways etc. Statistics, methodologies. Basic Language: Constants and Variables: Character set, constants, variables, Naming the variables getting data into memory, LET, INPUT, READ. DATA, Print Statement Expressions: Arithmetic expression, Hierarchy of operations, Rules of Arithmetic, Evaluation of expressions, Relational expressions, Logical operations, Library functions Printer Control: Comma and semicolon control, the TAB function, PRINT, LPRINT Functions and Subroutines: User defined functions, subroutines, subscripted variables The above concepts should be introduced practically to students with examples, while working on a computer system.	8
7.	Computer Graphics:	5
8.	Computer applications in pharmaceutical area and in clinical studies	5

Books:

1. Basic Electronics and Computer Applications, Rajiv Khanna, New Age International Publishers
2. Fundamentals of Computers, V. Rajaraman, Prentice Hall of India Pvt. Ltd.
3. Schaums Outline Series, Theory and Problems of Introduction to Computer Science, Francis Scheid, McGraw Hill Book Co.

SYLLABUS FOR S. Y. B. Pharm.

SEMESTER-III

BPH_C_301_T – Organic Chemistry I – (4 Hr/Wk)

Course Objectives

1. To introduce the system of naming organic compounds generally encountered in Pharmacy profession
2. To introduce the learner to the structural features of organic compounds with respect to 2D and 3D features, resonance forms, tautomerism, conjugation, and aromaticity.
3. To introduce the learner to the properties of compounds as dictated by their structures especially the functional groups.
4. To introduce the learner to concepts of reaction kinetics, first/second/zero order rates and equilibrium phenomenon.

Course Outcomes

The learner should be able to:

1. Assign IUPAC and stereochemical nomenclature of compounds containing multiple functional groups
2. Predict aromatic character, resonance and tautomerism of compounds
3. Explain the reactivity of compounds based on physicochemical properties
4. Understand the factors affecting equilibria, rates and reaction mechanisms
5. Explain the influence of structure on physicochemical properties and its application to various aspects of pharmaceuticals

No.	Details	Hours
1	Structure	
1.1	Nomenclature of mono/polyfunctional compounds (trivial and IUPAC) (Heterocycles to be excluded).	4
1.2	Hybridization states of C, O and N.	1
1.3	Atomic orbitals, Molecular orbitals of sp^3 (ethane), sp^2 (ethene), and sp (acetylene) and C attached to heteroatoms with lone pairs. HOMO and LUMO of ethene and the C=O group.	2
1.4	Basic concepts of electronegativity, hydrogen bonding, inductive effect, dipole moment, log P with examples of monofunctional compounds.	2
1.5	Concept of aromaticity: Huckel's rule, identification of aromatic, non-aromatic and anti-aromatic systems based on planarity, conjugation and Huckel's rule.	2
1.6	Resonance in aliphatic and aromatic systems: Rules of resonance and stability of the resonance structures. Tautomerism of keto-enol and imine-enamine systems. Hyperconjugation.	2
1.7	Stereochemistry: Concept of configuration and chirality, axes of symmetry, plane of symmetry, center of symmetry. Representation of molecules using projection formulae - Fischer, Wedge, Sawhorse and Newmann. Geometric Isomerism: Methods of determination of configuration of geometric isomers. Optical isomerism: Enantiomers and diastereomers. Nomenclature of stereoisomers including E and Z, D and L and R and S designations. Conformations of ethane, butane, cyclohexane with their energy profile diagrams. Conformational analysis of mono- and di-substituted cyclohexanes. Types of strains: Angle strain (Baeyer Strain), transannular strain (Prelog Strain), torsional strain (Pitzer strain).	6
2	Ionization, acidity, basicity and pK_a (excluding heterocyclic compounds).	6
3	Geometry, stability and properties of the following reactive intermediates: carbocations, carbanions, carbenes and carbon radicals. Electrophiles and nucleophiles (including charged and neutral species). Concept of leaving groups, alkyl shifts and migratory aptitude.	6
4	Equilibria, rates and mechanisms.	7
5	Mechanism of SN^1, SN^2, E1 and E2 reactions. Factors affecting substitution and elimination reactions. Comparison of substitution and elimination reactions.	4
6	Reactivity of the following functional groups: Alkenes, alkynes, alcohols, phenols, alkyl halides, ethers, aldehydes, ketones, carboxylic	4

	acid and derivatives, amines. (Molecular orbital diagrams for nucleophilic addition to carbonyl group and electrophilic addition to alkene).	
7	Influence of the physicochemical properties of the above mentioned functional groups on the following aspects: receptor binding, formulation and degradation.	2
	TOTAL	**48**

Books:

1. Organic Chemistry, Jonathan Clayden, Nick Greeves, and Stuart Warren, Oxford University Press.
2. Organic Chemistry, Stanley H. Pine, James B. Hendrickson, Donald J. Cram, and George S. Hammond, McGraw-Hill Book Co.
3. Organic Chemistry, John E McMurry, Brooks/Cole Cengage Learning.
4. Textbook of Organic Chemistry, P. S. Kalsi, MacMillan India Limited.

BPH_C_302_T – Physical Pharmacy I – (4 Hr/Wk)

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

The learner should be able to:

1. Understand the various physical phenomena involved in designing of various formulations.
2. Determine various physical parameters of drugs and formulations
3. Predict and anticipate in-process problems based on raw materials and manufacturing methods.
4. Apply the knowledge of physical phenomena in selecting raw materials, including drug, inactive ingredients of appropriate quality leading to stable formulations.

No.	Details	Hours
1.	**States of matter**	**11**
1.1	Binding Forces between molecules	1
1.2	Gaseous state: Ideal and Real gases, ideal gas equation and van der waal's equation (No derivation), Critical Phenomena	2
1.3	Liquid state: Liquefaction of gases, aerosols, vapor pressure, latent heat, boiling point	2
1.4	Solid state: Amorphous solids, crystalline solids: crystal lattice and unit cell, crystal defects, polymorphism, melting point, pharmaceutical significance of polymorphs and amorphous solids	4
1.5	Liquid crystalline state and supercritical fluid state: Properties and pharmaceutical significance	2
2	**Physical properties of Drug Molecules**	**7**
2.1	Additive, constitutive and colligative properties with examples; Concept of tonicity in pharmacy, methods to adjust isotonicity;	3
2.2	Dipole moment, Dielectric constant and significance to pharmacy	1
2.3	Refractive index and molar refraction, Principle and working of Abbe's refractometer and Application of molar refraction to determine structures	1
2.4	Optical rotation, Specific rotation, measurement of optical rotation and its applications	2
3	**Solubility and distribution phenomena**	**9**
3.1	Solvent – solute interactions, Ideal and real solutions, Raoult's law, deviation from Raoult's law, Azeotropic mixtures.	2
3.2	Phase equilibria and Phase rule (one, two and three component systems)	1
3.3	Solubility of gases in liquids, Henry's law and applications	1
3.4	Solubility of liquids in liquids, miscible and partially miscible liquids, critical solution temperature and applications.	2
3.5	Solubility of solids in liquids, solubility parameters	2
3.6	Distribution law, its limitations, modification for weak electrolytes (No derivation) and applications	1
4	**Ionic equilibria and buffers**	**6**

4.1 4.2 4.3	Strong electrolytes and weak electrolytes, dissociation of weak electrolytes, dissociation constant pH, Sorensen's pH scale, pH determination (glass electrode) Applications of buffers, buffer equation (Henderson- Hasselbalch equation), buffer capacity, buffers in pharmaceutical and biological systems	2 1 3
5 5.1 5.2 5.3 5.4 5.5	**Interfacial phenomena** Surface tension, Interfacial tension, Surface free energy Measurement of surface and interfacial tension-capillary rise method, drop number method, Drop weight method, Du Nuoy tensiometer method Spreading of liquids, Spreading coefficient, Surface active agents, Hydrophilic-Lipophilic balance, soluble monolayers Adsorption at solid interfaces, Adsorption isotherms, Freundlich adsorption isotherm, Langmuir adsorption isotherm Wetting, wetting agents and contact angle	**9** 1 1 3 3 1
6 6.1 6.2 6.3 6.4	**Rheology** Definition: Rheology, viscosity, Newton's law of flow, viscosity coefficients for Newtonian fluids Non- newtonian systems: Plastic, pseudoplastic and dilatant, thixotropy and its significance Measurement of flow for newtonian and non-newtonian systems Deformation of solids: Introduction to Elastic, plastic, viscoelastic and fragmentation	**6** 1 2 2 1
	TOTAL	**48**

Books:

Refer to latest editions

1. P. J. Sinko, 'Martin's Physical Pharmacy and Pharmaceutical Sciences' Fifth edition, Lippincott Williams and Wilkins, Indian Edition distributed by B.I. Publications Pvt. Ltd, 2006.
2. Pharmaceutical Dosage Forms And Drug Delivery Systems, Howard C. Ansel,Nicholas G. Popovich, Loyd V.
3. Pharmaceutics: The Science Of Dosage Form Design, Michael E.Aulton
4. Bahl and Tuli, 'Essentials of Physical Chemistry' S. Chand and Company Ltd. Ramnagar, New Delhi-110055.
5. Essentials of Physical Pharmacy , C.V.S Subrahmanyum, Vallabh Prakashan
6. Textbook of Physical Pharmaceutics, C.V.S Subrahmanyum, Vallabh Prakashan

BPH_C_303_T – Anatomy Physiology and Pathophysiology III – (4 Hr/Wk)

Course Objectives

1. To teach about anatomy and physiology of reproductive, cardiovascular, urinary and gastrointestinal system.
2. To teach pathophysiology of common diseases associated with reproductive, cardiovascular, urinary and gastrointestinal system.

Course Outcomes

The learner should be able to:

TOPIC	COURSE OUTCOMES	BLOOM'S LEVEL
T1,T3, T5,T8	Explain the anatomy, and physiology of the reproductive system, cardiovascular system, urinary system and digestive system and know the concept, significance and application of ECG	2
T2,T4, T7, T9	Comprehend the etiology, pathogenesis, signs and symptoms of common diseases of the reproductive system, cardiovascular system, urinary system and digestive system	2
T5, T6	State the relevance of various body fluid compartments, electrolyte distribution and acid-base balance.	1

No.	Details	Hours
1	Reproductive system - Anatomical and Physiological considerations of male and female reproductive system	6

	- Reproductive and endocrine functions of testes and ovaries - Menstrual cycle	
2	Pathophysiology of following diseases - Infertility - Sexually transmitted diseases (STD) - Dysmenorrhea	3
3	Cardiovascular System - 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	9
4	Pathophysiology of following diseases - Hypertension - Congestive Cardiac Failure - Cardiac Arrhythmia - Angina Pectoris - Ischemic Heart Disease - Arteriosclerosis/Atherosclerosis	5
5	Urinary system - Anatomy and Physiology of Urinary System - Formation of urine - water balance, electrolyte balance & acid – base balance	6
6	Formation of body fluids and fluid compartments.	4
7	Pathophysiology of following diseases - Renal failure - Glomerulonephritis - Renal calculi / kidney stones - Urinary Tract Infections (UTI)	4
8	Digestive System - Anatomy and physiology of digestive system - Digestion and absorption of carbohydrates, proteins and fats	7
9	Pathophysiology of following diseases - Peptic ulceration - Zollinger – Ellison's Syndrome -Inflammatory Bowel Disease (Ulcerative colitis, Crohn's disease) - Cholecystitis & Cholelithiasis - Jaundice - Hepatitis - Pancreatitis - Achalasia - Reflux esophagitis	4
	Total	**48**

Books:

1. Ross & Wilson, Anatomy & Physiology in Health & Illness by Anne Waugh and Allison Grant, Published by Churchill Livingstone
2. Gerard J. Tortora & Bryan Derrickson, Principals of Anatomy & Physiology, Published by John Wiley and Sons, Inc.
3. C. Guyton & J. E. Hall, Textbook of Medical Physiology, Published in India by Prism Books Ltd. On arrangement with W. B. Saunders Company, USA.
4. McNaught & Callander, Illustrated Physiology by B. R. Mackenna & R. Callander, Published by Churchill Livingstone
5. Kaplan, Jack, Opheim, Toivola, Lyon, Clinical Chemistry: Interpretation & Techniques.
6. Praful B. Godkar, Textbook of Medical Laboratory Technology, Published by Bhalani Publishing House, Mumbai, India
7. Harsh Mohan, Textbook of Pathology, Published by Jaypee Brothers Medical Publishers Pvt. Ltd., New Delhi.

BPH_C_304_T – Pharmaceutical Analysis I – (3 Hr/Wk)

Course Objectives

1. To introduce the learner to the scope and importance of sample preparation and analytical procedures, pharmacopoeial methods of analysis, and errors associated with analytical procedures.
2. To introduce the learner to the different titrimetric analytic methods like acid-base titrations, complexometric titrations, etc.
3. To introduce the learner to gravimetric and electro-analytical methods of analysis.

Course Outcomes

The leaner should be able to:

1. Explain the role of pharmaceutical analysis in the field of pharmacy and industry and delineate between qualitative- quantitative, manual, automatic and electrochemical methods of analysis.
2. Describe volumetric, gravimetric, electrochemical and solvent extraction methods of analysis.
3. Solve numerical problems related to volumetric, gravimetric and solvent extraction methods of analysis and apply simple statistics to numerical data.

No.	Details	Hours
1	**Introduction to Pharmaceutical Analysis**	**4**
1.1	• Scope of Pharmaceutical Analysis, Classification of Quantitative Analytical techniques (Instrumental and Non-Instrumental). • **Introduction to pharmacopoeial monograph** –Significance of a pharmacopoeial monograph. (Only relevance of all the tests and principle of the assay procedures in the monographs mentioned below to be discussed). Active Pharmaceutical Ingredient (API): Aspirin, Calcium gluconate and Dried aluminium hydroxide gel. Formulations: Soluble Aspirin tablets.	**2**
1.2	• **Types of Errors:** Determinate and Indeterminate, Causes of errors and ways to minimize them. • **Concept and numericals of:** Mean, Median, Standard deviation, relative standard deviation, Absolute and relative errors, precision, accuracy, significant figures.	**2**
2	**Aqueous acid-base titrations.**	**6**
2.1	• **Theoretical terms*:*** Titrimetric analysis, Titrant, Titrand, Theoretical end point or equivalence point, end point of titration, Titration error, conditions for titrimetric analysis, classification of reactions for titrimetric analysis, Expression of concentration of Standard solutions-Molarity- (Analytical and equilibrium molarity), Molality, percent concentration, ppm, ppb, Normality, Primary and Secondary standards. • Law of Mass Action, Equilibrium Constant, Application of Law of Mass Action to solutions of weak electrolytes, pH, pKa, pKb, hydrolysis of salts (weak base-strong acid, weak acid-strong base, weak acid-weak base), Buffer solutions, Buffer Capacity.	**2**
2.2	• **Neutralization curves-**(strong acid versus strong base, weak acid versus strong base, weak base versus strong acidand weak acid versus weak base). • **Neutralization indicators-**different theories (Ostwald's theory, Resonance theory), Mixed indicators, concept of range of indicators, Choice of indicators.	**2**
2.3	• **Methods of titration:** Direct titration, back titration and need, blank determination use, significance (one example for each type) and concepts of factor calculation for assay. • **Problems related to calculation of**- pH and its numericals with respect to neutralization curve, Strength of Electrolytes (molarity, normality, and milliequivalence), and assay. • **Applications**: Assay of benzoic acid, aspirin, sodium hydroxide.	**2**
3	**Non-aqueous titrations**	**2**
3.0	• **Theoretical considerations**-Need, Types of non-aqueous 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, Determination of Bases and Acids (solvent, titrants and indicator used). • **Applications:** Assay of Sodium benzoate and Acetazolamide.	**2**

4	**Complexometric titrations**	**3**
	• **Terms-**Complex, complexing agents (Complexones), chelate, ligand, co-ordination number, chelating agent, sequestering agent, metal-ligand complex. • **Aspects in complex formation with respect to Disodium edetate-** Dissociation constant, pH, Stability, colouration, titrability of polyvalent metal ions, pM indicators, presence of auxiliary complexing agent, and general structure of complexes formed with di-, tri- and tetravalent metal ions. • **Complexometric titrations:** Direct method, back titration, replacement titration, titration of mixture of metal ions, masking agent (auxiliary ligand) and demasking agents and titration curve with respect to disodium edetate. • **Applications:** Determination of individual cations (aluminium by back titration, nickel by direct titration), determination of mixture of lead, zinc and magnesium in a sample, and assay of calcium gluconate injection.	
5	**Oxidation – Reduction Titrations**	**6**
5.1	• **Terms:** Oxidation, Reduction, oxidising and reducing agents, standard reduction potential, Nernst equation, redox titration curve and equivalence point.	**1**
5.2	• Theory, indicators, and titrants for : Permanganometry and Cerimetry, • Applications- Assay of hydrogen peroxide solution (Permanganometry), Assay of Ascorbic acid tablets, Dried Ferrous sulphate, Paracetamol (Cerimetry).	**2**
5.3	• Theory, indicators, and titrants for : Iodometry, iodimetry, potassium dichromate, potassium iodate and potassium bromate titrations. • **Applications-** Assay of Ascorbic acid API (Iodimetry), Assay of potassium permanganate (Iodometry), Assay of Potassium iodide (Iodate titration)	**2**
5.4	• **Balancing of redox equation-**half cell reaction and net reaction.	**1**
6	**Precipitation Titration**	**3**
6.1	• **Theoretical considerations-**Common Ion Effect, Solubilty Product, Factors affecting solubility of precipitates, Fractional precipitation.	**1**
6.2	• **Types of Precipitation Titration**: Argentometric Titration methods -Mohr's method, Volhard's Method and Adsorption Indicator Method. • **Applications:** Standardization of silver nitrate, Assay of sodium chloride and potassium chloride.	**2**
7	**Gravimetry**	**3**
7.1	• **Theory:** Mass as measurement signal and precipitation equilibria, Unit operations in gravimetric analysis, Organic and inorganic precipitants, precipitation from homogeneous solution. • **Problems** associated with gravimetric analysis and methods to overcome (co-precipitation and reprecipitation, Ostwald's ripening, degree of supersaturation or Von Weimarn ratio, solubility of precipitate, peptisation).	**2**
7.2	• **Applications**-Assay of Nickel by dimethylglyoxime, Assay of aluminium by oxine reagent, Assay of Ba^{+2} as Barium sulphate. • **Numericals related to gravimetric factor**	**1**
8	**Miscellaneous methods**	**2**

8.1	• **Oxygen flask combustion method-**technique, apparatus, principle and determination of organically bound halogens, sulphur and phosphorus, **Application**- Diloxanide furoate. • **Nitrite titrations-** Concept of external indicator and application- Assay of Sulphacetamide sodium • **Determination of nitrogen (Kjeldahl method)-**Technique (direct and indirect method), reagents & apparatus used, reaction & factor calculation and numerical for estimation of nitrogen. Application-Assay of Urea (API)	
9	**Electro Analytical Techniques:**	**5**
9.1	**Polarography-** • **Apparatus-**Construction and working of Dropping mercury electrode (DME), advantages and disadvantages of DME. • **Theory-**Current-Voltage curve (Polarogram), supporting electrolyte, Oxygen wave, polarographic maxima, Ilkovic equation, factors affecting limiting current, half wave potential. • **Applications-**In brief. • **Pulse polarography-**Normal pulse polarography, Differential pulse polarography and square wave polarography**).**	**2**
9.2	• **Amperometry-**DME cell, four types of end points in amperometric titrations, advantages, general applications and Biamperometric titrations**.** • **Aquametry by Karl Fischer titration:** Principle, composition and stability of KFR, standardization of KFR as per I.P, determination of water in a sample-e.g. Amoxycillin trihydrate.	**1**
9.3	• **Coulometry and High Frequency Titration-**Faraday's first law of electrolysis, Current vs Time plot, Cells for coulometric titration and generation of titrant, Types of coulometric methods (potentiostatic and amperostatic), primary and secondary coulometric titrations, advantages of coulometric titrations, and applications in brief.	**1**
9.4	• **Electrogravimetry-** Theory of electrolysis – constant current electrolysis and constant potential electrolysis, theory of electrogravimetry- Ohm's Law, Faraday's second law of electrolysis, Terminology: polarization, overvoltage, current density, current efficiency, decomposition potential, polarized electrode, types of polarization-concentration and kinetic, apparatus for electrogravimetric determinations, characteristics of the deposit, factors affecting physical properties of the deposit, applications in brief.	**1**
10	**Liquid-Liquid Extraction**	**2**
10.1	• **Terms:** Nernst Distribution law and partition coefficient, Distribution coefficient, Distribution Ratio, Percent extraction or extraction efficiency, Separability factor. • **Types-**Single extraction (Batch), multiple extraction, Countercurrent Distribution and Continuous extraction. • **Factors** influencing solvent extraction, Emulsion formation problem in extraction and ways to minimize. • **Examples** –Assay of soluble Aspirin tablets.	**2**
10.2	• Problems based on distribution coefficient.	
	Total	**36**

Books:
1. Practical Pharmaceutical Chemistry by Beckett, A H & Stenlake, J B, 2005, 4th edition, Part I and II, CBS Publishers and Distributors, India.
2. A Textbook of Pharmaceutical Analysis by Kenneth A Connors, 2002, 3rd edition, John Wiley and Sons, Canada.
3. Principles of Instrumental Analysis by Douglas A. Skoog, F. James Holler, 1992, 5thedition, Saunders College Publishing, USA.
4. Fundamentals of Analytical Chemistry by Douglas A. Skoog, Donald M. West, F. James Holler, 1991, 7th edition, Saunders College Publishing, USA.
5. Analytical Chemistry by Gary D. Christian, 6th edition, John Wiley & Sons, Singapore.
6. Vogel's Textbook of Quantitative Chemical Analysis by Mendham J, R.C. Denney, J.D. Barnes, M. Thomas, 2002, 6th edition, Pearson Education Ltd.
7. Pharmaceutical Drug Analysis by Ashutosh Kar, 2005, 2nd edition, New Age International (P) Ltd Publishers, India.
8. Instrumental Methods of Analysis by S. S. Mahajan, 2010, 1st edition, Popular Prakashan Pvt Ltd, India.
9. Instrumental Methods of Chemical Analysis (Analytical Chemistry) by Gurudeep R. Chatwal and Sham. K. Anand, 2008, 5th revised and enlarged edition, Himalaya Publishing House Pvt Ltd.
10. Indian Pharmacopoeia, 2014 or latest edition.
11. Instrumental Method of Analysis by Willard H.H., L. L. Merritt& John A. Dean, 1986, 6th edition, CBS Publishers & Distributors, New Delhi.
12. Instrumental Method of Chemical Analysis by Ewing Galen W, 1969, 3rd edition, McGraw Hill Book Company, New York.
13. Undergraduate Instrumental Analysis by J.W. Robinson, E.M. Skelly Frame and G.M. Frame II, Pub. Marcel Deckker, 2009
14. Analytical Chemistry, 2nd edition, R. Kellnar, M. Mermet, M. Otto, M. Valcarcel, H. M. Widner.

BPH_C_305_T – Pharmaceutical Engineering – (3 Hr/Wk)

Course Objectives

To provide learner with basic understanding of unit operations and related aspects involved in pharmaceutical industry.

Course Outcomes

The learner should be able to:
1. Understand mechanics of fluid, fluid flow, and its measurements
2. Classify and describe pumps, heat measuring devices and conveyors
3. Understand basic principles involved in unit operations such as crystallization, evaporation, distillation and refrigeration and will able to describe the equipment and accessories involved therein.
4. Summarize construction material, discuss corrosion of equipment from pharmaceutical industry point.
5. Define and categorize the different industrial hazards.

Note: Under all topics no detailed derivations are to be considered.

No.	Details	Hours
1	**Fluid flow** Mention of fluid properties such as viscosity, compressibility and surface tension of fluids. Hydrostatics influencing fluid flow. Fluid dynamics- Bernoulli's theorem, flow of fluids in pipes, laminar and turbulent flow.	3
2	**Fluid and pressure measurements** Measurement of flow- Classification of flow meters, venturi meter, Orifice meter, pitot tube, rotameter and current flow meters. Pressure measurement - Classification of manometers, simple manometer, U tube manometer and modifications, Bourdon gauge.	3
3	**Pumps:** Positive displacement pumps-reciprocating pumps, rotary pumps. Centrifugal pumps	2
4	**Heat and Mass transfer** Modes of heat transfer- conduction, convection and radiation, Heat exchangers-tubular and plate. Temperature measurement-basic principles and devices. Mass transfer in turbulent and laminar flow. Concept of interfacial mass transfer	3
5	**Conveying of solids** Belt conveyor, Bucket conveyor, Screw conveyor and Pneumatic conveyor.	1
6	**Crystallization**	4

	Crystal forms and crystal habits, Mier's theory of supersaturation, Nucleation, Crystal growth. Crystallizers- Classification, Tank crystallizers, Agitated tank crystallizers, Swenson Walker crystallizer, Vacuum crystallizer and its modifications, Krystal or Oslo crystallizer. Factors affecting crystallization and Caking of crystals	
7	**Evaporation:** Introduction, concept of heat transfer across the wall of evaporator, factors influencing rate of evaporation, including scale formation Evaporators classification - Pan evaporators, Tubular evaporators -Horizontal tube evaporator, Vertical tube evaporators- short tube vertical evaporator, Long tube evaporators -Climbing film evaporator, Falling film evaporator, Forced circulation evaporator, Wiped film evaporator , and Centrifugal rotary evaporator. Multiple effect evaporator-principle, operation, economy, capacity efficiency and feeding methods of evaporation. Vapor recompression- mechanical and thermal compression principle Evaporator accessories- condensers, vacuum pumps, expansion and bucket traps, entrainment separators	6
8	**Distillation:** Revision of Vapour-liquid equilibrium. Distillation methods- Equilibrium distillation, Simple distillation Fractional distillation- Theory of batch fractionation, Columns (only construction and working) Bubble cap, sieve plate columns, valve plate column, packed columns. Concept of plate efficiency with respect to vapor equilibrium diagram and HETP (no detailed theories and derivations). Distillation under reduced pressure- Theory and applications of molecular distillation and equipment including falling film and centrifugal molecular distillation still. Azeotropic and Extractive distillation, Steam distillation- Theory and applications.	5
9	**Refrigeration:** Refrigeration – equipment and concept of refrigeration load, concepts of brine systems and absorption systems.	2
10	**Materials of construction and Corrosion:** Classification into metals and non-metals. Ferrous and its alloys-cast iron, mild steel and stainless steel. Copper and its alloys. Nickel and its alloys. Aluminium and its alloys. Plastics- Classification into thermoplastics and thermosetting plastics, properties and applications of polyvinyl chloride, polyethylene, polyporopylene, polystyrene, polyester, ABS, phenolic and epoxy plastics, fluorocarbon plastics, chlorinated plastics and polycarbonated plastics. **Corrosion:** Mechanism and types of corrosion. Factors influencing rate of corrosion. Methods of combating corrosion.	4
11	**Industrial Hazards and safety regulations:** Mechanical hazards and prevention. Electrical hazards and prevention Chemical hazards and prevention Fire hazards and extinguishers	3
	TOTAL	**36**

Books:

1. K. Sambamurthy, Pharmaceutical Engineering, New age international (P) Limited Publishers, 1998.
2. Dr. A. R. Paradkar, Introduction to Pharmaceutical Engineering, 10th Edition, Nirali Parakashan, 2007.
3. James Swarbrick & James C. Boylon, Encyclopedia of Pharmaceutical Technology, Marcel Dekker, INC, New York, 1994.
4. Walter I. Badger & Julius T. Bancher, Introduction to Chemical Engineering, Mc Graw Hill Inc, 1995.
5. M. E. Aulton, Ed, Pharmaceutics-The Science of Dosage Form Design, Churchill Livingstone Medical Division Of Longman Group UK Ltd, 2002.
6. S. J. Carter, Cooper and Gunn's Tutorial Pharmacy, 6th Edition, CBS Publishers & Distributors, New Delhi, 2005.

7. Robert H. Perry, Don W. Green, Perry's Chemical Engineers Handbook,7th Edition, Don W. Green, James O. Maloney, McGraw Hill,1997.
8. G. K. Jani, Pharmaceutical Engineering, Vallabh Prakashan.

BPH_C_306_L – Organic Chemistry Lab I – (4 Hr/Wk)

Course Objectives

1. To discuss the aspects of occupational safety and hazards of working in a chemistry laboratory.
2. To teach the learner the method for determination of some common and useful physical properties of organic compounds.
3. To teach the learner the method for determination of some common functional groups present in organic compounds.

Course Outcomes

The learner will be able to:

1. Practice and follow safety rules and precautionary measures in laboratory.
2. Explain theoretical aspects of physical constant determination, detection of functional groups and Log P
3. Characterize/ Identify/Spot monofunctional or bifunctional organic compounds by physical constant, elemental analysis and functional group analysis

DETAILS

1. Laboratory safety measures to be taken for:
   a. Fire and burns
   b. Spillage
   c. Inhalation of toxic fumes
   d. Dress code in a laboratory
   e. First aid measures to be taken in cases of accidents
   f. Use of fume hood, eye shower, body shower.

2. Discussion about theoretical aspects of physical constant determination, and detection of functional groups.

3. Organic spotting: Minimum eight samples of mono-functional groups, and two samples of bi-functional groups to be taken. Elemental analysis using environmentally friendly reagents should be done for at least two of the above samples of mono-functional groups.

4. Demonstration: Determination of Log P of benzoic acid and substituted benzoic acids.

Books:

1. A Laboratory Hand Book of Organic Qualitative Analysis and Separations, V. S. Kulkarni, S. P. Pathak, D. Ramchandra & Co., Pune
2. Textbook of Organic Practical Chemistry, V.S. Kulkarni, S. P. Pathak, D. Ramchandra & Co., Pune
3. The Systematic Identification of Organic compounds, R. L. Shriner, R. C. Fuson and D. Y. Curtin, 6th Ed., Wiley, New York, 1980
4. A Textbook of Practical Organic Chemistry, A. I. Vogel, 4th edition, Wiley New York, 1978
5. Comprehensive Practical Organic Chemistry: Qualitative Analysis, V.K. Ahluwalia, S. Dhingra, Universities Press (India) Limited, 2000
6. Comprehensive Practical Organic Chemistry: Preparation and Quantitative analysis, V.K. Ahluwalia, Renu Aggarwal, Universities Press (India) Limited, 2000
7. DST Monographs

BPH_C_307_L – Physical Pharmacy Lab I – (4 Hr/Wk)

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 evaluation.

Experiments

1. Determination of refractive index of solid.
2. Polarimetry: Different concentrations of sugar, determination of unknown concentration and specific rotation.
3. Determination of solubility of a drug at room temperature
4. Viscosity determination of Newtonian liquids using Ostwald's viscometer and to determine the composition of an unknown binary mixture.
5. Phenol water system – Critical solution temperature and composition
6. Determination of surface tension of given liquids by drop count/ OR drop weight method and study the effect of surfactants in reducing surface tension/enhance wetting properties.
7. To determine buffer capacity at various stages of titrations of a weak acid against a strong base and hence to determine pKa of the acid.
8. Determination of partition coefficient of Iodine in CCl_4 and water/ OR benzoic acid in benzene and water
9. Adsorption of acetic acid on activated charcoal and determination of specific surface area of charcoal.

Demonstration:

10. Determination of HLB number of a surfactant by saponification method

Books:

1. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee.
2. Practical Physical Pharmacy, U. B. Hadkar, T.N. Vasudevan and K.S. Laddha,

BPH_C_308_L – Pharmaceutical Analysis Lab I – (4 Hr/Wk)

Course Objectives

1. To introduce the learner to pharmacopoeial methods of analysis.
2. To teach the learner the procedures for conducting different titrimetric analysis like acid-base titrations, complexometric titrations, etc.
3. To teach the learner gravimetric methods of analysis.

Course Outcomes

The learner should be able to:

1. Employ practice of calibration and proper handling of volumetric apparatus, electronic analytical balance and safety measures in the laboratory.
2. Demonstrate eye- hand co-ordination required for titrimetric analysis.
3. Perform and record, calculate and interpret data obtained for experiments related to volumetric, gravimetric and solvent extraction methods of analysis.
4. Conduct and evaluate various tests mentioned in a pharmacopoeial monograph

NOTE: For all the experiments, Indian Pharmacopoeia 2014/ latest edition has to be referred.

No.	Details
	Acid-Base titrations:
1.	Assay of Aspirin (with special emphasis on the test for salicylic acid).
2.	Assay of Aspirin tablets
3.	Estimation of Total alkalinity in a solution of Sodium Hydroxide
4.	Assay of Benzoic acid
	Redox titrations:
5.	Assay of hydrogen peroxide solution (Permanganometry).
6.	Assay of Ascorbic acid tablets (Iodimetry).
7.	Assay of Sodium metabisulphite (Iodometry)
8.	Assay of potassium permanganate (Iodometry)
9.	Assay of Dried Ferrous sulphate/ Ferrous fumarate/ Paracetamol (Cerimetry).
10.	Assay of Potassium iodide (Iodate titration)
	Complexometric titrations:
11.	Assay of Calcium gluconate.
12.	Assay of Zinc sulphate.
13.	Assay of Magnesium sulphate.
	Miscellaneous titrations:

14.	Assay of Sulphacetamide sodium using external indicator.
15.	Assay of Soluble Aspirin tablets (Solvent extraction followed by Bromometry-iodometry
	Gravimetric analysis:
16.	Ni^{2+} using Dimethyl glyoxime/ Al^{3+} as Aluminium oxinate.
17.	Ba^{2+} as barium sulphate
	Introduction to the study of monograph:
18.	Monograph of ascorbic acid tablets/ Calcium gluconate
	Demonstration titrations:
19.	Assay of Pyridoxine hydrochloride/ Sodium benzoate using non-aqueous titration method
20.	Assay of Sodium chloride
21.	Assay of Potassium chloride

Books:

1. Indian Pharmacopoeia, 2014 or latest edition.
2. Practical Pharmaceutical Chemistry by Beckett, A H & Stenlake, J B, 2005, 4thedition, Part I and II, CBS Publishers and Distributors, India.
3. Analytical Chemistry by Gary D. Christian, 6thedition, John Wiley & Sons, Singapore.
4. Vogel's Textbook of Quantitative Chemical Analysis by Mendham J, R.C. Denney, J.D. Barnes, M. Thomas, 2002, 6th edition, Pearson Education Ltd.
5. Pharmaceutical Analysis –A Textbook for Pharmacy Students and Pharmaceutical Chemists by David G Watson.

SEMESTER-IV

BPH_C_401_T – Organic Chemistry – (4 Hr/Wk)

Course Objectives

1. To introduce the learner to the synthetic methods for the introduction of different functional groups in a molecule and different methods for interconversion of some functional groups using synthetic methods.
2. To introduce the learner to the different nucleophilic reactions of carbonyl compounds and different electrophilic reactions of alkenes.
3. To introduce the learner to nucleophilic and electrophilic reactions of aromatic compounds.

Course Outcomes

The learner should be able to:

1. Outline few methods of preparation for various functional groups
2. Understand how and why the C=O group reacts with nucleophiles (using molecular orbitals and curly arrows) to give varied products
3. Predict the molecules that can be synthesized by reaction of C=C groups with electrophiles
4. Understand reactivity of aromatic systems towards electrophiles and nucleophiles

Emphasis to be placed on reaction mechanisms of the reactions from Unit 2 onwards

No.	Details	Hours	References
1.0	Preparation of following functional groups: (Only reactions to be discussed without mechanisms)	**6**	Organic Chemistry, R. T. Morrison, R. N. Boyd, S. K. Bhattacharjee, Pearson Education, 7th Ed.
1.1	Alcohols by Grignards reagent, phenols by hydrolysis of diazonium salts		
1.2	Aldehydes & ketones by oxidation of primary & secondary alcohols, Oxidation of methyl benzenes		
1.3	Amines by reduction of nitro compounds		
1.4	Carboxylic acids by oxidation of alcohols and hydrolysis of nitriles		
2.0	**Nucleophilic addition to C=O group**	**6**	1. Organic Chemistry, Jonathan Clayden, Nick Greeves, and Stuart Warren, Oxford University Press, 2nd Ed., Chapter 6. 2. Organic Chemistry, R. T. Morrison, R. N. Boyd, S. K. Bhattacharjee, Pearson Education, 7th Ed., Chapter 12.
2.1	Nucleophilic addition to aldehydes, ketones (e.g. attack of cyanide, hydride, organolithium, Grignard reagents, water and alcohols to form hemiacetals in acidic/basic conditions)		
2.2	Cannizzaro and crossed - Cannizzaro reaction		
3.0	**Nucleophilic substitution to C=0 group**	**10**	1. Organic Chemistry, Jonathan Clayden, Nick Greeves, and Stuart Warren, Oxford University Press, 2nd Ed., Chapter 10. 2. Organic Chemistry, R. T. Morrison, R. N. Boyd, S. K. Bhattacharjee, Pearson Education, 7th Ed., Chapter 14
3.1	Concept of leaving group based on stability and pK_a with reference to carboxylic acid derivatives		
3.2	Discussion of tetrahedral intermediate		
3.3	Examples to be discussed: Conversion of acid chloride to esters and amides, transesterification reaction.		
3.4	Comparison of reactivity of various carboxylic acid derivatives, Interconversion of carboxylic acid derivatives		
3.5	Acid and base catalyzed hydrolysis of esters, amides.		
3.6	Strategies of converting ketones to esters		
3.7	Nucleophilic substitution at C=O with loss of carbonyl oxygen. (Examples to be discussed: Conversion of aldehydes and ketones to imine, oxime, hydrazine, semihydrazone and semi carbazide.)		1. Organic Chemistry, Jonathan Clayden, Nick Greeves, and Stuart Warren, Oxford University Press, 2nd Ed., Chapter 11. 2. Organic Chemistry, R. T.

			Morrison, R. N. Boyd, S. K. Bhattacharjee, Pearson Education, 7th Ed., Chapter 12
3.8	Wittig reaction		
4.0	**Electrophilic addition to alkene**	**8**	1. Organic Chemistry, Jonathan Clayden, Nick Greeves, and Stuart Warren, Oxford University Press, 2nd Ed., Chapter 19. 2. Organic Chemistry, R. T. Morrison, R. N. Boyd, S. K. Bhattacharjee, Pearson Education, 7th Ed., Chapter 6.
4.1	Addition of bromine*, water, HBr (in presence and absence of peroxide) to alkenes, dimerization, oxymercuration-demercuration*, hydroboration-oxidation*, oxidation of alkenes to epoxide*, periodate cleavage and ozonolysis*, reaction with N-bromo succinimide. (*Stereochemical aspects to be covered)		
5.0	Enols and Enolates	**6**	1. Organic Chemistry, Jonathan Clayden, Nick Greeves, and Stuart Warren, Oxford University Press, 2nd Ed., Chapter 20
5.1	Formation and stability of enols		(Pgs. 449-458)
5.2	Aldol condensation reaction, crossed Aldol and mixed aldol reaction, Claisen and Crossed Claisen, Mannich reaction, Dickmann reaction.		2. Organic Chemistry, R. T. Morrison, R. N. Boyd, S. K. Bhattacharjee, Pearson Education, 7th Ed.
5.3	Conjugate addition : 1,2 and 1,4 Michael addition reaction		Organic Chemistry, Jonathan Clayden, Nick Greeves, and Stuart Warren, Oxford University Press, 2nd Ed., Pg. 504.
6.0	**Electrophilic aromatic substitution**	**8**	1. Organic Chemistry, Jonathan Clayden, Nick Greeves, and Stuart Warren, Oxford University Press, 2nd Ed., Chapter 21. 2. Organic Chemistry, R. T. Morrison, R. N. Boyd, S. K. Bhattacharjee, 7th Ed., Pearson Education.
6.1	Nitration, sulphonation, halogenation, Friedel-Crafts alkylation and Friedel Crafts acylation.		
6.2	Kolbe reaction, Reimer-Tiemann reaction		
6.3	Orientation and reactivity of mono and di-substituted benzene towards electrophilic aromatic substitution reaction.		
7.0	**Nucleophilic aromatic substitution**	**4**	1. Organic Chemistry, R. T. Morrison, R. N. Boyd, S. K. Bhattacharjee, Pearson Education, 7th Ed. Ch. 9
7.1	Mechanistic approach of nucleophilic aromatic substitution (Bimolecular displacement and benzyne formation)		
	TOTAL	**48**	

Books:
Already referred to in the syllabus outline

BPH_C_402_T – Physical Pharmacy II – (4 Hr/Wk)

Course Objectives

On completion of the theory lectures, the learner should be familiar with the basic concepts of chemical kinetics, drug diffusion and dissolution, biopharmaceutics, complexation, coarse and colloidal dispersions, which in turn, will help the learner in design, development and evaluation of dosage forms.

Course Outcomes

The learner should be able to:

1. Identify order of reactions, pathways of drug degradation and types of drug complexes
2. Describe Fick's laws of diffusion, mechanism of drug dissolution and absorption
3. Acquire understanding of drug complexes, protein binding and their applications
4. Gain knowledge of the basic principles of coarse and colloidal dispersions
5. Apply basic principles of drug characterization to biopharmaceutical aspects of drug delivery

No.	Details	Hours
1	**Chemical kinetics and drug stability**	**11**
1.1	Molecularity, order of a reaction, specific rate constant	2

1.2	Reaction kinetics: zero, pseudo-zero, first & second order (problems), units of basic rate constants, determination of reaction order, Energy of activation	4
1.3	Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis.	3
1.4	Accelerated stability testing in expiration dating of pharmaceutical dosage forms.	2
2	**Dissolution and diffusion**	**9**
2.1	Diffusion: Concept, and applications, diffusion through biological membranes, drug release	2
2.2	Fick's Laws of diffusion, Steady state diffusion, driving forces for diffusion in pharmaceutical systems, permeability	3
2.3	Measurement of diffusion	1
2.4	Concept of dissolution, dissolution mechanism	1
2.5	Noyes Whitney equation, factors affecting dissolution	1
2.6	Intrinsic Dissolution Rate, Hixson – Crowell Law, measurement of dissolution rates	1
3	**Complexation and protein binding**	**6**
3.1	Introduction, classification of complexes	2
3.2	Pharmaceutical applications of complexes	1
3.3	Method of analysis of complexes	1
3.4	Protein binding, complexation and drug action, stability constants	2
4	**Coarse dispersions**	**8**
4.1	Classification of dispersions, properties of coarse, colloidal and molecular dispersions	1
4.2	Thermodynamic and kinetic stability of dispersed systems	1
4.3	Electric Properties of Interfaces: Nernst and zeta potential, effect of electrolytes	1
4.4	Suspensions: DLVO theory, flocculated and deflocculated systems, controlled flocculation, physical stability of suspensions	3
4.5	Emulsions: Theories of emulsification, physical stability of emulsions	2
6	**Colloids**	**7**
6.1	Classification and preparation	2
6.2	Colloid properties: optical, kinetic and electrical	2
6.3	Stability of colloids and Schultz Hardy rule, Protective colloid and gold number	2
6.4	Pharmaceutical applications of colloids	1
7	**Biopharmaceutics**	**7**
7.1	Introduction to biopharmaceutics and Pharmacokinetics, concept of ADME, bioavailability	2
7.2	Mechanisms of drug absorption	1
7.3	Factors affecting drug absorption: Physicochemical, physiological and dosage form factors	3
7.4	Introduction to Biopharmaceutical Classification System of drugs	1
	TOTAL	**48**

Books:

Refer to latest edition

1. P. J. Sinko, 'Martin's Physical Pharmacy and Pharmaceutical Sciences' Fifth edition, Lippincott Williams and Wilkins, Indian Edition distributed by B.I. Publications Pvt. Ltd, 2006.
2. Pharmaceutical Dosage Forms And Drug Delivery Systems, Howard C. Ansel, Nicholas G. Popovich, Loyd V.
3. Pharmaceutics: The Science Of Dosage Form Design, Michael E.Aulton
4. Bahl and Tuli, 'Essentials of Physical Chemistry' S. Chand and Company Ltd. Ramnagar, New Delhi-110055.
5. Essentials of Physical Pharmacy , C.V.S Subrahmanyum, Vallabh Prakashan.
6. Textbook of Physical Pharmaceutics, C.V.S Subrahmanyum, Vallabh Prakashan

BPH_C_403_T – Pharmaceutics I – (3 Hr/Wk)

Course Objectives

To furnish the students with introduction to Pharmaceutics and preliminary knowledge that is required in the field of formulation development and details of Monophasic liquids, Powders and Biological preparations.

Course Outcomes

The learner should be able to:

1. Describe the status of Pharma Industry in India and elaborate on the different official compendia, recall the various types of dosage forms, routes of administration and describe the alternate systems of medicine.
2. Explain the concepts and need for GMP & QA and preformulation.

3. Summarize the packaging of pharmaceuticals
4. Explain the formulation considerations, unit operations, Q.A. aspects of monophasic systems, and powders.
5. Classify, describe the various biological products, viz. sutures & ligatures, blood products and plasma volume expanders.

No.	Details	Hours
1.	**Introduction-** Historical background of Profession of Pharmacy in India in brief Brief overview of status of Pharmaceutical Industry in India Pharmacopoeias-IP, BP & BPC, USP/NF, International Pharmacopoeia, Eur. Pharmacopeia	2
2.	**Overview –** Revision of dosage forms and routes of administration Introduction to alternate systems of medicine-Ayurveda, Homeopathy, Unani & Siddha Concepts of GMP & Quality Assurance in Pharma Industry Preformulation-importance and need.	2
3.	**Packaging of Pharmaceuticals-** General concept of package and its components-primary & ancillary packs, basic packaging materials- glass, plastics, metals, rubber and paper; types of containers and closures; quality control tests; brief on adhesives and printing inks.	2
4.	**Monophasic Liquid dosage forms:Preformulation & formulation aspects** General considerations of liquid dosage form design and manufacture-selection of vehicle and excipients; solubility and solubilisation techniques, dissociation and partitition coefficient, polymorphism, organoleptic properties, stability with excipients. Large scale Manufacturing aspects-Unit operations and equipment used: liquid mixing, clarification and filtration, filling operations, packaging and quality control tests. Brief coverage of following monophasic dosage forms- Solutions, Aromatic waters, Syrups, Elixirs, Linctuses, Nasal & Ear drops, Paints, Sprays, Lotions & Liniments.	10
5.	**Micromeritics & Powder Technology: Preformulation & formulation aspects** Basics of micromeritics-Fundamental and derived properties of powders and their measurement-particle shape & size, surface area, densities, flow properties, packing properties, fluidization of powders. Large scale manufacturing aspects- Unit operations and equipment used: Size reduction, size separation, powder mixing, segregation of mixed powders; packaging & Q.C. of powders. Brief coverage of following powders-Dusting powders, Oral rehydration powders, Dry syrup formulations.	10
6.	**Biological products-** **Sutures & ligatures**- Definition, classification, cat gut manufacturing and processing, other absorbable sutures-natural & synthetic; Nonabsorbable sutures- silk, linen, polyamides, polyesters, polyolefins, and metallic wires; Quality control tests for sutures/ligatures **Blood products**: Need, problems/hazards, blood banking procedures Whole human blood, Red cell concentrate, Platelet concentrate, Plasmapheresis, plasma, serum; Fractionation of plasma, study of some fractions-clotting factors like fibrinogen, AHF, factor IX complex, prothrombin, albumin preparations, γ globulin preparations. Quality control aspects of blood products **Plasma substitutes (plasma volume expanders)-** Need, desired properties, examples- hydrolyzed gelatin based products, HETA starch, Dextran (in detail –source, preparation, official injections)	10
	Total	**36**

Books-

1. Lachman Leon, Lieberman Herbert A, Kanig Joseph L., "The Theory and Practice of Industrial Pharmacy, Varghese Publishing House, Mumbai.
2. Remington, The Science and Practice of Pharmacy, Vol I & II, B.L. Publications Pvt. Ltd.
3. Martin A., Physical Pharmacy, 4th Edition, Lea & Febiger, Philadelphia, London.
4. M.E. Aulton, Ed, Pharmaceutics-The Science of Dosage Form Design, Churchill Livingstone Medical Divison of Longman Group, UK Ltd.
5. Rawlings, Bentley's Text Book of Pharmaceutics, Bailliere Tindall, London.
6. Atmaram Pawar, "Introduction to Pharmaceutics", Career Publications, Nashik
7. Pharmacopoeias- IP, BP, USP

BPH_C_404_T – Pharmacology I – (4 Hr/Wk)

Course Objectives

1. To educate about general principles of Pharmacology, drug actions, routes of drug administration, pharmacodynamics and pharmacokinetics.
2. To impart knowledge on the effect of drugs on the human body and the mechanisms by which they produce biological/therapeutic/toxic effects.
3. To impart knowledge about the pharmacology of drugs acting via receptors of Autonomic nervous system.
4. To educate on the pharmacology of drugs used for cardiovascular disorders.
5. To educate on pharmacology of diuretic drugs.

Course Outcomes

The learner should be able to:

TOPIC	COURSE OUTCOMES	BLOOM'S LEVEL
T1	Define the scope, general principles and applications of Pharmacology. Comprehend pharmacokinetic and pharmacodynamic principles along with ability to compare and contrast various routes of administration with advantages and disadvantages. Understand the factors modifying drug action.	1 and 2
T2	Classify receptors and elucidate their role in drug/neurotransmitter/hormone action. Understand the mechanisms of drug action.	2
T3	Explain autonomic transmission and discuss the pharmacology of drugs acting on ANS and rationalize their therapeutic applications.	2 and 3
T4, T5	Explain the pharmacology of drugs acting on cardiovascular system and as diuretics and discuss their use in associated diseases	2 and 3

No.	Details	Hours
1	General Principles of Pharmacology • Introduction to Pharmacology • Routes of drug administration with special reference to their advantages and disadvantages. • Drug Absorption, Distribution, Metabolism & Excretion (ADME) • Factors modifying action of drug	8
2	Mechanisms of drug action • Brief introduction to physiological receptors • Structural and functional families of receptors • Mechanisms of drug action: -Drug receptor interaction -Dose response curve (DRC) -Drug antagonism	8
3	Autonomic nervous system • Autonomic neurotransmission • Parasympathomimetics • Parasympatholytics • Sympathomimetics • Sympatholytics • Drugs acting on autonomic ganglia • Skeletal muscle relaxants	16
4	Cardiovascular system • Drugs used in the treatment of: - Congestive cardiac failure - Hypertension - Cardiac arrhythmia - Angina pectoris - Hyperlipoproteinemia	13
5	Diuretics	3
	Total	**48**

Books:

1. Goodman & Gilman's Pharmacological Basis of Therapeutics; Joel. G, Hardmon Lee, E. Limbird, Alfred Goodman Gilman; 11th Ed.; The Mcgraw-Hill Companies, Inc; 2011.
2. Pharmacology and Pharmacotherapeutics; R.S. Satoskar, S.D. Bhandarkar, Nirmala N. Rege; 20th Ed.; Popular Prakashan; 2007.
3. Pharmacology; Rang and Dale; 7th Ed.; Churchill Livingstone; 2012.
4. Lippincott's Illustrated Reviews: Pharmacology, Lippincott-Raven; 3rd Ed.; Howland & Nycets Publishers, N.Y.; 2006.
5. Lewis Pharmacology; Crossland; 5th Ed. Churchill Livingstone.
6. Clinical Pharmacology- Lawrence, D.R and Bennet- 9th Ed.; Elsevier, N.Y. 2006.
7. Clinical Pharmacology- B.G. Katzung; 11th Ed.; Appleton & Lange Publications, 2009.
8. Pharmacology; George M. Brenner, Craig W. Stevens; 2nd Ed.; Elsevier Publishers, 2006.
9. Essentials of Medical Pharmacology, K. D. Tripathi, 7th ed, Jaypee Publishers.

BPH_C_405_T – Microbiology – (3 Hr/Wk)

Course Objectives

1. To discuss the scope, history of microbiology and applications in pharma industry, classification of microorganisms and Learn different microscopy techniques and principles of different staining techniques.
2. To understand Structural organization and multiplication of bacteria, viruses, algae, protozoa, and fungi, Nutritional requirements of bacteria and study diseases related to them ; different media used for bacterial culture; growth curve and different methods to quantify bacterial growth
3. To study physical and chemical control of microorganisms, different methods of sterilization, validation of sterilization methods
4. To learn Microbiological standardization of Pharmaceuticals: Bioassay, Microbial limit tests, Sterility testing of pharmaceutical products and preservation of pharmaceutical products

Course Outcomes

The learner should be able to:

1. Describe the classification of microorganisms and list some of the common diseases caused by them.
2. Use different microscopic techniques, staining techniques, and differential media for the identification of some common disease causing microorganisms.
3. Describe different methods for the control of growth of microorganisms and methods of preservation/sterilization of pharmaceutical products.
4. Describe the importance of microbial testing and microbial limit tests for some pharmaceutical products

No.	Details	Hours
1		**5**
1.1	Introduction to Microbiology, Brief history, Scope of Microbiology-Basic & Applied, Relevance and Applications in Pharmaceutical Industry.	1
1.2	Classification of Microorganisms, Prokaryotic and eukaryotic microorganisms, Microbes and the environment.	1
1.3	Microscopy, Simple microscope, Compound microscope, resolving power, magnification, angular aperture, numerical aperture, Dark field microscopy, phase contrast microscopy, fluorescent microscopy, electron microscopy.	2
1.4	Information used to characterize and identify microorganisms (in brief) - morphological, cultural, biochemical (metabolic), antigenic, pathogenic, genetic characteristics.	1
2		**15**
2.1	Bacteria - Morphology, Cell characteristics, Habitat, Nutritional requirements, Cultivation of bacteria, Culture media- Cultivation & Storage media, Cultivation of aerobes and anaerobes.	3
2.2	Pure culture, Methods to isolate pure cultures, Preservation of cultures. Reproduction of bacteria, Growth phases, Measurement of growth (enumeration), factors affecting growth, continuous cultivation.	2
2.3	Overview of bacterial diseases and the pathogens causing them- Mycobacterium sp., Salmonella sp., Shigella sp., Staphylococci sp., Pseudomonas sp., Klebsiella sp., Clostridium sp, Vibrio sp.	2
2.4	Viruses & related microorganisms - Morphological characteristics, Nutritional aspects, Cultivation and reproduction, HIV and Oncogenic viruses.	2
2.5	Rickettsiae and Chlamydiae- Morphological characteristics, Cultivation, Rickettsial &	1

	Chlamydial diseases.	
2.6	Major groups of Eukaryotic microorganisms -	
	Fungi-Morphological characteristics, Classification, Reproduction of fungi, Cultivation of fungi, Culture media, Study of some important fungi- Penicillium, Aspergillus, Candida, Saccharomyces. Fungal infections-Mycoses	2
	Algae - Classification, Morphological characteristics, reproduction, economic significance of algae.	1
	Protozoa- Morphological characteristics and classification, reproduction, pathogenic protozoa like Amoeba, Paramecium, Trichomonas, Plasmodium	2
3		**11**
	Control of Microorganisms	
3.1	Fundamentals of Microbial Control - Pattern of Death in a Microbial population, Conditions affecting Antimicrobial activity, Mechanisms of microbial cell damage, Survivor curves and concepts of D - value and Z- value. Inactivation factor.	2
3.2	Sterilization methods & Equipment- Heat Sterilization methods (Moist heat, dry heat, low temperature sterilization methods), Radiation Sterilization, Ionizing and non-ionizing radiations, Filtration Sterilization, Gaseous Sterilization. Evaluation of the efficiency of sterilization methods, Equipment employed in large scale sterilization, Sterility indicators.	5
3.3	Chemical agents used for control of microorganisms- Terminology of Chemical agents, Ideal properties, Major groups of disinfectants and antiseptics (with mechanisms and applications), Chemical sterilants, Evaluation of potency- Tube dilution & Agar plate methods, Phenol Coefficient technique, Tissue toxicity index	4
4		**5**
4.1	Introduction to Aseptic techniques (no equipment) Designing of aseptic area, laminar flow equipment; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification as per ISO and USFDA. General aspects-environmental cleanliness and disposal of microbial waste.	1
4.2	Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP	1
4.3	Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic and testing of antimicrobial activity of a new substance	1
4.4	Microbial limit tests : Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.	1
4.5	Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.	1
	Total	**36**

Books:

(Latest editions should be referred)
1. M.J. Pelzer Jr., E.C.S. Chan and N.R. Krieg "Microbiology Concepts and Applications" McGraw Hill, Inc., USA, 1993.
2. M.Frobisher, R.D. Hinsdill, K.T. Crabtree and C.R. Goodheart "Fundamentals of Microbiology", 9th Edn. Saunders College Publishing, Philadelphia 1968.
3. W. B. Hugo and A. D. Russel "Pharmaceutical Microbiology" 6th Edn. Blackwell Science Ltd. UK, 2003.
4. R. Ananthanarayan and Ck. J. Panicker "Textbook of Microbiology", 7th edn. Orient Longman Pvt. Ltd. Hyderabad, 2005.

BPH_C_406_T – Mathematics and Statistics – (3 Hr/Wk)

Course Objectives

1. To teach the learner the basic principles of calculus, differentiation and integration, and determinants and matrices and their application in several other specialized pharmacy subjects.
2. To convey to the learner the importance of statistics and statistical methods in data analysis and results interpretation and as an extension in experimental design.

Course Outcomes

The learner should be able to:
1. Know the theoretical concepts of topics and their application in Pharmacy
2. Solve the different types of problems by applying theoretical concepts.
3. Appreciate the important application of mathematics and statistics in Pharmacy.

No.	Details	Hours
1	**Calculus: Differentiation**	**5**
	Introductions, Derivative of a function, Derivative of a constant, constant and a function, sum or difference of two functions, product/quotient of two functions(product/quotient formula),Derivative of x^nw.r.t x, $log_e x$, a^n, Successive differentiation, Lagrange's and Rolle's Mean Value Theorems(Statements only), Taylors and Maclaurins Series with application.	
2	**Analytical Geometry: Integration**	**5**
	Definition, standard formulas, rules of integration, method of substitution, integration by parts, definite integration, Application(determination of the length of the curve, area and volume)	
3	**Differential Equations**	**4**
	Formation of differential equations, solution of first-order and first-degree equation, linear differential equations of higher order with constant coefficients.	
4	**Determinants and Matrices**	**4**
	Properties of determinants and application of Cramers method, types of matrices, inverse of matrix, rank of matrix.	
	Statistics	
5	**Measurement of Central Tendency**	**4**
	Arithmetic Mean, median and mode	
6	**Measures of Dispersion**	**7**
	Range, quartile deviation, mean deviation and standard deviation, coefficient of variation, probability, Binomial, Poisson and Normal distribution, Fitting of curves by the method of least squares{Y= a + bX, Y=ab^x, Y=aX^b}	
7	**Sampling distribution for mean and proportion**	**7**
	Test of hypothesis for specified values of mean and proportion for large samples, Testing equality of two means and proportions, Students "t" test for single sample and paired observation, F-test and analysis of variance, testing of attributes, Chi-square distribution.	
	Total	**36**

Books:
Latest editions to be adopted
1. Mathematics for Pharmacy Students (Vol.I), Gujar K. N., Bhavale Ashok, Career Publication.
2. Mathematics for Pharmacy Students (Vol.II), Gujar K. N., Bhavale Ashok, Career Publication.
3. Fundamentals of Statistics, Gupta S.C., Himalaya Publication.
4. Integral Calculus, Shanti Narayan, S. Chand Publication.
5. Differential Calculus, Shanti Narayan, S. Chand Publication.
6. Textbook of Applied Mathematics, Vols. I and II, Warlikar, P. N., Pune Vidyarthi Griha Prakashan.

BPH_C_407_L – Physical Pharmacy Lab II – (4 Hr/Wk)

Course Objectives

To familiarize the learner with methods to evaluate shelf life and physical stability of products 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, molecular weight, and critical micellar concentration

Experiments:

1. Determination of reaction rate constant, order of a reaction and relative strength of acids (first order).
2. Determination of reaction rate constant and order of a reaction (second order, a=b).
3. Determination of order of reaction by Ostwald isolation method
4. Accelerated stability studies
5. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method **OR** Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method
6. Determination of wetting property of solid by Wet point method or Flow point method
7. Determination of molecular weight of polymer using intrinsic viscosity
8. Determination of critical micellar concentration of a surfactant

Demonstration

9. Demonstration of Brookfield viscometer or any other rotational/multipoint viscometer.

Books:

1. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma Settee
2. Practical Physical Pharmacy, U. B. Hadkar, T.N. Vasudevan and K.S. Laddha

BPH_C_408_L – Pharmaceutics Lab I– (4 Hr/Wk)

Course Objectives

To train the learner in preparation of typical monophasic liquid and powder formulations and carry out their Q.C. tests, and acquaint them with some biological preparations available in market.

Course Outcomes

The learner should be able to:

1) Prepare monophasic liquid systems and powder systems, justify the components and method of preparation.
2) Demonstrate the properties of the developed dosage forms and biological products, comment on the quality.
3) Perform experiments as per GLP and record in the journals.

Experiments:

No.	Details
1	**Aromatic waters-** Chloroform Water IP 1966, Conc. Dill water IP 1966, Conc. Anise water IP 1973, Gripe water
2	**Syrups-** Syrup IP 1966, Artificial syrup, Cough Syrup-Codeine phosphate syrup-BPC
3	**Linctus-** Simple linctus BPC
4	**Elixirs-** Piperazine Citrate elixir BPC
5	**Ear drops-** Chloramphenicol ear drops BPC
6	**Nasal Drops-** Ephedrine sulphate nasal drops BPC
7	**Glycerites-**Glycerin of starch IP 1955, Glycerin of boric acid IP 1955, Glycerin of tannic acid IP 1966
8	**Solutions-**Aqueous Iodine solution IP 1966, Paracetamol solubilized paediatric drops, Cresol with soap solution IP, Magnesiun Citrate oral solution NF XIV, Chlorinated soda solution, surgical-BPC, Iodine paint compound BP 1968
9	**Powders-**Oral rehydration salt (ORS)
10	**Quality evaluations-** a) Liquids for –organoleptic properties, specific gravity, pH, viscosity b) Powders for-particle size, bulk density, flow properties (flow rate & angle of repose) c) Packaging materials-simple testing of dimensions, thickness, volume etc of containers and flexible packaging materials (films, paper, laminates).
11	**Biological products-Assignment** a) Sutures & ligatures- survey on marketed products- one absorbable & one non-absorbable, learn about its monographic testing and labelling. b) Blood products- survey on one blood product and one plasma volume expander (marketed), and its monographic

	testing.

Books:

1. Lachman Leon, Lieberman Herbert A, Kanig Joseph L., "The Theory and Practice of Industrial Pharmacy, Varghese Publishing House, Mumbai.
2. Remington, The Science and Practice of Pharmacy, Vol I & II, B.L. Publications Pvt. Ltd.
3. Martin A., Physical Pharmacy, 4th Edition, Lea & Febiger, Philadelphia, London.
4. M.E. Aulton, Ed, Pharmaceutics-The Science of Dosage Form Design, Churchill Livingstone Medical Division of Longman Group, UK Ltd.
5. Rawlings, Bentley's Textbook of Pharmaceutics, Bailliere Tindall, London.
6. Atmaram Pawar, "Introduction to Pharmaceutics", Career Publications, Nashik
7. Pharmacopoeias- IP, BP, USP

BPH_C_409_L – Pharmacology Lab I– (4 Hr/Wk)

Course Objectives

1. To impart practical (Laboratory) training in basic laboratory techniques like tissue (cock ileum) mounting and in vitro experimentation.
2. To teach plotting of dose response curve of acetylcholine in presence of antagonist and agonist.
3. To demonstrate the effect of various drugs on isolated organ (frog heart) using interactive audiovisuals.
4. To convey about ethical guidelines followed in animal experimentation.

Course Outcomes

The learner should be able to:

TOPIC	COURSE OUTCOMES	BLOOM'S LEVEL
P1	Perform *in vitro* experiment on cock ileum (tissue) to evaluate effect of drug (Ach) and its dose on response (contraction) to comprehend and infer drug effects on receptors and its outcomes.	1 and 2
P1, P4	State the principles behind plotting dose-response of drugs/agonist/antagonist and its applications. Define pA2 value and calculate pA2 value of antagonist.	1 and 3
P3	Summarize the impact of drugs on eye and GI and discuss their potential therapeutic utility.	2
P4	Observe and explain the mechanisms of action of neurotransmitters, drugs and ions on isolated frog heart.	2
P5	Knowledge of animal handling techniques and understanding of ethical guidelines governing animal experimentation.	1 and 2

No.	Details
1	Dose response curve (DRC) of Acetylcholine using suitable isolated tissue preparation (e.g. Cock ileum)
2	Demonstrations: Effect of drugs on isolated frog heart (CDs) -Adrenaline, Acetylcholine -Atropine, propranolol -Effect of excess calcium and potassium on isolated heart -Effect of lack of calcium and potassium on isolated frog heart -Effect of digitalis on hypodynamic heart
3	Simulated experiments (CDs) -Effect of drugs on eye
4	Demonstration with the help of CDs or kymograph recordings: –Effect of neostigmine on DRC of Ach –Effect of pancuronium on DRC of Ach (Give the readings to the students and ask them to plot the graphs and draw conclusions from the results e.g. Identify type of antagonism existing between two drugs by studying the nature of the graphs, competitive and non- competitive. Find out the potency of the drugs by studying the DRC and

	determining IC50 values) -Calculation of pA2 value of atropine using Ach as an agonist
5	Tutorials -Laboratory animal handling -Care and ethics in animal experimentation

Books:

1. Kulkarni, S.K. Handbook of Experimental Pharmacology; 3rd Ed.; Vallabh Prakashan, New Delhi. 2005.
2. Gosh M.N. Fundamentals of Experimental Pharmacology, 3rd Ed.; Hilton & Company, Calcutta. 2005.
3. S.B. Kasture A Handbook of Experiments in Pre-Clinical Pharmacology- 1st Ed. Career Publications. 2006.
4. W.I.M. Perry, Pharmacological Experiments on Isolated Preparations. 2nd Ed.; E & S Livingstone, Edinburgh & London, 1970.

UNIVERSITY OF MUMBAI
No. UG/68 of 2018-19

CIRCULAR:-

Attention of the Principals of the affiliated Colleges and Directors of the recognized Institutions in Science & Technology Faculty is invited to this office Circular No. UG/149 of 2008, dated 4th April, 2008 relating to syllabus of the Bachelor of Pharmacy (B.Pharm.) degree course.

They are hereby informed that the recommendations made by the Ad-hoc Board of Studies in Pharmacy at its meeting held on 13th June, 2018 have been accepted by the Academic Council at its meeting held on 14th June, 2018 **vide** item No. 4.53 and that in accordance therewith, the revised syllabus as per the (CBCS) for the T.Y.B.Pharm. and B.Pharm. Degree Course (Sem – V to VIII), has been brought into force with effect from the academic year 2018-2019 to 2019-2020, accordingly. (The same is available on the University's website www.mu.ac.in).

(Dr. Dinesh Kamble)
I/c REGISTRAR

MUMBAI – 400 032
6th July, 2018

To

The Principals of the affiliated Colleges & Directors of the recognized Institutions in Science & Technology Faculty. (Circular No. UG/334 of 2017-18 dated 9th January, 2018.)

A.C./4.53/14/06/2018

****

No. UG/68 -A of 2018 MUMBAI-400 032 6th July, 2018

Copy forwarded with Compliments for information to:-

1) The I/c Dean, Faculty of Science & Technology,
2) The Chairman, Ad-hoc Board of Studies in Pharmacy,
3) The Director, Board of Examinations and Evaluation,
4) The Director, Board of Students Development,
5) The Co-Ordinator, University Computerization Centre,

(Dr. Dinesh Kamble)
I/c REGISTRAR

AC 14.6.2018

Item Number : 4.53

UNIVERSITY OF MUMBAI

Bachelor of Pharmacy

B. Pharm. Choice Based Credit System (CBCS)

Third Year B. Pharm. and Final Year B. Pharm

(Semester V to Semester VIII),

from Academic Year 2018 -19 and 2019-20

From Coordinator's Desk:

To meet the challenge of ensuring excellence in engineering education, the issue of quality needs to be addressed, debated taken forward in a systematic manner. Accreditation is the principal means of quality assurance in higher education. The major emphasis of accreditation process is to measure the outcomes of the program that is being accredited. In line with this Faculty of Technology of University of Mumbai has taken a lead in incorporating philosophy of outcome based education in the process of curriculum development.

Faculty of Technology, University of Mumbai, in one of its meetings unanimously resolved that, each Board of Studies shall prepare some Program Educational Objectives (PEO's), give freedom to affiliated Institutes to add few (PEO's) course objectives course outcomes to be clearly defined for each course, so that all faculty members in affiliated institutes understand the depth approach of course to be taught, which will enhance learner's learning process. It was also resolved that, maximum senior faculty from colleges and experts from industry should to be involved while revising the curriculum. I am happy to state that, each Board of studies has adhered to the resolutions passed by Faculty of Technology, developed curriculum accordingly. In addition to outcome-based education, **Choice Based Credit and Grading System** is also introduced to ensure quality of engineering education.

Choice Based Credit and Grading System enables a much-required shift in focus from teacher-centric to learner-centric education since the workload estimated is based on the investment of time in learning not in teaching. It also focuses on continuous evaluation which will enhance the quality of education. University of Mumbai has taken a lead in implementing the system through its affiliated Institutes. Faculty of Technology has devised a transparent credit assignment policy adopted ten points scale to grade learner's performance. Credit grading-based system was implemented for First Year of B. Pharmacy from the academic year 2016-2017. Subsequently this system was carried forward for Second Year B. Pharmacy in the academic year 2017-2018, Third Year in the academic years 2018-2019 and Final Year B. Pharmacy in the academic year 2019-2020.

Dr. S. K. Ukarande
Dean – Faculty of Science and Technology,
Member - Academic Council
University of Mumbai, Mumbai

B. Pharm. Choice Based Credit System (CBCS)

Scheme Examination Semesters V to VIII

&

Syllabus Semesters V to VIII

EXAMINATION SCHEME FOR THE

CHOICE BASED CREDIT SYSTEM (CBCS)

SEMESTER V

Course Code	Name	Credits	Hr/Wk	Weightage Internal	Weightage End Semester Exam	Total Marks
BPH_C_501_T	Organic Chemistry III	4	4	20	80	100
BPH_C_502_T	Pharmaceutics II	4	4	20	80	100
BPH_C_503_T	Pharmaceutical Biotechnology	4	4	20	80	100
BPH_C_504_T	Pharmacology II	4	4	20	80	100
BPH_E_5xx_T	Choice Based Course I	2	2	10	40	50
BPH_E_5xx_T	Choice Based Course II	2	2	10	40	50
	TOTAL Theory	**20**	**20**	**100**	**400**	**500**
BPH_C_505_L	Organic Chemistry Lab II	2	4	10	40	50
BPH_C_506_L	Pharmaceutics Lab II	2	4	10	40	50
BPH_C_507_L	Experimental Techniques in Microbiology and Biotechnology Lab	2	4	10	40	50
	TOTAL Lab	**6**	**12**	**30**	**120**	**150**
	TOTAL SEM V	**26**	**32**	**130**	**520**	**650**

SEMESTER VI

Course Code	Name	Credits	Hr/Wk	Weightage Internal	Weightage End Semester Exam	Total Marks
BPH_C_601_T	Pharmaceutical Chemistry I	4	4	20	80	100
BPH_C_602_T	Pharmaceutics III	4	4	20	80	100
BPH_C_603_T	Pharmaceutical Analysis II	4	4	20	80	100
BPH_C_604_T	Pharmacognosy II	4	4	20	80	100
BPH_E_6xx_T	Choice Based Course III	4	4	20	80	100
BPH_E_6xx_T	Choice Based Course IV	2	2	10	40	50
	TOTAL Theory	**22**	**22**	**110**	**440**	**550**
BPH_C_605_L	Pharmaceutical Chemistry Lab I	2	4	10	40	50
BPH_C_606_L	Pharmaceutics Lab III	2	4	10	40	50
BPH_C_607_L	Pharmaceutical Analysis Lab II	2	4	10	40	50
	TOTAL Lab	**6**	**12**	**30**	**120**	**150**
	TOTAL SEM VI	**28**	**34**	**140**	**560**	**700**

SEMESTER VII

Course Code	Name	Credits	Hr/Wk	Weightage Internal	Weightage End Semester Exam	Total Marks
BPH_C_701_T	Pharmaceutical Chemistry II	4	4	20	80	100
BPH_C_702_T	Pharmacognosy III	4	4	20	80	100
BPH_C_703_T	Pharmaceutical Analysis III	4	4	20	80	100
BPH_C_704_T	Pharmacology III	4	4	20	80	100
BPH_C_705_T	Pharmaceutical Jurisprudence	3	3	20	80	100
BPH_E_7xx_T	Choice Based Course V	2	2	10	40	50
	TOTAL Theory	**21**	**21**	**110**	**440**	**550**
BPH_C_706_L	Pharmacognosy Lab II	2	4	10	40	50
BPH_C_707_L	Pharmaceutical Analysis Lab III	2	4	10	40	50
BPH_C_708_L	Pharmacology Lab II	2	4	10	40	50
	TOTAL Lab	**6**	**12**	**30**	**120**	**150**
	TOTAL SEM VII	**27**	**33**	**140**	**560**	**700**

SEMESTER VIII

Course Code	Name	Credits	Hr/Wk	Weightage Internal	Weightage End Semester Exam	Total Marks
BPH_C_801_T	Pharmaceutical Chemistry III	4	4	20	80	100
BPH_C_802_T	Pharmaceutics IV	4	4	20	80	100
BPH_E_8xx_T	Choice Based Course VI	4	4	20	80	100
BPH_E_8xx_T	Choice Based Course VII	4	4	20	80	100
	TOTAL Theory	**16**	**16**	**80**	**320**	**400**
BPH_C_803_L	Pharmaceutical Chemistry Lab II	2	4	10	40	50
BPH_C_804_L	Pharmaceutics Lab IV	2	4	10	40	50
BPH_E_805_D	Project	6	12	-	200	200
	TOTAL Lab	**10**	**20**	**20**	**280**	**300**
	TOTAL SEM VIII	**26**	**36**	**100**	**600**	**700**

SYLLABUS FOR T. Y. B. Pharm.

SEMESTER-V

BPH_C_501_T – Organic Chemistry III- (4 Hr/Wk)

Course Objective

Organic chemistry provides a foundation for understanding:
1) synthesis, nature, nomenclature of various heterocycles and their importance in medicinal chemistry,
2) nomenclature, nature and significant role of biomolecules like steroid hormones, peptide and DNA molecules in the organic and pharmaceutical chemistry and
3) To learn the basic concepts of polymers. Polymerization methods, measurement of molecular weight and its application in pharmaceutical industries

Course Outcomes

1. Upon successful completion of this course, a learner will be able to
2. Identify, nomenclate, and to employ fundamental heterocyclic organic reactions in the synthetic design of biologically active molecules containing heterocyclic nucleus
3. Recognize the steroid molecules, synthetic methods, nature and their role in our body.
4. Outline the synthesis, chemical reactions of steroids, conversion of cholesterol to progesterone, estrone and testosterone and elucidation of structure of cholesterol.
5. State basic terminologies in polymers, different mechanisms involved in the polymer preparation, different polymerization techniques, details about the glass transition temperature and the factors affecting it and the types of polymers with some specific examples of each

No.	Details	Hours
1	**1 Heterocyclic Chemistry** 1.1 Nomenclature of mono, bi- and tri-cyclic hetero-aromatic, fused heterocyclic ring and bridge head system of the drug molecules along with drug examples. Synthesis, Discussion of aromaticity, resonance, properties of heterocycles, acidity and basicity and reaction of the following heterocycles 1.2 **Five membered Heterocycles with One Heteroatom:** a. Furan: Synthetic methods including synthesis using carbohydrates, Paal-Knorr synthesis b. Pyrrole: Synthetic methods including synthesis using furan, Knorr synthesis, Paal-Knorr synthesis, Hantzsch synthesis. c. Thiophene: Synthetic methods including synthesis using Paal-Knorr synthesis. Reactions of Furan, Pyrrole and Thiophene: With acids, Electrophilic Aromatic Substitution (EAS), Nucleophilic Aromatic substitution (NAS) reaction, oxidizing and reducing agents. 1.3. **Five membered heterocycles with Two heteroatoms**: a. Imidazole: Synthetic methods including synthesis from imidazolines, α-haloketones, Radiszewskii reaction. b. Oxazole: reaction between acid amides and α-halogenoketones eg. Acetamide and bromoacetone form 2,4-dimethyloxazole, Robinson–Gabriel synthesis by dehydration of 2-acylaminoketones, Reaction with Tosylmethyl isocyanide and aldehydes (The Van Leusen reaction) c. Thiazole: preparation α-chlorocarbonyl compound and thioacid amide– Hantzsch synthesis, Gabriel synthesis by reaction of a-Acylamino Ketones with Phosphorus Pentasulfide, Cook-Heilborn's synthesis from a-Aminonitriles, Reactions of Imidazole, Thiazole, Oxazole with acids, Electrophilic Aromatic Substitution (EAS), nucleophilic aromatic substitution (NAS), oxidizing and reducing agents,. 1.4 **Six membered heterocycles with One and Two heteroatoms**: a. Pyridine: Synthetic methods including synthesis using 1,5-diketones and Hantzsch synthesis. b. Pyrimidine: Synthesis using malonic ester; 2,4-dichloropyridine, amidine and maleic acid, Reactions of pyridine and pyrimidine with acids, Electrophilic Aromatic Substitution (EAS), nucleophilic aromatic	**5** **4** **5** **4**

	substitution (NAS), Hetaryne formation, oxidizing and reducing agents and Reactions of pyridine-N-oxide 1.5 **Fused heterocycles with One heteroatoms** a. Quinoline: Synthetic methods including Skraup synthesis, Doebner-Miller synthesis, Friedlander synthesis, Conrad-Limpach synthesis. Reactions with acids, Electrophilic Aromatic Substitution (EAS), nucleophiles, oxidizing and reducing agents b. Isoquinoline: Synthetic methods including Bischler-Napieralski and Pomeranz-Fritsch, Reactions including EAS, nucleophiles, oxidizing and reducing agents. c. Indole: Synthesis by Fischer indole synthesis, Madelung synthesis. Reactions with acids, EAS, Metallic K, Mannich reaction, oxidizing and reducing agents. 1.6 **Non-aromatic heterocyclic chemistry**: Synthesis and properties of the following heterocycles- Morpholines, Piperazines, Piperidine	**5** **4**
2	**Biomolecules:** **I. Chemistry of Steroids** 2.1 Definition of steroids and sterols, numbering and ring letters, orientation of projection formulae, stereochemistry of ring junction and side chain attachments, stereochemistry of substituents in the side chain. 2.2 Types of steroid hormones: androgens, estrogens, progestins, corticosteroids. Structure and biosynthesis of steroids from cholesterol. Conformation and chemical reactivity, steroid specific reactions of A and B rings, Addition-elimination, epoxide opening, relative rates of esterification, oxidation of epimeric alcohols, reduction of ketones. **II. Peptides:** Isoelectric point, synthesis of alpha amino acids (Strecker synthesis and amidomalonate and reductive amination of alpha keto acids), co-valent bonding in peptides, structure determination of peptides, sequencing of peptides (Edman synthesis, C-terminal residue determination- carboxy peptidase), partial hydrolysis of peptides using chemical (aq. Acids) and enzymatic methods (trypsin and chymotrypsin), synthesis of peptides – protection and deprotection of N and C-terminal amino acids, solution phase and solid phase (Merrifield) peptide synthesis. **III. DNA:** Merrifield solid phase synthesis of DNA **IV. Polymers** Chain growth polymers (free radical polymerization) Stereochemistry of polymerization Ziegler Natta catalyst, co-polymer, step growth polymers, co-polymers, polymer structure and physical properties, biodegradable polymers, characterization of molecular weight – average molecular weight, molecular weight distribution, size exclusion chromatography	**7** **5** **3** **6**
	TOTAL	**48**

Books:

Latest editions of following books to be adopted.

1. I. L. Finar: Organic chemistry- Volumes 1 and 2, Pearson Education, Ed:5
2. Morrison and Boyd, Organic chemistry, Prentice Hall.
3. Clayden and Greeves, Organic chemistry, Oxford University Press.
4. S. H. Pine et al, Organic chemistry, McGraw-Hill Science/Engineering/Math.
5. D. Lednicer: Steroid chemistry at a glance, Wiley.
6. Heterocyclic Chemistry, Volume I, Volume II, Volume III by R. R. Gupta, M. Kumar, V. Gupta, Publisher: Springer Nature (SIE) (2009)
7. Fundamental Principles of Polymeric material, Stephen L. Rosen, Second edition, John Wiley and sons, Inc. (1993)

BPH_C_502_T – Pharmaceutics II- (4 Hr/Wk)

Course Objectives

To provide knowledge to the students related to dosage forms such as biphasic liquid dosage forms, Semisolids, Suppositories and Aerosols with emphasis on their formulation and evaluation, and an introduction to cosmetics

Course Outcomes

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

1. Understand the formulation of liquid biphasic, semisolid, suppository and aerosol dosage forms
2. Describe the evaluation of such dosage forms
3. Summarize the packaging of liquid biphasic, semisolid, suppository and aerosol dosage forms
4. Explain the basic concepts of cosmetic science

No.	Details	Hours
1	Biphasic Systems: Suspensions and Emulsions	**15**
1.1	Physicochemical aspects: surface & interfacial tension, surface free energy, Gibb's equation, thermodynamic & kinetic stability of disperse systems Definition, advantages and disadvantages, desirable features and pharmaceutical dispersions	1
1.2	**Suspensions** Wetting phenomenon, particle-particle interactions, DLVO theory, flocculated and deflocculated systems, Schulze Hardy rule, Sedimentation process, Ostwald ripening and crystal factors, rheology	3
1.3	Formulation of suspensions: Excipients & additives Methods of preparation, Large scale manufacture (including equipment), filling and packaging, Layout of manufacturing area	3
1.5	Quality evaluation and stress testing, Official formulation examples	1
1.6	**Emulsions** Emulsifiers- need and mechanisms, droplet stabilization, classification, Selection of emulsifiers-HLB method, Davies method, PIT method, Cloud point method	3
1.7	Preparation of Emulsions-formulation additives, rheological aspects, physical stability of emulsions, symptoms of instability.	2
1.8	Methods of preparation, Large scale manufacture (including equipment), filling and packaging, Layout of manufacturing area. Concept of low energy emulsification.	1
1.9	Quality evaluation and stress testing, Examples of Official formulations	1
2	**Semisolids: Ointments, Creams, Pastes and Gels**	**10**
2.1	Factors influencing skin penetration-physiological and physicochemical factors, vehicles and penetration enhancers, methods to evaluate skin penetration.	3
2.2	Raw materials for semisolids, types of vehicles, ointment bases, creams, pastes, gels: Formulation additives; Rheological aspects.	4
2.4	Large scale manufacture with equipment involved in each step and layout. Quality evaluation, Examples of Official formulations.	3
3	**Suppositories**	**6**
3.1	Suppositories: Introduction, definition, advantages and disadvantages, desirable features of suppositories, factors affecting rectal absorption.	1
3.2	Suppository bases- specifications and desired features, classification and selection of suppository bases, special bases.	2
3.3	Formulation and specific problems involved in formulating suppositories, large scale manufacture with equipment, packaging.	2
3.4	Quality control tests, Examples of official formulations.	1
4	**Pharmaceutical Aerosols**	**9**
4.1	Definition, advantages & disadvantages, desirable features. Components of aerosol package, Two phase & three phase aerosol systems	1
4.2	Components in detail-Propellants-types – Liquefied propellants and Gaseous propellants, selection of propellants. Containers – Tin Plate, Aluminium, Glass, Plastics Valve and Actuator, Metered dose valve Product concentrate - Different formulation systems- solution, dispersions, foams. Dry Powder Inhalations-concept.	6
4.3	Manufacture of Aerosols-Cold filling and Pressure filling. Quality Control testing, Stability studies	2
5	**Introduction to Cosmetics**	**8**
5.1	Definition of cosmetics, classification.	1

Books:

Latest Editions

1. Lachman Leon, Liberman Herbert A., Kaing Joseph L., "Theory and practice of Industrial Pharmacy"

5.2	Raw materials including water, Oils, Fats, Waxes, Emulsifiers, Thickeners and Gums, colours, antioxidants, preservatives, perfumes, Fragrance selection, stability and Testing	3	3rd
5.3	Microbiological aspects of cosmetics.	1	
5.4	Safety testing and toxicology, Efficacy Testing Instrumental and Sensorial Evaluation of cosmetics	2	
5.5	Labelling, Legislation and regulations for cosmetics (Drug and Cosmetics Act, 1940 & Rules 1945), BIS specifications	1	
	TOTAL	**48**	

edition,1987, Varghese Publishing house,Mumbai.
2. Liberman Herbert A., rieger, "Pharmaceutical dosage Forms-Disperse Systems", vol 1/2/3, 2nd edition,2005, Marcel Dekker Inc., New York.
3. Allen, Loyd v V.Jr, "Remingtons- the Science and Practice of Pharmacy, Vol 1 / 2, 22nd edition, Pharmaceutical Press
4. Patrik Sinko Ed."Martin's Physical Pharmacy and Pharmaceutical Sciences", 6th edition, 2010,Lippincott Williams and Wilkins.
5. M.E. Aulton Ed.,"Pharmaceutics-The Science of Dosage Form Design"3rd edition,2007,
Churchill livingstone Elsevier Ltd., UK.
6. E.A. Rawlins Ed.,"Bentley's Textbook of Pharmaceutics", 2010, Elsevier Publications.
7. S.J.Carter Ed.,"Tutorial Pharmacy-Cooper & Gunn", 6th edition,1986, CBS Publishers & distributors, India.
8. Pharmacopeias-IP, BP, USP-latest editions
9. Harry's Cosmeticology Edited by J. B. Wilkinson and R. J. Moore, Longman Scientific & Technical Publishers
10. Cosmetics Science and Technology, Edited by M. S. Balsam, E. Sagarin, S. D. Gerhon, S. J. Strianse and M. M. Rieger, Volumes 1,2 and 3.Wiley-Interscience, Wiley India Pvt. Ltd.
11. Poucher's Perfumes, cosmetics & Soaps, Editor- Hilda Butler, Klewer Academic Publishers,Netherlands
12. Cosmetic Technology, Ed. By S. Nanda, A. Nanda and R. Khar, Birla Publications Pvt. Ltd., New Delhi
13. Encyclopedia of Pharmaceutical Technology, Vol. 6, Eds. James Swarbrick, James C. Boylan, Marcel Dekker Inc.
14. BIS Guidelines for different cosmetic products.
15. Formulation and function of cosmetics by Jellinek Stephan, Wiley Interscience.
16. Remington: The Science and Practice of Pharmacy, Lippincott Williams & Wilkins, 2006.

BPH_C_503_T – Pharmaceutical Biotechnology- (4 Hr/Wk)

Course Objectives

On completion of following theory topics, learner should be able to understand basic of modern biotechnology, fermentation technology, enzyme technology and immunology, working of tools used in molecular biotechnology, applications of conventional, modern biotechnology in pharmaceutical industries.

Course Outcomes

1. To discuss the tools, techniques, ethics and environmental safety involved in gene cloning, and the applications of Recombinant DNA technology
2. Discuss basics of immunology and explain the antigen-antibody interactions and defense mechanism and explain technique of monoclonal antibodies production for treating the human diseases
3. Study fermentation technology and understanding the basic concepts for production of safer vaccines and antibiotics
4. To study different techniques and applications of microbiological assay, enzyme immobilization and cell culture

No.	Details	Hours
1	**Introduction to Biotechnology**	**1**
1.1	Definitions, scope, relevance to Pharma Industry.	1
2	**Fermentation Technology**	**5**
2.1	Types of fermenters (mechanically stirred, air-lift, tray), Batch and continuous fermentation, design of fermenter, factors affecting fermentation (innoculum preparation, temperature, pH, media composition, aeration, agitation, antifoam agents, strain optimization, growth kinetics), Example of products of fermentation (microbial, animal and plant), and downstream process.	4
2.2	Production of penicillin Self-study: Production of dextran, Vitamin B12	1

3	**Recombinant DNA technology**	**10**
3.1	Steps involved in rDNA technology, Enzymes involved in DNA technology, Cloning vectors (Plasmid, Cosmid, YAC), Gene expression System	7
3.2	Application of rDNA technology and genetic engineering for production of pharmaceutical products e.g. Hormone (Insulin), Hepatitis B (Vaccines) and Interferon. Self-study: Preparation of a list of approved biotech derived products.	3
4	**Techniques used in molecular biology**	**7**
4.1	Introduction to following molecular biology tools. Polymerase chain reaction, DNA sequencing (Sangers dideoxynucleotide method and Maxam and Gilbert method), Restriction Fragment Length Polymorphism, cDNA library, Blotting techniques (Southern, Northern and Western blotting), Gene therapy.	6
4.2	Transgenic animal, transgenic plants, ethics in Biotechnology and disposal of biological waste Self-study: SDS- PAGE.	1
5	**Enzyme and cell immobilization.**	**5**
5.1	Methods for enzyme immobilization (adsorption, covalent binding, entrapment, microencapsulation) with examples and its applications in Pharmaceutical Industries.	2
5.2	Biosensor- Working and applications in Pharmaceutical Industries e.g. glucose oxidase, penicillinase.	2
5.3	Use of microbes in industry. Production of Enzymes-General consideration e.g Amylase	1
6	**Immunology**	**11**
6.1	a) Host-microbe interactions, Introduction to terms-infection, infestation, pathogen, resistance, susceptibility etc. b) Factors affecting pathogenicity and infection, c) Innate defense mechanism – first line of body defense, physiological phenomena-inflammatory response, fever, cellular, mediators; soluble (humoral) mediators, phagocytosis. d) Specific defense Mechanism – Characteristics, Antigen, Cell-mediated immunity, humoral immunity. e) Antibody structure and types, pathways of immune response, clonal selection theory. Self-study: Innate defense mechanism, Specific defense Mechanism, organization of immune system-organs & cells involved.	5
6.2	**Serology**-Precipitation, agglutination, complement fixation tests, immunofluorescence, RIA, ELISA.	2
6.3	Introduction to Hypersensitivity & Allergy. Immunodeficiency states- Primary & acquired, autoimmunity. Hybridoma technology – Production and application of monoclonal antibodies.	4
7	**Vaccines & Sera**	**4**
7.1	Definitions and classification, outline of general method of preparation of bacterial & viral vaccines, typical examples of each type (diphtheria, TAB, polio), antisera (anti-tetanus sera)	2
7.2	Q. C. aspects, Storage conditions and Stability of official vaccines, recent trends in vaccines (recombinant vaccines) Self-study: Outline of general method of preparation of BCG and rabies vaccine	2
8	**Cell culture (plant and animal)**	**2**
8.1	Tissue culture media, primary cell culture, continuous cell culture, pharmaceutical applications of animal cell culture.	2
9	**Microbial biotransformation**	**1**
9.1	Introduction to Microbial biotransformation and Applications.	1
10 10.1	**Introduction to Bioinformatics** Definition, History and Application of Bioinformatics in Pharmaceutical Industry.	**2**

	TOTAL	**48**

Books:

Latest editions of the following books to be adopted.

1. R. C. Dubey, A textbook of biotechnology
2. B. D. Singh, Biotechnology.
3. S. P. Vyas and Dixit, Pharmaceutical Biotechnology, CBS publisher & distributers.
4. S. S. Kori, Pharmaceutical Biotechnology.
5. H. D. Kumar, Biotechnology, Affiliate East-West press Pvt. Ltd New Delhi.
6. Ananthnarayan, A textbook of microbiology, Orient Longman Pvt. Ltd.
7. W. B. Hugo and A. D. Russell, Pharmaceutical Microbiology, Blackwell Science.
8. David, Nelson, Lehninger - Principle of Biochemistry, W. H. Freeman & Co.
9. Pelezar, Chan & Krieg, Microbiology-Concepts and Applications, International Edn., McGraw Hill, Inc.,
10. Weir Stewart: Immunology, Churchill Livingstone.
11. Chandrakant Kakote, Pharmaceutical Biotechnology.
12. Desmond S.T. Nicholl, An introduction to genetic engineering, Panima Publishing Corporation, New Delhi.
13. Stanbury F. P., Whitakar A., and Hall J.S. Principles of fermentation technology, 2nd edition. Aditya books LTD., New Delhi.

BPH_C_504_T – Pharmacology II- (4 Hr/Wk)

Course Prerequisites

- Basic knowledge of receptors and their physiological role in the human body.
- Understanding of concepts of immunology and endocrinology.
- Basic knowledge about blood and blood components.

Course Objectives

1. Study of drugs used in treatment of Bacterial, fungal, viral and microbial infections, cancer, HIV, endocrine and hematological disorders.

Course Outcomes

1. Discuss pharmacology of drugs used in chemotherapy and justify the need for rational use of antimicrobials.
2. Explain pharmacology of drugs used as immunomodulators.
3. Explain pharmacology of drugs used in endocrine disorders & haematological disorders.

No.	Details	Hours
1	**Chemotherapy**	**28**
1.1	Introduction to chemotherapy including drug resistance.	2
1.2	Sulfonamides, trimethoprim, fluoroquinolones, nitrofurantoin.	3
1.3	Penicillins, cephalosporins and cephamycins.	3
1.4	Tetracyclines, chloramphenicol, macrolides, clindamycin, linezolid, streptogramins and fusidic acid.	3
1.5	Aminoglycosides.	2
1.6	Antifungal agents.	2
1.7	Antiviral agents.	3
1.8	Chemotherapy of tuberculosis and leprosy.	3
1.9	Chemotherapy of malaria and amoebiasis.	3
1.10	Anthelmintic drugs.	1
1.11	Chemotherapy of neoplastic diseases (Anticancer drugs).	3
2	**Immunomodulators**	**3**
2.1	Immunology: Regulation of immune system, signaling pathways for its activation and inhibition.	1
2.2	Immunostimulants and immunosuppressants.	2
3	**Drugs in Endocrine Disorders**	**11**

3.1	Thyroid and anti-thyroid drugs.	2
3.2	Insulin, anti-diabetic agents including DPP-IV inhibitors.	3
3.3	Agents affecting bone mineral homeostasis.	2
3.4	Oxytocics.	1
3.5	Oral contraceptives.	1
3.6	Corticosteroids	2
4	**Drugs in Haematological Disorders**	**6**
4.1	Drugs used in anemia.	2
4.2	Coagulants and anti-coagulants.	2
4.3	Thrombolytics and anti-platelet agents.	2
	TOTAL	**48**

Books:

Latest editions of the following books to be adopted

1. Goodman & Gilman's Pharmacological Basis of Therapeutics, McGraw Hill Companies Inc.
2. Satoskar R.S. Bhandarkar S.D. & Rege N. N. Pharmacology & Therapeutics, Popular Prakashan.
3. Rang & Dale Pharmacology, Churchill Livingstone.
4. Lippincott's Illustrated Reviews: Pharmacology- Lippincott-Raven Howland & Nyeets Publishers NY.
5. Laurence D. R. & Bennett Clinical Pharmacology, Elsevier NY.
6. Kulkarni S. K. Handbook of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
7. Katzung B. G. -Basic and Clinical Pharmacology, Appleton and Lange publications.
8. Ghosh M. N. Fundamentals of Experimental Pharmacology Hilton & Company, Kolkata.

BPH_C_505_L – Organic Chemistry Lab II- (4 Hr/Wk)

Course Objectives

1. To introduce the learner to the basic techniques of separation of compound mixtures.
2. To introduce the learner to the procedure for identification of organic compounds
3. To introduce the learner to the methods for recrystallization of compounds

Course Outcomes

The learner will be able to:

1. To carry out the separation of simple compound mixtures.
2. To identify organic compounds based on simple tests
3. To recrystallize compounds use single solvent and binary solvent mixtures

List of Experiments:

1) Separation and quantification of binary mixtures by physical and chemical methods.
Identification of one component and confirmation by preparation of a suitable derivative.
Minimum eight binary mixtures, covering a wide variety of types to be studied
2) Theoretical aspects of recrystallization
3) Recrystallization of organic compounds: at least two with the use of different solvents.

Books:

Latest editions to be adopted

1. A laboratory handbook of organic qualitative analysis and separation, V.S. Kulkarni, S. P. Pathak, D. Ramchandra & Co., Pune.
2. Text book of organic practical chemistry, V.S. Kulkarni, S. P. Pathak, D. Ramchandra & Co., Pune.
3. R. L. Shriner, R. C. Fuson and D. Y. Curtin, The systematic Identification of Organic compounds, 6th Ed., Wiley, New York, 1980.
4. A. I. Vogel, A textbook of practical organic chemistry, 4th edition, Wiley New York, 1978.
5. Comprehensive Practical Organic Chemistry: Qualitative Analysis, V. K. Ahluwalia, S. Dhingra, Universities Press (India) Limited, 2000.
6. Comprehensive Practical Organic Chemistry: Preparation and Quantitative analysis, V.K. Ahluwalia, Renu Aggarwal, Universities Press (India) Limited, 2000.

BPH_C_506_L – Pharmaceutics Lab II- (4 Hr/Wk)

Course Objectives

To teach the learner the practical aspects of preparation and evaluation of biphasic suspensions and emulsions, semisolid ointments and creams, suppositories and aerosols formulations for pharmaceutical and cosmetic applications.

Course Outcomes

Upon completion of the course, the learner shall be able to:
1. Understand the formulation aspects of biphasic and semisolid dosage forms
2. Explain calculations involved in formulations
3. Describe the importance of quality evaluation of biphasics, semisolids, suppositories, aerosols

No.	Details
	Formulation and Preparation of the following:
1	**Biphasics: Suspensions and Emulsions** 1. Paracetamol Paediatric Oral Suspension IP 2. Dry suspension for reconstitution (any one) 3. Antacid Suspension 5. Liquid Paraffin Emulsion IP 6. White Liniment BPC/ Turpentine Liniment IP 7. Evaluation of any one suspension & one emulsion Evaluation Parameters: Organoleptic Properties, Particle/droplet size, Sedimentation/Creaming volume , pH, stability studies, rheology of any one preparation
2	**Semisolids** 1. Compound Benzoic acid Ointment IP 2. Aqueous Calamine Cream IP 3. Cetrimide Cream IP 4. Diclofenac Gel BP Evaluation of any one Ointment / Cream
3	**Suppositories** 1. Glycerin Suppositories USP 2. Paracetamol Suppositories BP/Indomethacin Suppositories IP / Bisacodyl suppositories IP/ Aspirin Suppositories USP Evaluation of any one suppository
4	**Pharmaceutical Aerosols** Introduction to different devices for inhalation and demonstration of evaluation of a suitable commercial product for simple tests related to spray and weight / drug content per discharge
5	**Cosmetics: Preparation & Evaluation** 1. Toothpaste 2. Clear liquid Shampoo 3. Lipstick/ Nail lacquer 4. Vanishing Cream/Cold cream

Books:
Latest Editions

1. Indian Pharmacopoeia, Indian Pharmacopoeia Commission, Government of India, Ministry of Health and Family Welfare.
2. The United States Pharmacopoeia
3. British Pharmacopoeia
4. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
5. Pharmaceutical dosage form disperse system by Liberman & Lachman
6. Remington: The Science and Practice of Pharmacy, Lippincott Williams & Wilkins, 2006.
7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill Livingston
8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea & Febiger, Philadelphia
9. Cosmetic formularies

BPH_C_507_L– Experimental Techniques in Microbiology and Biotechnology Lab- (4 Hr/Wk)

Course Objectives

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

Course Outcomes

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. Study of microscope and common laboratory equipment e.g., B.O.D. incubator, laminar air flow unit, aseptic hood, autoclave, hot-air sterilizer, deep freezer, refrigerator.
2. Sterilization of glassware and preparation and sterilization of nutrient broth, agar slants, plates and inoculation techniques.
3. Isolation of pure culture by T plate, pour plate and streak plate methods. Colony characterization and growth patterns in broth, slant.
4. Study various staining techniques such as Gram Staining, Spore, Negative staining, Cell wall staining, Capsule, Motility by hanging drop technique.
5. Bacteriological analysis of water (IMVIC and MPN)
6. Test for sterility as per IP (Injection water/ nonabsorbent cotton/soluble powder/ear drops).
7. Antimicrobial assay of antibiotic using cup plate method, introduction to zone of inhibition and calculation.
8. Study drug resistance using antibiotic sensitivity testing
9. Biochemical tests (Catalase, Oxidase, Urease, Nitratase, Protease, Gelatinase, Phosphatase, Amylase).
10. Demonstration experiments
    a. Thermal death time and thermal death point.
    b. Effect of Ultra-Violet exposure on growth of E. coli.
    c. Selection and isolation of bacteria by replica plating.
    d. Widal test
    e. Counting of bacteria by total count, viable count, and biomass determination methods

Books:

1. C. R. Kokare "Pharmaceutical Microbiology Experiments and Techniques", Career Publication, Nashik.
2. R. S. Gaud and G. D. Gupta "Practical Microbiology", Nirali prakashan, Pune.
3. C. H. Collins, Patricia M. Lyne, J. M. Grange "Microbiological Methods "7th Edn. Butterworth-Heinemann Ltd, Oxford, London

ANY TWO SUBJECTS FROM THE FOLLOWING 2 CREDIT SUBJECTS TO BE CHOSEN AS ELECTIVES FOR A TOTAL OF 4 CREDITS

BPH_E_508_T – Nutraceuticals and Dietary Supplements -(2 Hr/Wk)

Course Objectives

1. To make the learner understand the concept of nutraceuticals and dietary supplements along with the classification with respect to health benefits, chemical nature and mechanism of action
2. To expose the learner to the health benefits of various classes of phytochemicals along with their salient chemical features, pharmacokinetics, doses and marketed preparations
3. To introduce to the learner the formulation challenges of nutraceuticals and health supplements and the importance of the safety and stability of nutraceutical formulations
4. To make the learner aware of the regulatory aspects of nutraceuticals in India and major countries

Course Outcomes

Upon completion of the course student will be able to –

1. Explain concept of nutraceuticals and dietary supplements, classify these based on chemical nature, health benefits and mechanism of action
2. Discuss the chemistry of phytochemicals, their health benefits, pharmacokinetics, interactions with food and recommended doses along with the marketed preparations
3. Explain the challenges in formulating nutraceuticals
4. Understand the significance of safety and stability studies of nutraceuticals
5. Describe the labeling and regulatory aspects for manufacture and sale of nutraceutical products.

No.	Details	Hours
1	**Introduction to Nutraceuticals** Definitions of Nutraceuticals, Functional foods, and Dietary supplements, Nutrigenomics. Link between Food and Medicine. Food and No- food sources of nutraceutical factors, Nutraceutical factors in specific foods. Classification of Nutraceutical. Factors based on chemical nature and mechanism of action. Safety, Scientific evidence and market trends: Local and Global. Self-study: Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community, Limitations of Nutraceuticals	3 1
2	**Phytochemicals as Nutraceuticals**: Occurrence, Structure, Properties, Metabolism and Pharmacokinetics, Therapeutic uses, Recommended Doses and Marketed Preparations of following a) **Carotenoids**- Lycopene, Lutein, Zeaxanthene, Astaxanthene b) **Phenolics and Polyphenolics as Antioxidants** - - Reservetrol , Grapeseed extract, Tea, Pycnogenol, Avenanthramides from Oats, Rutin, Soy Isoflavones, Curcumin c) **Sulphur Compounds**- Glucosinates d) **Prebiotics / Probiotics**-Fructo-oligosaccharides, Lactobacillum. e) **Dietary fibres** – Soluble and insoluble any two examples each. f) **Lignans** – Flax Lignans g) **Essential Fatty acids**- Fish oils, α- Linolenic acid from Flax. h) **Quinones**- Tocopherol. i) **Proteins and Minerals**- Melatonin, Glutathione, Shilajit, Carnitine. j) **Marine nutraceuticals** – Collagen from fish skin	9
3	**Formulations and Challenges** Challenges involved in processing, extraction and concentration of nutraceutical constituents, formulations and delivery systems, safety, storage and stability evaluation of formulations. Labeling of Nutraceuticals	4
4	**Safety and Toxicity of Nutraceuticals** Adverse Effects, Interactions, Adulteration- Intentional, counterfeiting, undeclared labeling, toxic contaminants	3
5	**Regulatory issues of Nutraceuticals and Dietary Supplements** a) EU, US and Indian guidelines. 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	4
	TOTAL	**24**

Books:

1. Handbook of Nutraceuticals and Functional Foods, Second Edition, Eds Robert E.C. Wildman, CRC Press, Taylor and Francis
2. Nutraceuticals: A Guide for Healthcare Professionals, Brian Lockwood
3. Nutraceuticals in Health and Disease Prevention edited by Klaus Kramer, Peter-Paul Hoppe, Lester Packer, Marcel Decker New York
4. Nutraceuticals: Efficacy, Safety and Toxicity edited by Ramesh C. Gupta Academic Press, Elsevier Publication
5. Handbook of Nutraceuticals Volume I: Ingredients, Formulations, and Applications edited by Yashwant Vishnupant Pathak, CRC Press, Taylor and Francis
6. Nutraceuticals edited by Alexandru Grumezescu, Academic Press Elsevier
7. Nutraceuticals, Glycemic Health and Type 2 Diabetes, Eds Vijai K. Pasupuleti, James W. Anderson, Wiley Blackwell Publications
8. Regulation of Functional Foods and Nutraceuticals: A Global Perspective, Ed Clare M. Hasler, Blackwell Publishing
9. Developing New Functional Food and Nutraceutical Products edited by Debasis Bagchi, Sreejayan Nair, Academic Press, Elsevier Publishing
10. Phytosterols as Functional Food Components and Nutraceuticals, Ed Paresh C. Dutta, Marcel Decker Publishing
11. Phenolics in Food and Nutraceuticals, Fereidoon Shahidi, Marian Naczk, CRC press
12. Bioactive Proteins and Peptides as Functional Foods and Nutraceuticals, Eds Yoshinori Mine, Eunice Li-Chan, Bo Jiang, Wiley Blackwell
13. Marine Nutraceuticals and Functional Foods, Ed Colin Barrow, Fereidoon Shahidi, CRC press
14. Role of dietary fibres and nutraceuticals in preventing diseases, K. T Agusti and P.Faizal, B S Publication

15. Goldberg, I. *Functional Foods*. Chapman and Hall, New York.
16. Labuza, T.P. Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods*, Eds M.K. Sachmidl and T.P. Labuza, Aspen Press.

BPH_E_509_T – Microbial Genetics -(2 Hr/Wk)

Course Objectives:

1. To introduce the learner to the conceptual and practical tools for generating, processing and understanding biological genetic information.
2. To develop a knowledge of the underlying theories of genetics and understanding of genetic exchange among prokaryotes.
3. To give the learner competence in fundamental molecular biology theories and laboratory techniques.

Course Outcomes:

The learner should be able to-

1. Understand basic concepts of homologous recombination and genetic exchange among prokaryotes.
2. Understand natural plasmids and transposons present in prokaryotes
3. Give an account of prokaryotic gene structure and the mechanisms controlling gene expression

No.	Details	Hours
1	**GENETIC EXCHANGE - Gene transfer mechanisms in bacteria & homologous recombination**	**12**
	1.1. Transformation i. Introduction and History ii. Types of transformation in prokaryotes--Natural transformation in Streptococcus pneumoniae, Haemophilus influenzae, and Bacillus subtilis iii. Mapping of bacterial genes using transformation. iv. Problems based on transformation.	3
	1.2. Conjugation i. Discovery of conjugation in bacteria ii. Properties of F plasmid/Sex factor iii. The conjugation machinery iv. Hfr strains, their formation and mechanism of conjugation v. F' factor, origin and behavior of F' strains, Sexduction. vi. Mapping of bacterial genes using conjugation (Wolman and Jacob experiment). vii. Problems based on conjugation	3
	1.3. Transduction i. Introduction and discovery ii. Generalised transduction iii. Use of Generalised transduction for mapping genes iv. Specialised transduction v. Problems based on transduction	3
	1.4. Recombination in bacteria General/Homologous recombination i. Molecular mechanism ii. Holliday model of recombination Site –specific recombination	3
2	**PLASMIDS, TRANSPOSONS & OPERONS (REGULATION)**	**12**
	2.1. Plasmids a. Physical nature b. Detection and isolation of plasmids c. Plasmid incompatibility and Plasmid curing d. Cell to cell transfer of plasmids e. Types of plasmids i. Resistance Plasmids, ii. Plasmids encoding Toxins and other Virulence characteristics	3

	iii. col factor iv. Degradative plasmids **2.2. Transposable Elements in Prokaryotes** a. Insertion sequences b. Transposons i. Types ii. Structure and properties iii. Mechanism of transposition iv. Transposon mutagenesis c. Integrons **2.3. Lac operon and problems on Lac operon, Trp operon**	3 6
	TOTAL	24

Books:

1. Peter J. Russell (2006), "Genetics-A molecular approach", 2nd ed.
2. Benjamin A. Pierce (2008), "Genetics a conceptual approach", 3rd ed., W. H. Freeman and company.
3. R. H. Tamarin, (2004), "Principles of genetics", Tata McGraw Hill.
4. D. Nelson and M. Cox, (2005), "Lehninger's Principles of biochemistry", 4th ed., Macmillan worth Publishers.
5. M. Madigan, J. Martinko, J. Parkar, (2009), "Brock Biology of microorganisms", 12th ed., Pearson Education International.
6. Fairbanks and Anderson, (1999), "Genetics", Wadsworth Publishing Company.
7. Prescott, Harley and Klein, "Microbiology",. 7th edition Mc Graw Hill international edition.
8. Robert Weaver, "Molecular biology", , 3rd edn. Mc Graw Hill international edition.
9. Nancy Trun and Janine Trempy, (2004), "Fundamental bacterial genetics", Blackwell Publishing
10. Snustad, Simmons, "Principles of Genetics", 3rd edn. John Wiley & sons, Inc.

BPH_E_510_T – Biochemistry III- (2 Hr/Wk)

Course Prerequisites

Basic knowledge of Cell Biology, Microbiology

Course Objectives

To introduce the learner to the details of DNA replication, DNA transcription and RNA translation, Gene regulation, DNA mutation, and DNA repair

Course Outcomes

The learner will be able to:

1. Explain how DNA topology and chromatin structure affects the processes of DNA replication, repair, and transcription
2. Compare and contrast the mechanisms of bacterial and eukaryotic DNA replication, transcription, and translation.
3. Describe mechanisms by which DNA can be damaged, mutated and describe the molecular mechanisms by which protein complexes repair different forms of DNA damage
4. Explain the molecular mechanisms behind different modes of gene regulation in bacteria

No.	Details	Hours
1	Genome organization in prokaryotes and eukaryotes: Structure of DNA, RNA, Chromosome, chromatin, mitochondrial genome. Justification of the large nature of the genome, genome complexity, tandem repeats, micro and mini satellites	2
2	Replication of DNA: Details of DNA replication, differences between prokaryotes/eukaryotes. Semi-conservative DNA replication, DNA Polymerases and its role, E. coli Chromosome Replication, Bidirectional Replication of Circular DNA molecules. Rolling Circle Replication, D-Loop model for replication. DNA Replication in Eukaryotes and differences with respect to prokaryotes. DNA Recombination – Holliday Model for Recombination Transformation. Examples of drugs modulating these pathways (polymerase inhibitors, telomerase inhibitors, topoisomerase inhibitors) and	8

	polymorphisms involved in disease states. Brief description of telomeres and telomerase activity. DNA polymorphisms and SNPs.	
3	Transcription in prokaryotes and eukaryotes, (role of proteins and factors of transcription), RNA splicing and RNA	2
4	Translation in Prokaryotes and Eukaryotes: Steps of translation, Initiation of translation, initiation factors, role of Met-tRNA, elongation and its factors, termination and protein stability. Drugs modulating translation.	2
5	Transcriptional and translational differences in prokaryotes and eukaryotes especially with respect to post-transcriptional and post-translational modifications. Examples of drugs modulating these pathways with emphasis on protein synthesis inhibitors used as drugs. Discussion of solid phase peptide synthesis, peptide synthesizers and comparison between biosynthesis and chemical synthesis	4
6	DNA Repair: Photo repair, Base Excision Repair, Nucleotide Excision Repair, Mismatch Repair, SOS Repair and Recombination Repair	2
7	Definition and Types of Mutations. Mutagenesis and Mutagens. (Examples of Physical, Chemical and Biological Mutagens)	2
8	Gene regulation in prokaryotes, operon models, Gene regulation in eukaryotes, gene activators, enhancers and silencers, Lac Operon and Catabolite repression	2
	TOTAL	**24**

Books:

1. Meyers, R. A., Molecular Biology and Biotechnology, Wiley-VCH, 2000.
2. Lodish, H. Molecular Cell Biology, 6th Edition, W. H. Freeman and Co., NY, USA.
3. Rose, P. Molecular Biotechnology, Panima, 2000.
4. Brown, T. A., Molecular Biology, Vol. I and II, Academic Press, 2000.
5. B. Lewin, Genes IX, 9th Edition, Jones and Barlett Pub., USA, 2007.
6. Watson J. D. Molecular Biology of the Gene, Benjamin Cummings; 6th Edition, 2007.
7. D,.Nelson and M.Cox, (2005), "Lehninger's Principles of biochemistry", 4th ed., Macmillan worth Publishers.

BPH_E_511_T – Synthon Approach - (2 Hr/Wk)

Course Objectives

1. To teach the learner to analyse a target structure in order to design a synthetic scheme.
2. To acquire the expertise toward synthesis by the manipulation of both activation methods and selectivity control.

Course Outcomes

1. Learner will also gain confidence for drawing the schematic retrosynthetic pathway from the course.
2. Learner will be able to analyze the retrosynthetic scheme synthesis planning and route analysis for any given target molecule.

No.	Details	Hours
1.	Definition of retrosynthesis or disconnection approach, synthon, disconnection, synthetic equivalent, functional group interconversion, functional group addition, functional group removal.	1
2.	Guidelines for disconnection a. Order of events b. Reversal of polarity c. Protecting groups	4
3. 3.1 3.2 3.3	 Disconnection of simple alcohols, alkyl halide, ethers, olefins, esters, carboxylic acids, aldehydes, ketones and amines. Two group disconnections – 1,2-, 1,3-, 1,4- difunctionalized compounds Strategies for synthesis of aromatic heterocycles pyrrole, thiophene, furan, pyridine, pyrimidine	8 3 3 2

4	Design of retrosynthesis of drugs: Paracetamol, benzocaine, sulfadiazine, ibuprofen, propranolol, nifedipine, isoniazid, ranitidine, diphenhydramine	4
	TOTAL	**24**

Books:

1. Designing organic syntheses: A programmed introduction to the synthon approach, Stuart Warren; Wiley India Pvt Ltd., 2012
2. Designing Organic Syntheses: A Programmed Introduction to the Synthon Approach; Stuart Warren; ISBN: 978-0-471-99612-5, 285 pages, January 1991
3. Organic Synthesis the Disconnection Approach, Stuart Warren, 391pages, ISBN 0 471 10161 3 Paper 1982 by John Wiley and Sons LTD
4. Synthesis of Drug, A synthon approach by Radhakrishnan P. Iyer & Anant v. prabhu, 1st Edition, (1985) Sevak Publications, Mumbai.
5. Clayden and Greeves, Organic Chemistry, Oxford University Press (2001)
6. site for solving synthon problems
http://highered.mheducation.com/sites/0073375624/student_view0/chapter22/synthesis_problem_1-2.html

BPH_E_512_T – Cosmeticology- (2 Hr/Wk)

Course Objectives

To provide 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 w.r.t. raw materials, large scale manufacturing and functional and physicochemical evaluation
4. Know the regulatory guidelines and sensorial assessment for cosmetics

No.	Details	Hours
1.	General Aspects of Cosmeticology	**5**
1.1	Definition of Cosmetics, historical background, classification Structure of skin, hair, nails, teeth; Regulatory aspects- Schedules to Drug and Cosmetics Rules - M II, S, Q; BIS specifications, Marketing aspects of Cosmetics	2
1.2	Raw materials including oils, fats, waxes, colours, perfumes, antioxidants, preservatives, surfactants, and water, herbal ingredients (Self study and follow up)	1
1.4	Toxicology of cosmetics-irritation and sensitization reactions to cosmetics, sensitivity testing and safety aspects	2
2.	Cosmetic formulations: Raw materials, formulation, and functional evaluation of:	**17**
	a) Skin creams-- Cleansing, cold, vanishing, moisturizing, hand and body products, Face packs, antiacne, antiwrinkle, bleach products	3
	b) Protective preparations- Barrier products; sunscreen, suntan & anti-sunburn products, insect repellants.	2
	c) Coloured cosmetics-Foundation products, face powders, lipsticks, rouge, eye cosmetics (Large scale manufacture of lipsticks and face powders, including compact face pwder)	4
	d) Nail specialty products-cuticle softener, nail bleach, nail strengthener, nail whites, nail lacquer	1
	e) Hair care products-Shampoos (including antidandruff & anti lice), hair grooming products [hair setting products, hair sprays, hair tonics, hair conditioners, hair rinses, hair waving & hair straightening products (principles), hair colorants]	3
	f) Depilatories & Shaving products (Wet, Dry & After shave)	1
	g) Oral and personal hygiene preparations-tooth powder, tooth paste, mouth washes, denture cleansers, bath products (soaps, bath salts, bubble baths, shower gels, body washes, anti-perspirants &deodorants	2
	h) Baby toiletries-oils, creams, lotions, shampoos, powders	1
6.	Sensorial evaluation of cosmetics- concept and need, sensory perception, requirements for sensory testing, methods used, interpretation and documentation/representation.	**2**
	TOTAL	**24**

Books:

Latest editions

1. Harry's Cosmeticology Edited by J.B. Wilkinson and R. J. Moore, Longman Scientific & Technical Publishers
2. Cosmetics Science and Technology, Edited by M.S. Balsam, E. Sagarin, S.D. Gerhon, S.J.Strianse and M.M.Rieger, Volumes 1,2 and 3.Wiley-Interscience, Wiley India Pvt. Ltd.,2008
3. Poucher's Perfumes, Cosmetics & Soaps, 10th Ed, Editor- Hilda Butler, Klewer Academic Publishers, Netherlands, 2000
4. Cosmetic Technology, Ed. By S.Nanda, A. Nanda and R. Khar, Birla Publications Pvt. Ltd., New Delhi, 2007
5. Handbook of Cosmetic Science and Technology, edited by M. Paye, A.O.Barel, H. I. Maibach, Informa Healthcare USA,Inc. 2007.
6. Encyclopedia of Pharmaceutical Technology, Vol. 6, Eds. James Swarbrick, James C. Boylan, Marcel Dekker Inc., 1992
7. Kemp S.E., Hollowood T, Hort J., "Sensory evaluation-A practical handbook," John Wiley & Sons, 2009.
8. Sensory Evaluation Techniques, Fourth Edition, Morten C. Meilgaard, B. Thomas Carr, Gail Vance Civille, CRC Press
9. **ISO 13299:2016(en)** Sensory analysis — Methodology — General guidance for establishing a sensory profile
10. BIS Guidelines for different cosmetic products.
11. Formulation and function of cosmetics by Jellinek Stephan, Wiley Interscience.

BPH_E_513_T – Packaging of Pharmaceuticals - (2 Hr/Wk)

Course Objectives

To provide the learner with knowledge of types of packaging materials, and packaging methods for Pharmaceuticals, evaluation and regulatory guidelines for the same.

Course Outcomes

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

1. Classify Packaging materials and explain the functions and design aspects
2. Discuss the different primary and ancillary packaging materials, their functions and evaluation
3. Elaborate on labelling aspects of pharmaceuticals
4. Discuss sterilization and stability of packaging materials.

No.	Details	Hours
1.0	Introduction to Packaging, Classification of Packaging materials into Primary & secondary packaging, Essential Requirements, Functions of Packaging, Properties of Ideal Package, Packaging formats in Pharma Industry, Packaging recycling symbols, FDA Definition; Approach to package design.	**3**
2.0	**Packaging Materials**	**21**
2.1	Glass**:** Glass types, their manufacture, chemical composition, Performance testing and quality control, Defects.	2
2.2	Plastics & polymers: Classification, physio-chemical, mechanical and biological properties, Additives and fabrication processes, Plastic containers for Parenteral and transfusion sterile drip kits, ophthalmic products; disposable devices. Quality control testing and issues related to leachables, biocompatibility, biodegradation, environmental safety; evaluation aspects-performance and toxicity	3
2.3	Metals: Aluminum and tinplate cans, drums and collapsible tubes. Aerosol containers, Lacquering, coating and lining	2
2.4	Flexible packaging: Materials and laminates, Co-extruded films, foils, coating and laminates, shrink and stretch films, blisters including ALU- ALU blisters and Strip Packaging.	2
2.5	Strip and Blister Packaging- Strip Packs- High Barrier Laminates, Strip Packaging Process, Properties of Materials, Child-resistant strip package, Strip Sealing Machine, Strip Packing Machinery, Multi-Dose Strip Packaging Blister packs- Design parameters, Materials, Formation, Types of Blisters, Advantages and disadvantages of Blister Packaging, Types of Problems/ Defects, Blister Packing Machine, Other packages-shrink wrapping and stretch wrapping, sachets.	3
2.6	Caps and Closures: Types of caps, closures, liners, child resistant caps. Elastomeric closures for parenterals, classification of Elastomers, physical chemical and biological properties and their quality control.	2
2.7	Corrugated and solid fibre boards and boxes, Paper and paperboard and Quality control, Common defects	1
3.0	Ancillary materials in packaging-	1

	Cushioning materials-applications for impact, vibration, temperature & humidity protection Fasteners, tapes	
4.0	Sterilization of containers and closures	1
4.0	**Labels and labelling**: Types of labels, adhesives, Printing of labels- printing inks, toxicity and safety of printing inks, inject and bar coding and printing of labels, Quality control and common defects in printing of labels	2
5.0	**Stability of Packages** Introduction, Legislation, Regulation, Pharmaceutical Stability Testing in Climatic Cabinets, Pharmaceutical Stability Testing Conditions, Photo-Stability Testing, Review of Pharmaceutical Product Stability, Packaging and the ICH Guidelines	2
	TOTAL	**24**

Books:

Latest editions

1. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis, London.
2. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester, New York, USA.
3. Wilmer A. Jenkins, Kenton R. Osborn. Packaging drugs and pharmaceuticals.
4. Salvatore J. Turco, Sterile dosage forms: their preparation and clinical applications
5. Remington: The Science and Practice of Pharmacy, Lippincott Williams & Wilkins, 2006.
6. Michael E. Aulton, Kevin Tylor (Ed.). Aulton's Pharmaceutics: The design and Manufacture of Medicine.
7. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
8. Leon Lachman; Lieberman Herbert A.; Kanig, Joseph L. The theory and Practice of Industrial Pharmacy.
9. Hanlon J., Robert J. Kelsey, "Handbook of Package Engineering" 2nd Edition, McGraw-Hill, New. York. 1984
10. Paine A., "Packaging User's Handbook", Springer, 1990
11. K. Avis, Liberman and Lachman, Pharmaceutical Dosage Forms: Parenterals, Vol. I, Marcel Dekker, Expanded ad revised edition, 2008.

SEMESTER-VI

BPH_C_601_T – Pharmaceutical Chemistry I- (4 Hr/Wk)

Course objectives

1. Learn about pharmacodynamic attributes like drug targets, drug-receptor binding, proteins as drug targets, receptors and enzyme as drug targets, nucleic acids as drug targets and metabolism of drugs
2. Learn how physicochemical properties / QSAR play role to design and optimize the structure of leads
3. Learn about the Drug Metabolism, types of Phase I and Phase II Reactions by taking suitable drug examples
4. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of anti-infective agents like antibiotics, sulfonamides and fluoroquinolones
5. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of antiparasitic agents like antimalarials, antitubercular, anthelmintics, amoebiasis, giardiasis, trichomoniasis, pneumocystis, trypanosomiasis, leishmaniasis and fungi

Course outcomes

Learner will be able to:

1. Identify and study the suitable drug targets for treatment of disorders
2. Identify the relationship between the physicochemical properties of the chemical entity and biological response
3. Draw a schematic metabolic pathway for any given drug
4. Identify the SAR of all the classes of antimalarial, antitubercular, anti-infective, antibiotic, antiparasitic disorders

No.	Details	Hours
1	Pharmacodynamics	
1.1	Drug Targets at Molecular Level – Lipids, Carbohydrates, Proteins and Nucleic Acids as drug targets	**2**
1.2	Intermolecular Bonding Forces like Electrostatic, Hydrogen Bonding, van der Waal's Interactions, Dipole-dipole and Ion-dipole Interactions and Hydrophobic Interactions	**3**
2	Proteins as Drug Targets	
2.2	Proteins as Drug Targets / Drugs Monoclonal Antibodies, Peptides Introduction to Proteomics	**2**
2.3	Enzymes as Drug targets	
2.3.1	Enzyme Inhibitors – Reversible and Irreversible (Self Study)	**1**
2.3.2	Enzyme Inhibitors against microorganisms, viruses, body's own enzymes	**1**
2.4	Receptors as Drug Targets	
2.4.1	Types of Receptors and signal transduction - Ion Channels, G-Protein Coupled Receptor (GPCR), Kinases, Nuclear Receptors	**6**
2.4.2	Concept of Agonist, Antagonist, Partial agonist, Inverse agonist, Concept of desensitization/sensitization, Tolerance, Affinity, Efficacy, Potency (Self Study)	**1**
3	Nucleic Acids as Drug target	
3.1	Primary, Secondary and Tertiary Structure of DNA (Self Study)	**1**
3.2	DNA Intercalation, DNA Alkylation, Antisense Therapy	**1**
4	Pharmacokinetics and Physicochemical Properties of Drug Action	
4.1	Solubility, Partition Coefficient, Acidity-Basicity, pK_a, Bioisosterism, Stereochemistry (geometrical, optical and conformational), Protein Binding	**2**
4.2	Drug Metabolism – Phase I and Phase II Reactions	**6**
Discussion on the following classes of drugs including classification, chemical nomenclature, structure including stereochemistry, generic names, chemistry, SAR, metabolism, molecular mechanism of action, introduction to rational development, drug resistance, if any, of following classes of drugs		
5. Anti-infective Agents		
5.1	Antibiotics Penicillins (natural and semisynthetic penicillins like Penicillins G, Penicillins V, ampicillin*, amoxicillin, cloxacillin*, oxacillin, naficillin, methicillin and ampicillin prodrugs like bacampicillin and hetacillin); β-lactamase inhibitors like clavulinic acid, (self study – tazobactam) Cephalosporins (cephalexin, cefadroxil, cefazolin, cefamandole, cefoxitin, cefuroxime, cefotaxime, ceftriaxone, cefpodoxime proxetil) Tetracyclines (tetracycline, chlortetracycline, oxytetracycline, doxycycline, and minocycline and its prodrug – rolitetracycline); Macrolides, (erythromycin, roxithromycin, azithromycin - only highlights of structure to be discussed);	**7**

	Aminoglycosides (gentamicins, and neomycins, - only highlights of structure to be discussed); Only highlight the structures of the following compounds: Carbapenems (Emepenem, Meropenem) Monobactams (Aztreonam, Tigemonam) Linezolid,	
5.3	Fluoroquinolones Norfloxacin, ciprofloxacin*, sparfloxacin, gatifloxacin, levofloxacin, lomefloxacin	**2**
6	Antiparasitic Agents	
6.1	Antimalarial Agents Natural products like cinchona alkaloids (with stereochemistry and drug action) and artemisinin and its derivatives like artether, artemether and artesunate, Synthetic antimalarials such as 8- aminoquinolines eg. primaquine*, 4- aminoquinilines eg. chloroquine*, Quinoline methanols eg. mefloquine; misc like halofantrine, lumefantrine and; DHFR inhibitors like pyrimethamine* and proguanil, cycloguanil, atovaquone, sulfadoxine Combination therapy.	**3**
6.2	Drugs for treatment of amoebiasis, giardiasis and trichomoniasis (Self Study) Metronidazole*, tinidazole, secnidazole, diloxanide furoate*, nitazoxanide	**1**
6.3	Anthelmintics (Self Study) Albendazole, Mebendazole*, Thiabendazole, Diethylcarbamazine, Ivermectin, Praziquantel, Pyrantel Pamoate	**1**
7	AntiMycobacterial Agents Antitubercular drugs PAS*, ethionamide, isoniazid, pyrazinamide, ethambutol*, antitubercular antibiotics (streptomycin, rifampin, rifapentine, capreomycin, cylcoserine – the first four only highlights of structure to be discussed), fluoroquinolones, bedaquiline, Antileprotic drugs Dapsone*, clofazimine, rifampin, Combination therapy	**4**
8	Antifungal Agents Natural products like griseofulvin, amphotericin B and nystatin (later two only general aspects of structure related to activity) Antifungal azoles like clotrimazole*, ketoconazole, fluconazole, and itraconazole Allyl amines like naftifine, and terbinafine, Flucytosine Miconazole, econazole, flutrimazole, sulconazole, sertaconazole, voriconazole, butenafine and tolnaftate (Self-Study)	**3** **1**
	TOTAL	**48**

Books:

Latest Editions of the following books should be used.

1. 'An Introduction to Medicinal Chemistry', Graham L. Patrick, Oxford University Press, (Latest Edition)
2. 'Fundamentals of Medicinal Chemistry', Gareth Thomas, Wiley, New York, (Latest Edition)
3. 'The Organic Chemistry of Drug Design and Drug Action', Richard B.Silverman, Academic Press
4. 'Foye's Principles of Medicinal Chemistry', Thomas L. Lemke, David A Williams, Lippincott Williams & Wilkins
5. 'Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry', John M. Beale, John H. Block, Lippincott Williams & Wilkins.
6. 'Medicinal Chemistry', Ashutosh Kar, New Age International Publishers
7. 'Introduction to Medicinal Chemistry', Alex Gringauz, Wiley
8. 'The Organic Chemistry of Drug Synthesis', Daniel Lednicer, Lester A. Mitscher, John Wiley and Sons
9. Pharmaceutical Chemistry, Volume 1, Organic Synthesis, H. J. Roth & A. Kleemann, Ellis Horwood Series in Pharmaceutical Technology, Halsted Series.
10. 'Synthesis of Essential Drugs', Ruben Vardanyan and Victor Hruby, Elsevier
11. 'Pharmaceutical Substances: Syntheses, Patents, Applications', Kleemann & Engel, Thieme Publications.

BPH_C_602_T – Pharmaceutics III- (4 Hr/Wk)

Course Objectives

To familiarize the learner with various aspects of formulation development, large scale manufacturing and evaluation of solid oral dosage forms. Also to teach the learner the important aspects of stability, quality control and quality assurance.

Course Outcomes

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

1. Know the various solid oral dosage forms and their manufacturing techniques
2. Know various considerations in development of pharmaceutical dosage forms including stability
3. Formulate solid dosage forms and evaluate them for their quality
4. Understand the responsibilities of quality assurance & quality control departments
5. Appreciate the importance of documentation

No.	Details	Hours
1	**TABLETS**	**15**
1.1	Definition, advantages and limitations, ideal characteristics of tablets preformulation aspects; Types of tablets-Effervescent, buccal, chewable, sublingual, dispersible, soluble, orodispersible, compression coated and layered tablets.	2
1.2	Tablet formulation and design, additives, excipients with examples.	3
1.3	Manufacture of tablets- • Direct compression, wet granulation, dry granulation; Characterization and evaluation of granules • Large scale manufacturing process and equipment for: Mixing, drying, wet granulation, slugging and roller compaction. Tablet tooling • Compression – (Single station tablet press and Rotary press), physics of tablet compression (brief. Only the steps. No equations) • Layout of tablet section	6
1.4	Processing problems in tableting and tablet defects.	1
1.5	Packaging & labelling of solid dosage forms (tablets & capsules)- strip, blister & bulk packaging, including flexible packaging materials (laminates), and equipment used (schematic).	1
1.6	In process quality control tests for tablets. Evaluation of tablets as per IP, BP, USP	2
2	**COATING OF TABLETS**	**8**
2.1	Need for tablet coating, tablet core properties.	1
2.2	Types of tablet coating: Sugar, Film & Enteric coating., compression coating Materials, and processes employed	3
2.3	Coating equipment – Conventional & modified pans, coating columns (fluidized bed coating), Spray equipmen Equipment for compression coating (schematic)	2
2.4	Problems encountered in coating, coating defects & remedies (in all types of coatings)	1
2.5	Evaluation of coated tablets	1
3	**CAPSULES**	**9**
3.1	Definition, types of capsules, advantages and limitations, and raw materials including gelatin and HPMC. Manufacture of gelatin & HPMC (Schematic representation of steps)	2
3.2	Hard capsule shells: Manufacturing of empty capsule shells (gelatin & HPMC)-schematic representation of steps only ; Additives, size, sealing, size selection, storage, defects of shells, Quality evaluation of of empty shells.	1
3.3	Hard capsule fill formulation aspects: , types of fill and excipients; Large scale manufacturing steps with detailed study of Filling of hard capsule shells; Filling equipments : classification-volumetric, dosator type and tamping type. (one example of each type of equipment-schematic representation only). Problems in capsule filling & remedies Layout of capsule section. Humidity control in capsule manufacturing and filling area. Quality control aspects of hard capsules.	4
3.4	Soft gelatin capsules: Properties, nature of shell and contents, Formulation aspects- types of fills and excipients, Concept (minim/gm) Large scale manufacturing- Rotary Die Process, Quality control aspects of soft capsules	2
4	**Stability Studies**	**7**
4.1	Importance of stability studies, kinetic principles, Arrhenius equation and derivation of shelf life based on Arrhenius equation, limitations and advantages of Arrhenius equation,	3

Books:

4.2	Degradation pathways- hydrolysis, oxidation, photolytic degradation, methods to enhance stability of drugs - **Self-study with follow up.**	1
4.3	Accelerated stability studies, introduction to ICH guidelines	2
4.4	Interactions with containers and closures	1
5.0	**Quality Assurance:** • Concepts of Quality Assurance & Quality Control, Responsibilities of Q.A. department. • Raw material control, actives and inactive, Q.C. standards for raw materials. (identity, purity, quality and potency • Sanitization, environmental and microbiological control, packaging and labeling control, finished product control, • Statistical Quality control-concept, Q.C. charts, sampling & Sampling Plans, Sampling tools.	**6**
6.0	**Documentation** Documentation – need/importance, master formula records, batch manufacturing records, SOPs, Maintenance & Retrieval of Documents.	**3**
	TOTAL	**48**

Latest

Editions

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman & J. B. Schwartz
2. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes.
3. Remington: The Science and Practice of Pharmacy, Pharmaceutical Science (RPS)
4. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
5. Pharmaceutics- The science of dosage form design by M.E. Aulton, Churchill Livingstone.
6. Cole, Graham, "Pharmaceutical Production Facilities: Design and Applications".
7. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, Marcel Dekker Series, Vol 107.
8. Quality Assurance Guide by organization of Pharmaceutical Products of India.
9. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I, WHO Publications.
10. How to Practice GMP's - P. P. Sharma.
11. GMP for Pharmaceuticals, Sidney H. Willing, Marcel Decker Series

Note: References to latest amendments of Schedule M and Schedule U of Drugs and Cosmetics Act 1940 to be made wherever it is appropriate

BPH_C_603_T – Pharmaceutical Analysis II- (4 Hr/Wk)

Course Objectives

On completion of following theory topics, learner should be able to describe the working principle, instrumentation and applications of instrumental techniques useful for obtaining qualitative and quantitative information of an analyte and apply statistics for data analysis.

Course Outcomes

The students will be able to:

1. Comprehend underlying principle, instrumentation, application and limitations in instrumental techniques involving molecular as well as atomic absorption and emission techniques such as UV-Visible, Fluorescence, Infra-Red, Raman, Atomic absorption spectroscopy and Atomic emission spectroscopy.
2. Explain fundamentals, working principle and applications of X-ray diffraction technique, potentiometric titrations and thermal methods of analysis like TG, DSC and DTA.
3. Generalize the concepts and quality control aspects related to radiopharmaceuticals.
4. Calculate and interpret the results for spectral analysis and statistical data analysis.

No	Details	Hours
1	**UV-Visible spectroscopy**	**10**
1.1	***Terms***- Electromagnetic radiation, Visible light, electromagnetic spectrum, molecular spectra, absorption spectroscopy, wavelength, wave number, frequency, absorbance, transmittance, auxochrome, bathochromic shift, hypsochromic shift, hyperchromism, hypochromism, wavelength maxima, specific absorbance, molar absorptivity, cut-off wavelength for solvents, isoabsorptive point, spectral bandwidth	2
1.2	**Concepts-**Types of absorbing electrons, electronic transitions. • Beer-Lambert's law-statement, derivation of mathematical expression, limitations • Choice of solvents • Chemical derivatization	2

1.3	***Instrumentation of UV-VIS spectrophotometer:*** • Sources of UV-VIS radiation • Monochromators (Filters, prisms, gratings) • Sample cells • Detectors • Colorimeter and UV-VIS spectrophotometer (single beam and double beam with diagram)	3
1.4	***Applications of UV-VIS spectrophotometry:*** • Application of Beer's law in quantitative spectrophotometric assays-Single component assays-use of a standard absorptivity value - use of a calibration graph-single and double point standardization • Measurement of Equilibria constant. • Measurement of rate constant.	2
1.5	Numericals based on Beer-Lambert's law.	1
2	**Fluorescence spectroscopy**	**4**
2.1	Terms-singlet state, triplet state, fluorescence, phosphorescence and energy transitions, molecular emission spectroscopy.	0.5
2.2	• Origin of fluorescence and phosphorescence spectra Fundamental equation for fluorescence intensity, factors affecting fluorescence intensity (intensity of radiation source, quantum yield, molecular structure and rigidity, temperature, solvents, pH, dissolved oxygen, quenchers & concentration)	1.5
2.3	***Instrumentation of fluorimeter:*** • Filter fluorimeter and Spectrofluorimeter (including Block diagram) • Sources of radiation • Monochromators (Filters, gratings) • Sample cells • Detectors ***Quantitative applications:*** Fluorescent compounds and non-fluorescent compounds (Chemical derivatization to fluorescent compound, e.g. use of Dansyl chloride, Fluoresamine, o-phthalaldehyde) & Choice of fluorimetry over UV-Vis spectroscopy with respect to Sensitivity and Specificity.	2
3	**Infrared / Near IR spectroscopy**	**6**
3.1	***Theoretical concepts:*** • I.R regions, requirements for I.R. absorption, vibrational and rotational transitions, dipole changes, types of molecular vibrations, potential energy diagrams (harmonic oscillator and anharmonic oscillator), Vibrational frequency, factors influencing vibrational frequencies, force constants, vibrational modes (normal mode, combination bands and overtone bands), fingerprint region Instrumentation of FTIR	2
3.2	***Sample preparation & applications of I.R. spectroscopy:*** • 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: Attenuated Total Reflectance and Diffuse Reflectance. • Pharmaceutical applications of IR spectroscopy (including characteristic IR absorption frequencies of some common bond types such as hydroxyl stretch, nitrile stretch and carbonyl stretch of aldehydes and ketones, aliphatic and aromatic C-H stretch) Pharmaceutical applications of Near IR spectroscopy including PAT (Process Analytical Techniques)	4
4	**Raman Spectroscopy**	**4**
4.1	• Principle of Raman scattering • Comparison between I.R Spectroscopy and Raman Spectroscopy • Raman instrumentation-Sources of light, Sample illumination system (Liquid, solid and fiber optic sampling), Block diagram of Raman spectrometer. Applications	4
5	**Atomic absorption spectroscopy (AAS) and Atomic emission spectroscopy (AES)**	**4**
5.1	***Terms:*** Atomic spectra, atomic absorption spectroscopy, atomic emission spectroscopy	0.5
5.2	***Instrumentation:*** • For AAS: Radiation sources (Hollow cathode lamp, Electrode discharge lamps) • Plasma sources: Inductively coupled plasma and Direct current plasma source For AES- Flame atomization (types of flames, flame structure, flame atomizers)	1.5
5.3	***Interferences & Applications:*** • Cationic, Anionic and Physical interferences in Flame photometry • Spectral Interferences and Chemical Interferences in AAS. Pharmaceutical applications	2

6	**X-Ray Diffraction Technique**	**4**
6.1	***Fundamentals & Applications:*** • Fundamentals- Origin of X-ray, Bragg's law and its mathematical derivation, Bravais lattices and Miller indices Pharmaceutical applications- Crystal structure determination, polymorphism	2
6.2	***Instrumentation & working principle:*** • X-Ray source (X-ray tube source) X-ray monochromator and detector	2
7	**Radiochemistry and Radiopharmaceuticals**	**4**
7.1	• Terms: 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	1
7.2	• Measurements of radioactivity- Geiger-Muller Counting, liquid Scintillation Counting • Requirements of radiopharmaceuticals- Properties of radionuclides, Pharmaceutical properties, chemical properties • Radionuclide generator- ^{99m}Tc generator • Quality control of radiopharmaceuticals: Physical, Chemical (Radionuclidic purity, Radiochemical purity) Radiochemical methods in analysis: Isotope dilution analysis (Direct and Inverse), Radioimmunoassay	3
8	**Potentiometric titration**	**3**
8.1	• Construction and working of reference electrode (only Silver- silver chloride electrode to be studied) • Indicator electrode (only glass electrode to be studied) • Rejuvenation of glass electrodes • Potentiometric titrations (Only aqueous acid-base titrations -Strong acid vs strong base, strong acid vs weak base, weak acid vs strong base, weak acid vs weak base) • Calibration of pH meter and measurement of pH Determination of pKa by potentiometric titration	3
9	**Thermal methods of analysis**	**4**
9.1	***Principle, Instrumentation, working and applications of:*** a) Thermogravimetry (TG) b) Differential thermal analysis (DTA) c) Differential scanning calorimetry (DSC) Factors affecting the above thermal methods of analysis	4
10	**Statistical data handling**	**5**
10.1	***Normal Distribution numerical based on:*** • Confidence limits and Tests of significance (F-test, Student t-test-paired and unpaired) • Linear regression analysis and correlation coefficient Rejection of results (Q-test)	5
	TOTAL	48

Books:

Latest editions of the following books to be adopted

1. D. A. Skoog, F. J. Holler and S. R. Crouch, Principles of Instrumental Analysis, Saunders College Publishing, USA.
2. K. A. Connors, A Textbook of Pharmaceutical Analysis, John Wiley and Sons, Canada.
3. A. H. Beckett and J. B. Stenlake, Practical Pharmaceutical Chemistry, Part I and II, CBS Publishers and Distributors, India.
4. D. A. Skoog, D. M. West, F. J. Holler and S. R. Crouch, Fundamentals of Analytical Chemistry, Saunders College Publishing, USA.
5. G. D. Christian, Analytical Chemistry, John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd.
6. H. H. Willard, L. L. Merrit and J. A. Dean, Instrumental Method of Analysis, CBS Publishers and Distributors, New Delhi.
7. Ashutosh Kar, Pharmaceutical Drug Analysis, New Age International (P) Ltd. Publishers, India.
8. S. S. Mahajan, Instrumental Methods of Analysis, Popular Prakashan Pvt Ltd., India.
9. G.R. Chatwal and S. K. Anand, Instrumental methods of chemical analysis, Revised and enlarged, Himalaya Publishing House Pvt. Ltd.
10. Indian Pharmacopoeias, The Indian Pharmacopeia Commission, Ghaziabad, Government of India.
11. United States Pharmacopoeia.
12. J. Mendham, R. C. Denney, J. D. Barnes, M.J. K. Thomas, Vogel's Textbook of Quantitative Chemical Analysis, 6th Ed., Pearson Education Ltd.
13. D.G. Watson, Pharmaceutical Analysis –A textbook for pharmacy students and pharmaceutical chemists, Churchill Livingstone Elsevier.

14. J.W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, Marcel Dekker, New York, USA.
15. R. Kellnar, J. M. Mermet, M. Otto, M. Valcarceland, H. M. Widmer, Analytical Chemistry: A modern approach to analytical science, Wiley-VCH, USA.
16. J. W. Munson, Pharmaceutical Analysis: Modern methods (in two parts), Marcel Dekker Inc., USA.
17. W. Kemp, Organic Spectroscopy, Reprinted, Palgrave Publishers Ltd., New York, USA.
18. R. M. Silverstein, F. X. Webster and D. J. Kiemle, Spectrometric identification of organic compounds, John Wiley & Sons, Inc. (Indian edition), New Delhi.
19. D.B. Troy and P. Beringer, Remington-The Science and Practice of Pharmacy, Vol. I & II, Walters Kluwer/ Lippincott Williams & Wilkins (Indian edition), New Delhi.
20. J.W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, 6th Ed., Marcel Dekker, New York, USA.
21. J.R. Dyer, Applications of Absorption Spectroscopy of Organic Compounds, Prentice- Hall of India Pvt. Ltd, New Delhi, India.

BPH_C_604_T – Pharmacognosy II- (4 Hr/Wk)

Course Objectives

1. To make the learner understand
    a. Extraction of phytoconstitutents, concept of adulteration and substitution
    b. Utility of natural products as excipients utilized in pharmaceutical preparations
    c. Applications of plant tissue culture techniques for production of secondary metabolites and edible vaccines
2. To introduce the learner to the chemistry, sources, cultivation and collection of crude drugs containing phytoconstituents like volatile oils, resins and tannins
3. To introduce the learner to the biosynthesis of volatile oil constituents belonging to the classes of monoterpenoids and phenylpropanoids
4. To make the learner understand the chemistry of phytoconstituents belonging to the classes of iridoids, sesquiterpenes, diterpenes, tetraterpenes and sulphur containing compounds along with sources and utility of representative examples of crude drugs in therapeutics.

Course Outcomes

Upon completion of the course the learner will be able to –

1. Explain the concept of adulteration and substitution in crude drugs, extraction process for phyto-constituents using different methods and principles.
2. Write the source, composition, general methods of extraction, evaluation, chemical tests, therapeutic uses of crude drugs containing volatile oils, resins and tannins
3. Write the biosynthesis of monoterpenoids and phenypropanoid constituents of volatiles
4. Understand the chemistry of phytoconstituents belonging to the classes of terpenoids, sulfur containing constituents and quinones and write source composition and structures of phytoconstituents of crude drugs belonging to these classes
5. Write the significance of excipients of natural origin, used in pharmaceutical formulations and describe various classes of excipients like binders, colours, sweetners and flavorants along with the examples of their utility.
6. Describe the applications of plant tissue culture techniques with respect to production of secondary metabolites and edible vaccines.

No.	Details	Hours
1	**Evaluation of commercial crude drugs intended for use.** Adulteration &Substitution of drugs of natural origin. **Case Studies: Adulteration & Substitution with 4 examples** Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties as per WHO guidelines for quality control of herbal drugs	6
2	**Extraction**: Basic principles of extraction with two examples each of extraction using physical (Solubility) and chemical properties, general solvents to be used, Successive and exhaustive extraction, Soxhlet extraction, microwave, supercritical extraction.	5
3	**Volatile Oils:** Source, Composition, chemistry, general methods of extraction, evaluation, chemical test, therapeutic uses of volatile oils listed below. • Introduction and application of terpeneless volatile oils. a. Umbelliferous fruits (Dill, Fennel, Coriander, Cumin, Caraway). b. Alcohol – Peppermint, Cardomom c. Aldehyde volatile oil –Lemongrass, Vanillin d. Ketone volatile oil - Spearmint (mint oils) e. Ester volatile oil - Oil of Wintergreen	8

	f. Ether volatile oil - Eucalyptus oil g. Miscellaneous - Sandalwood, Jatamansi. h. Phenylpropanoids - Cinnamon, Clove, Nutmeg. • Salient features of cultivation, collection, preparation of Umbelliferous fruits, Clove, Cinnamon • Isolation, Identification and Analysis of Phytoconstituents Terpenoids: Menthol, Citral **Interactive session** • *Comparative study of Umbelliferous fruits* (Dill, Fennel, coriander, cumin, caraway). • Commercially significant volatile oils, eg. Palmarosa Oil, Citrus Peel Oil, Patchouli Oil, Primrose Oil, Tea Tree Oil.	 1 1
4	**Biosynthetic Pathways:** Acetate mevalonate pathway, shikimic acid pathway, Biosynthesis of Menthol, citral, cinnamaldehyde	3
5	**Resins and resin combinations** Study of occurrence, preparation, composition, uses and specific tests for identification of the following a. Natural resins - Colophony, Benzoin, Asafoetida, Boswellia b. Prepared resins - Turmeric, Ginger, • Separation, Identification and Analysis of Phytoconstituents – Resin – Curcuminoids **Interactive Session:** • Processing and Preparations for market - Ginger, Turmeric and Asafoetida	3 1 1
6	**Study of the following Classes of Phytoconstituents with respect to sources, chemistry and therapeutic uses.** a. Iridoids Study of piccrohiza, gentian b. Sesquiterpenes and Diterpenes Artemisia, Andrographis. c. Tetraterpenoids- carotenoids - lutein, crocin, d. Organo sulphur- *Allium cepa, Allium sativa* e. Quinones: Napthoquinones - Chitrak , Henna and Benzoquinone - Vidang	5
7	**Tannins** Introduction of tannins and their definition, classification, Study of sources, composition, extraction and applications of Galls, Amla, Harda, Behra, Catechu (Pale & Black, Arjuna, Green Tea, Pomegranate Peel. • **I**solation, Identification and Analysis of Phytoconstituents Ellagic acid from Myrobalan **Interactive Session** • Preparation containing tannins in healthcare with suitable examples Commercial Application of tannins in synthesis of drugs eg. Trimethoprim • Abuse of Tannins	4 1 1
8	**Plant Tissue Culture**: Different methods of manipulation of secondary metabolites Introduction and application of transgenic plants with special reference to Edible vaccines	4
9	**Excipients of natural origin** – Significance of substances of natural origin as excipients a. colorants – bixin, saffron, b. Sweeteners- thaumatin, stevia c. binders, diluents, viscosity builders, disintegrants d. Flavors & Perfumes with two suitable examples each from the class of volatile oils. **Interactive Session** Study of two examples of each type of excipient (binders, diluents, viscosity builders, disintegrants) from natural sources and its applications in pharmaceutical formulations.	3 1
	TOTAL	48

Books:

Latest editions of the following books to be adopted.

1. Trease D. & Evans W.C.: Text Book of Pharmacognosy: W.B. Saunders.

2. Tyler V. E. Brady L. R. & Robbers J. E.: Pharmacognosy; Lea Feibger, USA.
3. Wallis T. E.; Text Book of Pharmacognosy; CBS Publishers, Delhi.
4. Kokate C. K., Purohit A. P. & Gokhale S. B.: Pharmacognosy; Nirali Publications, Pune.
5. Harbone J. B.: Phytochemical Methods: A guide to modern techniques Analysis: Chapman & Hall, London.
6. Bruneton J.: Pharmacognosy, Phytochemistry, Medicinal Plants: Intercept Limited.
7. Vasudevan T. N. & Laddha K. S.: A Textbook of Pharmacognosy, Vrinda Publication House, Jalgaon.
8. The Indian Pharmacopeia: The Controller of Publication; Delhi.
9. R. S. Guad, S. J. Surana, G. S. Talele, S. G. Talele, Mr. S. B. Gokhale. Natural Excipients, Pragati Books Pvt. Ltd., 2006
10. Biren Shah, Avinash Seth, Textbook of Pharmacognosy and Phytochemistry , Elsevier Health Sciences,
11. Ashutosh Kar, Pharmacognosy And Pharmacobiotechnology, New Age International, 2003
12. Quality Control Methods for Medicinal Plant Materials, World Health Organization World Health Organization, 1998 - Botanical drug industry
13. WHO Monographs on Selected Medicinal Plants, World Health Organization World Health Organization, 1999
14. ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, ESCOP, European Scientific Cooperative on Phytotherapy, Thieme, 2003 -
15. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, Max Wichtl CRC Press, 2004 - Health & Fitness
16. Pulok K. Mukherjee Evidence-Based Validation of Herbal Medicine, Elsevier, 17-Feb-2015
17. Adverse Effects of Herbal Drugs 2, Springer Science & Business Media, 06-Dec-2012
18. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals, Pulok K. Mukherjee Business Horizons, 2002
19. Brain K. R. & Turner T. D.: The Practical Evaluation of Phytopharmaceuticals: Wright, Scientica, Bristol.
20. Iyengar M. A. & Nayak S. G.: Anatomy of Crude Drugs: Manipal Power Press, Manipal
21. Iyengar M. A.: Pharmacognosy of Powdered Drugs; Manipal Power Press, Manipal

BPH_C_605_L – Pharmaceutical Chemistry Lab I- (4 Hr/Wk)

Traditional methods of synthesis to be followed for each of the Unit Operations in addition to specific methods as indicated.

1. Acetylation - Synthesis of aspirin using Microwave Procedure **or** Synthesis of Acetanilide as per Green Chemistry DST Monograph
2. Halogenation – Synthesis of p-bromoacetanilide as per Green Chemistry, DST Monograph
3. Esterification of-PABA to benzocaine
4. Oxidation - Synthesis of benzoic by oxidation of toluene **or** benzyl alcohol with alkaline potassium permanganate.
5. Hydrolysis of methyl benzoate.
6. Reduction - synthesis of m-nitroaniline by partial reduction of m- dinitrobenzene with sodium polysulfide.
7. Nitration: Synthesis of p-nitroacetanilide as per Green Chemistry, DST Monograph.
8. Synthesis of benzimidazole.

Books:

1. Vogel's A Text book of Practical Organic Chemistry by Vogel, Longman group limited, London.
2. Practical Organic Chemistry by Mann FC & Saunders BC, Longman Group Limited, London.
3. Laboratory Techniques in Organic Chemistry, Ahluwalia V.K. I.K. Publishers.
4. Green Chemistry, V. K. Ahluwalia.
5. New Trends in Green Chemistry, V K Ahluwalia and M Kidwai, KluwerAcademic Publishers
6. Monograph on Green laboratory Experiments, Grenn Chemistry Task Force Committee, DST.
7. Practical Organic Synthesis: A Student's Guide - Reinhart Keese, Martin Brändle, Trevor Toube.
8. Advanced practical Medicinal Chemistry by Ashutosh Kar, New Age International Publications.

BPH_C_606_L – Pharmaceutics Lab III- (4 Hr/Wk)

Course Objectives

To teach the learner the practical course dealing with the various aspects of formulation and evaluation of solid oral dosage forms. To familiarize the learner with the important aspects of accelerated stability testing and shelf life calculations.

Course Outcomes

Upon completion of the course, the learner shall be able to:
1. Formulate solid dosage forms like tablets and capsules and evaluate them for their quality.
2. Understand the tablet coating process.
3. Learn the concepts of accelerated stability testing and shelf life calculations.

No.	Details
1.	Evaluation of excipients a. Bulking agents: Comparison of at least one excipient in conventional and directly compressible form for: Flow properties, Bulk density, Tapped density, Carr's index, Hausner's ratio and particle size by microscopy and sieve analysis. b. Disintegrating agents-Swelling index c. Lubricants and glidants: Influence on flow properties of granules.
2.	Preparation and evaluation of any one tablet formulation based on each of the following: a) Direct compression technique b) Non-aqueous wet granulation technique c) Aqueous wet granulation technique
3.	Preparation and evaluation of any one formulation of the following types of tablets: a) Mouth dissolving tablet b) Chewable tablet
4.	Filling and evaluation of any one hard gelatin capsule formulation
5.	Evaluation of anyone marketed immediate release tablet formulation including dissolution testing as per IP.
6.	Accelerated stability testing of any suitable drug/ formulation. Problems based on Arrhenius equation for shelf life calculations.
7.	Demonstration of film coating of tablets

Books:
All books listed in the theory syllabus as well as current editions of IP, BP and USP.

BPH_C_607_L–Pharmaceutical Analysis Lab II- (4 Hr/Wk)

Course Objectives

On performing the following experiments, learner should be able to operate the instruments, understand its instrumentation, prepare solutions with accurate concentrations, measure the readings, calculate and interpret the results obtained.

Course Outcomes

1. Record the absorbance and calculate concentration of analyte in formulation or as an API by use of A(1%, 1cm), single point and double point standardisation by UV spectrophotometer.
2. Relate and construct linear regression analysis data for colorimetric assays and operate a colorimeter instrument.
3. Record and calculate the concentration of an analyte by measure of fluorescence of an analyte in absence and presence of quenching agent.
4. Operate a pH meter, measure equivalence point by potentiometric titration, calculate pKa and normality for a given acid or mixture of acids.
5. Understand the sample preparation technique for FTIR spectroscopy, interpret the IR spectra to identify the functional groups of an analyte, and understand the working of a flame photometer.

No.	Experiments
1	**Assay of finished products by UV spectroscopy, using A (1%, 1 cm)-** Minimum assay of 5 formulations: • Paracetamol tablets • Propranolol tablets • Atenolol tablets • Hydrochlorothiazide tablets • Frusemide tablets • Albendazole tablet • Rifampicin capsules
2	**Assay of drug by UV spectroscopy.** • Use of single point and double point standardization method e.g. Paracetamol
3	**Colorimetric assay** (Construction of calibration curve using linear regression analysis) **A.** Assay of streptomycin injection **B.** Assay of salicylic acid.
4	**Fluorimetric analysis** **A.** Assay of quinine sulphate

	B. Effect of different concentrations of iodide ions on fluorescence of quinine sulphate.
5	**Potentiometric aqueous acid-base titrations using pH meter** (All experiments must be performed by use of titration curve and calculations based on equivalence point determination) **A.** Determination of pKa and normality of phosphoric acid (First & Second end-point) **B.** Determination of normality of individual acids in a mixture of acids. (e.g: HCl and H_3PO_4) **C.** Determination of normality of strong acid (HCl)Vs standard solution of strong base (NaOH) as a titrant **D.** Determination of Normality of weak acid (acetic acid) Vs standard solution of strong Base (NaOH) as a titrant
6	**Demonstration experiments:** **A.** Determination of Na+/K+ by Flame photometry. **B.** Working of FTIR and Interpretation of IR spectra of any one drug.

Books:

Latest editions of books to be adopted

1. Indian Pharmacopoeia, The Indian Pharmacopoeia Commission, Ghaziabad, Government of India.
2. G. D. Christian, Analytical Chemistry, John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd.
3. A. H. Beckett and J. B. Stenlake, Practical Pharmaceutical Chemistry, Part I and II, CBS Publishers and Distributors, India.
4. United States Pharmacopoeia.
5. J. Mendham, R. C. Denney, J. D. Barnes, M. J. K. Thomas, Vogel's Textbook of Quantitative Chemical Analysis, Pearson Education Ltd.
6. D. G. Watson, Pharmaceutical Analysis –A textbook for pharmacy students and pharmaceutical chemists, Churchill Livingstone Elsevier.
7. R. M. Silverstein, F. X. Webster and D. J. Kiemle, Spectrometric identification of organic compounds, John Wiley & Sons, Inc. (Indian edition), New Delhi

ANY TWO SUBJECTS (ONE EACH OF 4 CREDIT AND 2 CREDIT SUBJECT) FROM THE FOLLOWING SUBJECTS TO BE CHOSEN AS ELECTIVES FOR A TOTAL OF 6 CREDITS

BPH_E_608_T – Pharmaceutical Management- (4 Hr/Wk)

Course Objectives

1. To introduce the learner to the pharmaceutical industry with emphasis on Indian Market.
2. Give the learner an understanding of companies' financial statements & its components.
3. To enhance the knowledge about marketing and its importance to a learner's career.
4. To provide knowledge of management & its importance.
5. To introduce the importance of management in quality control & government regulation.

Course Outcomes

The learner will be able to

1. Study and interpret companies' financial statements & its components.
2. State the importance of marketing in the pharma industry.
3. Outline the basic principles of management
4. Discuss the importance of management in quality control & government regulation.

No.	Details	Hours
1.1	**Indian Pharmaceutical Industry**	6
a)	Structures	
b)	Components	
c)	Present Scenario	
d)	Foreign Trade	
e)	Future	
1.2	**Government Policy**	2

Books:

1. Sachin Itkar: Pharmaceutical Organisation

a)	Growth & Investment	
b)	Employment	
c)	Taxes & Subsidies	
1.3	**Share of Pharmaceutical Industry in the Economy**	
2	**Financial Management**	4
3	**Management**	4
a)	*Management Thoughts*	
b)	Management Function	
c)	Organization	
d)	Motivation	
e)	Leadership	
f)	Conflicts & Measures to Solve it.	
4	**Marketing**	8
a)	Brand & Branding & Brand Plan	
b)	Market Segmentation	
c)	Product Positioning	
d)	Marketing Mix	
e)	Packaging	
5.1	Product Life Cycle	4
5.2	New Product Development	
5.3	Marketing Models (BCG & Porter's 5 Force)	
6	**Production Management**	8
a)	Quality Control Concepts of Quality Assurance & Quality Control, Responsibilities of Q.A. department. Raw material control, actives and inactive, Q.C. standards for raw materials. (identity, purity, quality and potency) QA before start up- environmental and microbiological control, manufacturing working formula procedures, cleaning, sanitization, in process control packaging and labelling control, finished product control. Specimen documents-formats cGMP Statistical Quality Control -Q. C. Charts, sampling and sampling plans, sampling tools.	
b)	Six Sigma's	
c)	Quality Control Methods & Regulations	
d)	Inventory Management	
e)	Production Management & Control	
f)	Quality Control Standards in Pharmaceutical Industries	
g)	FDA & Other Regulations	
7	**Market**	5
a)	Perfect and Imperfect Competition	
b)	Mergers & Collaborations	
c)	Investments Trends in Pharmaceutical Industries	
d)	Distribution Distributors, direct distribution, direct home delivery, dispensing, scheme, etc.	
8	**Costing & Pricing**	4
a)	Different types of costs including production cost, selling cost and overhead costs	
b)	Pricing of Products - Government Regulations including DPCO	
9	**Industrial Psychology**	3
a)	Human Relation	
b)	Stress & its Management	
c)	Present Life, Pharmaceutical Industry, Its Impact on Employees & health measures	
d)		

	TOTAL	48	

2. Vidya Sagar: Pharmaceutical Industry & Organisation
3. I.M. Pandey or Prasanna Chandra: Financial Management
4. L.M. Prasad: Principle & Practice of Management
5. Philips Kolter: Principle of Marketing
6. Rama Swamy & Nama Kumari: Marketing Management
7. I.M. Juram & F.M. Gryna: Quality Planning & Analysis (Tata Mcgraw Hill)

BPH_E_609_T – Biopharmaceutics and Pharmacokinetics- (4 Hr/Wk)

Course Objectives

To provide knowledge of basic concepts of Biopharmaceutics and Pharmacokinetics and corelate these concepts to properties of drugs and dosage form design.

Course Outcomes

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

1. Explain the basic terms used in Biopharmaceutics and Pharmacokinetics
2. Understand the concept of pharmacokinetics models and significance of various pharmacokinetic parameters
3. Understand BCS Classification, theories of Dissolution and methods of dissolution testing
4. Explain the concepts of Bioavailability and Bioequivalence and IVIVC
5. Solve problems based on principles of Pharmacokinetics

No.	Details	Hours
1.	Introduction to Biopharmaceutics and Pharmacokinetics. Fate of drugs in the body. Definitions of ADME, Bioavailability, Bioequivalence, Pharmacokinetics, Clinical Pharmacokinetics. Different models to study the processes of ADME	**2**
2	**ABSORPTION**	**6**
2.1	Physiology of cell membrane and passage of drugs across cell membrane	1
2.2	Different Mechanisms of drug absorption	1
2.3	Factors affecting drug absorption-Physicochemical properties, formulation and dosage form features, physiological conditions and parameters.	2
2.4	Absorption of drugs from extravascular routes	2
3	**DISTRIBUTION**	**4**
3.1	Factors affecting distribution, Physiological barriers, Tissue permeability and perfusion limited distribution.	2
3.2	Volume of Distribution – Concept, significance of apparent volume of distribution, real volume of distribution	1
3.3	Protein Binding of drugs and its significance	1
4	**METABOLISM/BIOTRANSFORMATION**	**7**
4.1	Phase I and Phase II reactions	3
4.2	Factors affecting drug metabolism: Age, species difference, genetic difference, induction and inhibition, drug-drug interaction	2
4.3	First pass metabolism, concept of clearance, hepatic clearance and factors affecting hepatic clearance, Hepatic extraction ratio, limits of values of organ clearance	2
5	**EXCRETION**	**4**
5.1	Renal excretion, Renal clearance, factors affecting renal clearance, renal function and excretion ratio	2
5.2	Non-renal routes of excretion	2
6	**DISSOLUTION**	**4**
6.1	Introduction to Biopharmaceutical Classification System of drugs	1
6.2	Theories of dissolution, Dissolution rate and methods of enhancing dissolution rate-**Self-study with follow up**	1
6.3	Official and nonofficial methods of dissolution rate testing. Application to different dosage forms	2
7	**PHARMACOKINETICS**	**17**
7.1	Pharmacokinetics: Introduction to compartmental and physiological models. Introduction to the one compartmental open model and its assumptions. Concept of zero order and first order rate kinetics	2

7.2	Mathematical treatment of pharmacokinetics upon One compartment open model IV bolus dosing: Importance of volume of distribution, Clearance, elimination rate constant, half- life, area under the curve (trapezoid rule).	4
7.3	Mathematical treatment of pharmacokinetics upon One compartment open model extravascular dosing; Absorption rate constant, absorption half- life, bioavailability, Area under the curve and the method of residuals, concept of C_{max} and t_{max}. Introduction to Rate of excretion method and Sigma minus method for urine analysis after IV administration.	3
7.4	Mathematical treatment of pharmacokinetics upon multiple IV bolus dosing, concept of accumulation, fluctuation and steady state levels	3
7.5	Linear and non-linear kinetics and description of factors resulting in non- linear kinetics.	2
7.6	Application of PK principles through simple problem solving (for i.v. bolus, multiple i.v. and oral).	3
8	**BIOAVAILABILITY AND BIOEQUIVALENCE**	**4**
8.1	Concept of absolute and relative bioavailability	1
8.2	Method of assessment and enhancement of bioavailability	1
8.3	Bioequivalence: Study design, IVIVC, introduction to the concept of biowaiver	2
	TOTAL	**48**

Books:

Latest Editions to be adopted

1. Leon Shargel, Susanna Wu – Pong, Andrew B.C., Applied Biopharmaceutics and Pharmacokinetics, Singapore.
2. Brahmankar D.M. and Jaiswal Sunil B, Biopharmaceutics and pharmacokinetics – A Treatise, Vallabh Prakashan.
3. Robert E. Notari, Biopharmaceutics and Pharmacokinetics – An Introduction, Marcel Dekker Inc., New York.
4. Milo Gibaldi, Biopharmaceutics and Clinical Pharmacokinetics, USA
5. Malcom Roland, Thomas Tozer, Clinical Pharmacokinetics: Concept and Applications, A Lea – Febiger book, USA.
6. Banakar Umesh, Pharmaceutical Dissolution Testing, Volume 49, Marcel Dekker Inc, New York.

BPH_E_610_T – Basic Principles of Toxicology- (2 Hr/Wk)

Course Prerequisites

- Understanding of Anatomy, Physiology, Pharmacology and its applications.

Course Objectives

1. To define basic toxicological terminologies and explain mechanisms and factors behind the toxic effects.
2. To describe modes of action by which different chemicals produce toxic effects on different organs and systems of human body.
3. To explain different tests and their importance to discover toxic potential of drugs.
4. To introduce to regulatory toxicological frameworks within the professional disciplines and different risk assessment criteria.

Course Outcomes

1. Define toxicological terms mentioned in the course.
2. Discuss mechanism of toxicity, factors influencing toxicity and management of poisoning.
3. Explain metal poisoning and basic principles with suitable example of drug induced toxicity.
4. Discuss in brief about different types of toxicity test.
5. Demonstrate the knowledge of regulatory toxicology and able to apply this knowledge for design of nonclinical toxicology and clinical development of drugs.

No.	Details	Hours
1	**Introduction to toxicology**	**5**
1.1	Definitions: Toxicology, Poisons, Hazards, Risk Classification of toxicity	1
1.2	Factors influencing toxicity	1
1.3	Mechanisms of toxicity	2

1.4	General Management of poisoning	1
2	**Drug induced toxicities**	**6**
2.1	Introduction to the terms with suitable examples of drugs and its clinical repercussions: genotoxicity, carcinogenicity, teratogenicity, mutagenicity, hepatotoxicity, nephrotoxicity, cardiotoxicity, neurotoxicity, haematotoxicity and local toxicity	3
2.2	Clinical symptoms and management of alcohol, barbiturate and morphine poisoning.	3
3	**Toxicity testing**	**5**
3.1	Types of toxicological testing: Acute, Sub acute and Chronic toxicity studies	4
3.2	Brief introduction to alternatives to Animal Models for toxicological testing	1
4	**Regulatory toxicology**	**8**
4.1	Overview of regulatory laws and agencies: Local Drug Regulatory Agencies, OECD and ICH	3
4.2	Schedule Y: Design of non-clinical toxicity studies and clinical development	3
4.3	Risk assessment and management of toxicological risks	2
	TOTAL	**24**

Books:

Latest edition of the following books to be adopted:

1. General and applied toxicology by Bryan Ballantyne, Timothy Marrs, Paul Turner, Stockton Press.
2. Satoskar R.S. Bhandarkar S.D. & Rege N. N. Pharmacology & Therapeutics, Popular Prakashan.
3. Rang & Dale Pharmacology, Churchill Livingstone.
4. Toxicological and Risk assessment Principles, Methods and applications by Anna Fan, Louis Chang, Marcel Dekker.
5. Laurence D. R. & Bennett Clinical Pharmacology, Elsevier, NY.
6. Kulkarni S. K. Handbook of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
7. Katzung B. G. -Basic and Clinical Pharmacology, Appleton and Lange publications.
8. Ghosh M. N. Fundamentals of Experimental Pharmacology Hilton & Company, Kolkata.
9. Curtis D. Klaassen, Casarett & Doull's Essentials of Toxicology, McGraw Hill.
10. Karen Stine, Thomas M. Brown. John B. Watkins, Principles of Toxicology, CRC Press
11. Harsh Mohan Text Book of Pathology, Jaypee publication.
12. Shayne C. Gad, Regulatory Toxicology, Taylor & Francis.
13. A. Wallace, Hayes Principles and Methods of Toxicology, CRC Press.

BPH_E_611_T – Cell and Tissue Culture- (2 Hr/Wk)

Course Prerequisites

Basic knowledge of Cell Biology, Microbiology and Animal Physiology.

Course Objectives

1. To examine and analyze practical and theoretical principles of cell culture.
2. To explain the conditions under which cells can be cultured outside the body.
3. To explain the advantages and limitations of cell culture in biomedical research and applications.

Course Outcomes:

The learner will be able to:

1. Understand the basic requirements of cell and tissue culture.
2. Plan experiments using cultured cells.
3. Carry out cell culture, and associated laboratory techniques.
4. Explore the concepts of cell and tissue culture in production of pharmaceutical products.

No.	Details	Hours
1	**Introduction to Animal Cell culture:** 1.1 Historical background. Advantages of Tissue Culture, Limitations, Major Types of Tissue Culture - Primary and secondary cell culture. 1.2 Laboratory Design & Layout of Animal Tissue Culture (ATC) laboratory, Equipment and Materials of a Tissue Culture Laboratory, Media Preparation and Sterilization techniques.	1 1
2	**Media and reagents:** 2.1 Types of cell culture media, Ingredients of media, Physiochemical properties, Antibiotics, growth supplements, Foetal bovine serum; Serum free media, Trypsin solution, Conditioned media, Other cell culture reagents, 2.2 Selection of medium and serum. 2.3 Preparation and sterilization of cell culture media, serum and other reagents.	2 1 1
3	**Cell culture Techniques:** 3.1 Different types of cell cultures, Trypsinization, Cell separation, Continuous cell lines, Suspension culture, Organ culture. 3.2 Cloning and selection of Animal cells, the Culture Environment, Cell Adhesion, Cell Proliferation, Differentiation, Cell Signaling, Energy Metabolism, Maintenance of cell lines, Cryopreservation. 3.3 Primary Culture: Initiation of a Primary Cell Culture, Isolation of the Tissue, Types of Primary Culture, Subculture and Development of Cell Lines. 3.4 Common cell culture contaminants. 3.5 Scale-up & Automation.	2 3 1 1 1
4	**Applications of Cell and Tissue Culture:** 4.1 Stem cell Culture, Embryonic Stem Cell Culture: Current status and application in medicine, Cell based therapies, Nanomedicine. 4.2 Application of animal cell culture for *in vitro* testing of drugs. 4.3 Application of cell culture technology in production of human and animal viral vaccines and pharmaceutical proteins. 4.4 Production of recombinant hemoglobin, blood substituents, Artificial blood, General account of *in vitro* regulation of blood cells production. 4.5 Antibody Engineering and Large-scale Production of Pharmaceutical Products.	2 2 2 2 2
	TOTAL	24

Books:

1. Ed. John R.W. Masters, Animal Cell Culture - Practical Approach, 3rd Edition, Oxford University Press, 2000.
2. Ed. Martin Clynes, Animal Cell Culture Techniques., Springer, 1998.
3. B.Hafez, E.S.E Hafez, Reproduction in Farm Animals, 7th Edition, Wiley- Blackwell, 2000.
4. Louis-Marie Houdebine, Transgenic Animals: Generation and Use, 1st Edition, CRC Press, 1997.
5. Culture of Animal Cells: A Manual of Basic Technique and Specialized Applications By R. Ian Freshney; 5th Edition, Wiley-Liss, 2005
6. Animal Cell Culture (Introduction to Biotechniques): Sara j. Morgan, David C. Darling; Published by BIOS Scientific Publishers Ltd., 1993

BPH_E_612_T – Pharmaceutical Process Chemistry and Technology- (2 Hr/Wk)

Course Objectives

On completion of the following theory topics, learner should be able to understand basic concepts from process chemistry, appreciate importance of unit processes, regulations and safety aspects at manufacturing of Active Pharmaceutical Ingredients (APIs) and New Chemical Entities (NCEs) at drug development stage

Course Outcomes

The learner will be able to:

1. Describe the basic concepts of process chemistry and process development
2. Describe chemical process, reaction systems and equipment used in API manufacturing
3. Outline the regulatory guidelines related to API manufacturing

4. Appreciate the importance of safety in pharmaceutical industry

No.	Details	Hours
1	**Process chemistry**	**3**
1.1	Overview of fine chemicals industry	
1.2	Stages of scale up process: Bench, pilot and large-scale processes	
1.3	Process control for large scale process: • Definitions: process, process control, Process variables and set point and • Importance of process control	
2	**Process development**	**5**
2.1	Process development: Definition, steps involved with examples	1
2.2	Process equipment/ production plants Dedicated plants, multipurpose and mixed plants Typical equipment: reactors, filters, centrifuge, driers, extractors and evaporators	2
2.3	Chemical process kinetics: Factors affecting chemical processes, Reactor shape and effect of back mixing	2
3	**Unit processes**	**12**
3.1	Nitration: • Nitrating agents, Aromatic nitration, • Kinetics and mechanism of aromatic nitration, • Process equipment for technical nitration, mixed acid nitration • Examples to be covered: Nitrobenzene, p-nitroacetanilide	2
3.2	Amination by reduction: • Reduction methods for amines • Iron/acid reduction: Mechanism, chemical, physical factors, equipment • Sulfide reduction with example of manufacture of m-Niroaniline by Na_2S: Zinnin reduction	2
3.3	Halogenation: • Kinetics of halogenations, types of halogenations, catalytic halogenations. • Case study on industrial halogenation process: Chloral	2
3.4	Oxidation: • Introduction, types of oxidative reactions, • Liquid phase oxidation with oxidizing agents • Non-metallic Oxidizing agents: H_2O_2, sodium hypochlorite, Oxygen gas	2
3.5	Esterification: Esterification of Organic acids, inorganic acids, case study: glyceryl trinitrate, cellulose nitrate	1
3.6	Hydrolysis: Definition and scope, Hydrolyzing agents, Materials susceptible to hydrolysis, mechanism of hydrolysis, Equipment for hydrolysis, Case study	2
4	**API technology**	**2**
	• Impurities in API: Types and sources including genotoxic impurities • Brief overview of guidelines in API manufacturing • Chirality and polymorphism in API	
5	**Industrial Safety and environment**	**2**
	Basic knowledge about Material Safety Data Sheet (MSDS) for safety and handling of chemicals without health hazards. • Fire hazards, types of fire & fire extinguishers • Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and • ISO-14001(Environmental Management System), Effluents and its management	
	TOTAL	**24**

Books:

1. A. Cybulski, Fine Chemicals Manufacture- Technology and Engineering, Elsevier Publication, 2001
2. Pharmaceutical Process Validation: An International Third edition, Revised and expanded, Edited by Robert Nash and Alfred Wachter, Marcel Dekker, 2003
3. ICH Guidelines, www.ich.org (FDA Guidance for industry, Q3A, Q7)
4. Organic Synthesis, Groggins P. H, (Fifth edition). P. H. Groggins , McGraw-Hill, 1958
5. Neal G. Andreson, "Practical Process Research and Development" academic Press, 2000

6. Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up, Peter J. Harrington, John Wiley and Sons Inc. Publication 2011
7. Process Chemistry in Pharmaceutical Industry, Kumar Gadamasetti, Vol I & II, CRC Press; First edition, 2007.
8. Performance of Pharmaceutical Companies in India: Contribution to economics Authors: Mazumdar, M. Springer Verlag Berlin, 2013, Chapter 2, 17-44
9. Principles of Process Research and Chemical Development in the Pharmaceutical Industry by O. Repic, John Wiley & Sons.Inc Publication New York, NY, 1998.

BPH_E_613_T – Pharmaceutical Excipients- (2 Hr/Wk)

Course Objectives

To provide the learner an understanding of types, functions, applications and regulatory aspects of excipients used in development Pharmaceutical dosage forms

Course Outcomes

Upon completion of the course, the learner shall be able to:
1. Define, classify and elaborate on regulatory aspects of Pharmaceutical excipients.
2. Understand the characterization and interactions of excipients with APIs and packaging materials
3. Elaborate on common and novel excipients in Pharmaceuticals
4. Explain the role of polymers as excipients

No.	Details	Hours
1.0	Excipients - Introduction, Definition, Functional classification of excipients.	1
1.1	Excipient Characterization, Active–excipient interactions-Physical, Chemical and Physiological/biopharmaceutical; Excipients-packaging material interactions, storage conditions for excipients	4
1.2	Regulatory guidelines for the pharmaceutical excipients, Pharmacopoieal, Harmonization of the Excipients, safety testing of excipients	3
2.0	**Study of some common Conventional excipients** with respect to source, chemical nature, role/functions, manufacture/processing steps, interactions, safety: Lactose, Starch, Magnesium stearate, Talc, Bentonite, Glycerol, Paraffins, Sodium Lauryl Sulphate, Sodium saccharin, Tweens and Spans, Arachis oil, Wool fat, Glyceryl mono stearate **Self-study with follow up**	4
3.0	**Organoleptive additives-** colours, flavours and sweeteners-sources, mechanism/basic principles and examples **Self-study with follow up**	2
4.0	**Excipients for solubility/dissolution and permeation enhancement**-Need, basic principles and examples **Self-study with follow up**	2
5.0	**Excipients for stabilizing / preservation of dosage forms-** Study of antioxidants, chelating agents, buffering agents, antimicrobial preservatives with respect to need, mechanisms and examples. **Self-study with follow up**	2
6.0	**Improved and Novel Excipients –** Need, sources of new excipients-co-processing and particle engineering, benefits of co-processed excipients, characterisation, examples, regulatory aspects.	3
7.0	**Polymers as excipients** - Introduction to polymers, classification, important properties for applications, use of polymers in conventional formulations, modified /controlled release formulations, **Self-study with follow up**-of following polymers-HPMC, Gelatin, Carbopol and Eudragits	3
	TOTAL	**24**

Books:

1. Rowe, R. C., Sheskey, P. J., & Owen, S. C. (Eds.)Handbook of pharmaceutical excipients (6th ed.). London: Pharmaceutical Press and A.A.P.S., 2009
2. Robert, W. M., & Aloysius, O. A., Pharmaceutical Dosage Forms—Tablets Vol 3 (Revised and expanded). (H. A. Lieberman, L. Lachman, & J. B. Schwartz, Eds.) Informa Health Care., 2008

3. Lachman, L., Lieberman, H. A., & Kanig, J. L.. The Theory and Practice of Industrial Pharmacy (3rd ed.). Mumbai: Varghese Publishing House. ,1991.
4. Rawlins, E. A. Bentley's text book of Pharmaceutics (8th ed.). London: Bailliere Tindal., 1995.
5. Rubinstein, M. H.,Tablets. In M. E. Aulton, Pharmaceutics: the science of dosage form design, London: ELBS Longman Group Ltd., 1988.
6. Rudnic, E. M., & Schwartz, J. D. ,Remington: The Science and Practice of Pharmacy, (A. R. Gennaro, Ed.) Philadelphia: Lippincott Williams & Wilkins, 2006
7. Saha, S., & Shahiwala, A. F.,Multifunctional coprocessed excipients for improved tabletting performance . Expert Opinion on Drug Delivery , 6 (2), 2009.
8. Kadtare A. and Mahesh Chaube, Excipient Development for Pharmaceutical, Biotechnology and Drug Delivery Systems, Informa Healthcare USA, Inc. 270 Madison Avenue, New York 10016, 2006.

SYLLABUS FOR Final. Y. B. Pharm.

SEMESTER-VII

BPH_C_701_T – Pharmaceutical Chemistry II- (4 Hr/Wk)

Course Objective

1. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of anticancer agents
2. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of antiviral agents
3. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of cardiovascular drugs like antianginal agents, antiarrhythmic agents, diuretics, drug affecting the RAS pathway, vasodilators, antihyperlipidemic agents drugs
4. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of antihistaminics
5. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of hypoglycemic agents and insulin analogs

Course Outcome

Students will gain knowledge in the thurst areas chemotherapy for cancer, antiviral diseases, cardiovascular drugs like antianginal agents, antiarrhythmic agents, diuretics, drug affecting the RAS pathway, vasodilators, antihyperlipidemic agents. They will be apply this knowledge in research areas.

No	Details	Hours
	Discussion of the following classes of drugs including classification, chemical nomenclature, structure including stereochemistry, generic names, SAR and metabolism, molecular mechanism of action, synthesis(*) and rational development if any	
1	**Anti-Cancer agents:** • Alkylating agents like mechlorethamine , chlorambucil* (self study), melphalan*, cyclophosphamide*, busulfan, carmustine, lomustine, streptozocin, dacarbazine and procarbazine, timozolomide • Antimetabolites like azaserine, methotrexate*, pralatrexate, azacytidine, 5-fluorouracil, cytarabine (Ara–C), 6-MP and 6-TG. • Antibiotics like dactinomycin, daunorubicin, doxorubicin , bleomycin and other natural products like vincristine, vinblastine, paclitaxel, docetaxel, topotecan, irinotecan (only highlights of structure to be discussed for bleomycin and natural products) • Platinum compounds like cisplatin and oxaliplatin • Histone Deacetylase Inhibitors: romidepsin, vorinostat • Tyrosine Kinase Inhibitors: imatinib, dasatinib, lapatinib • Combination therapy for breast cancer, leukemia **(Self study)**	7 1
2.	**Antivirals agents including anti-HIV agents:** Amantadine*, rimantadine, oseltamivir, zanamivir, acyclovir and its prodrugs, ganciclovir, famciclovir, penciclovir, idoxuridine, vidarabine Reverse transcriptase inhibitors: , azidothymidine*, stavudine, lamivudine, zalcitabine, didanosine, abacavir, Non-nucleosides reverse-transcriptase inhibitors: delaviridine, nevirapine, efavirenz. HIV-protease inhibitors: raltegravir, saquinavir, ritonavir, (only highlights of structure of protease inhibitors). Drugs like nelfinavir, lopinavir, atazanavir, amprenavir, telaprevir and Combination anti-therapy **(Self Study)**	4 2
3.	**Cardiovascular Drugs**	
3.1	**Antianginal Agents**	3

	Antianginal agents: Amyl nitrite, isosorbide dinitrate, pentaerythritol tetranitrate, verapamil, bepridil, diltiazem, nifedipine, dipyridamole*	
3.2	**Antiarrythmic Agents** Antiarrhythmic agents: quinidine, procainamide*, disopyramide, lidocaine, mexilitine, amiodarone, propafenone, verapamil, diltiazem, propranolol, sotalol*	4
3.3	**Diuretics** • Site 1. Carbonic anyhydrase inhibitors: acetazolamide*, methazolamide, brinzolamide, ethoxzolamide • Site 2. High celing or loop diuretics: Sulphamoyl anthranilic acids like furosemide*, azosemide and bumetanide and phenoxyacetic acids ethacrynic acid* • Site 3. Thiazide and Thiazide like diureties, chlorthiazide***(self study)** hydrochlorthiazide, benzthiazide, methyclothiazide, trichlormethiazide, chlorthalidone, metolazone, quinethazone, indapamide • Site 4. Potassium sparing diureties such as spironoloactone, eplerenone **(self study)** triamterene and amiloride. Osmotic diuretics- mannitol, isosorbide.	4 1
3.4	**Agents affecting Renin-Angiotensin Pathway and Calcium Blockers** • ACE Inhibitors- captopril* Lisinopril, perindopril • Angiotensin II receptor blockers- losartan, valsartan, , telmisartan, olmesartan, azilsartan. • Also valsartan + sacubitril combination • Calcium channel blockers- verapamil , diltiazem, nifedipine, amlodipine, nimodipine, , cilnidipine, benidipine, efonidipine • Renin Inhibitors- aliskiren**(self study)** • Aldosterone antagonists: spironolacone, eplerenone **(self study)**	4 1 1
3.5	**Vasodilators/Sympatholytics** • Vasodilators- Hydralazine* • Non-selective beta blockers- propranolol, nadolol • Selective beta-1 blockers- acebutalol, atenolol, esmolol • Selective alpha-2 blockers- prazosin* terazosin • Mixed alpha-beta blockers- carvedilol, labetalol • K-channel agonists- Minoxidil	4
3.6	**Antihyperlipoproteinemics** Clofibrate*, gemfibrozil, gemfibrate, fenofibrate • HMG-CoA reductase inhibitors: lovastatin, atorvastatin, simvastatin, rosuvastatin, ezetimibe.	3
4	**Antihistaminics** Antihistaminies:H_1 and H_2 receptors, general SAR of classical H1 antihistaminics, Emphasis to be on the second generation H_1 antagonists such as fexofenidine, , loratidine, cetrizine, , andacrivastine, ebastine and bepotastine; combination of H1 antihistaminics and monteleukast H_2 receptor antagonists like cimetidine ranitidine*, famotidine, nizatidine, lafutidine; proton pump inhibitors like omeprazole, rabeprazole, pantoprazole and lansoprazole.	4 1
5	**Hypoglycemics and Insulin Analogues** Hypoglycemics (Insulin not to be discussed) • Biguanides e.g. metformin • Sulfonylureas: 1st Generation like tolbutamide, chloropropamide, tolazamide and acetohexamide***(self study);** 2nd Generation like glyburide* glypizide and glimepride,glyclazide and meglitinides like repaglinide, nateglinide. • Thiazolidinediones such as troglitazone, ciglitazone, rosiglitazone and pioglitazone. • GLP-1 agonists and DPP-IV inhibitors- exenatide and liraglutide (no structures), saxagliptin, vildagliptin, sitagliptin, linagliptin • β – Glucosidase inhibitors like voglibose, and miglitol. Insulin analgoues:Lisproinsulin, glargineinsulin	4
	Total	**48**

*Synthesis to be taught

Latest editions of the following books to be adopted.

12. An Introduction to Medicinal Chemistry, Graham L. Patrick, Oxford University Press.
13. Fundamentals of Medicinal Chemistry, Gareth Thomas, Wiley, New York.

14. The Organic Chemistry of Drug Design and Drug Action, Richard B.Silverman, Academic Press.
15. Foye's Principles of Medicinal Chemistry, Thomas L. Lemke, David A Williams, Lippincott Williams & Wilkins.
16. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, John M. Beale, John H. Block, Lippincott Williams & Wilkins.
17. Medicinal Chemistry, Ashutosh Kar, New Age International Publishers.
18. Introduction to Medicinal Chemistry, Alex Gringauz, Wiley.
19. The Organic Chemistry of Drug Synthesis, Daniel Lednicer, Lester A. Mitscher, John Wiley and Sons.
20. Pharmaceutical Chemistry, Volume 1, Organic Synthesis, H. J. Roth & A. Kleemann, Ellis Horwood Series in Pharmaceutical Technology, Halsted Series.
21. Synthesis of Essential Drugs, Ruben Vardanyan and Victor Hruby, Elsevier.
Pharmaceutical Substances: Syntheses, Patents, Applications, Kleemann& Engel, Thieme Publications.

BPH_C_702_T – Pharmacognosy III- (4 Hr/Wk)

Course Objectives

1. To introduce the learner to the chemistry, sources, cultivation and collection of crude drugs containing phytoconstituents like steroidal, triterpenoidal, anthraquinone, flavonoid glycosides and alkaloids.
2. To introduce the learner to the biosynthesis of alkaloids obtained from different amino acids
3. To introduce the learner to glycoproteins with the representative examples and their utility in diagnosis or therapeutics.
4. To make the learner aware of regulatory requirements for manufacture and sale of Ayurvedic, Siddha and Unani (ASU) Medicines and Phytopharmaceuticals, monographs of herbal drugs
5. To make the learner understand formulation aspects and challenges of Herbal formulations, standardization and interactions of drugs of natural origin
6. To apply the spectroscopic techniques in characterization of phytoconstituents of both aliphatic and aromatic nature

Course Outcomes

Upon completion of the course student will be able to:

1. Write the source, composition, general methods of extraction, evaluation, chemical tests, therapeutic uses of crude drugs containing phytoconstituents like steroidal, triterpenoidal, anthraquinone, flavonoidal glycosides, alkaloids glycoproteins.
2. Write the biosynthesis of biosynthesis of alkaloids obtained from different amino acids
3. Understand regulatory requirements for manufacture and sale of Ayurvedic, Siddha and Unani (ASU) Medicines and Phytopharmaceuticals, monographs of herbal drugs
4. Apply the knowledge of excipients from natural origin and pharmaceutical technology to herbal formulation and understand the challenges in herbal formulation
5. Understand the concept of herbal drug standardization and its application to herbal formulation
6. Apply the knowledge of pharmacology to understand pharmacodynamic and pharmacokinetic interactions of herbal drugs with food
7. Apply spectroscopic techniques to characterize small molecules both from the categories of aromatic and aliphatic nature

No.	Details	Hours
1	**Steriodal and Triterpenoidal glycosides** • Detailed study of drugs with respect source, chemistry, and therapeutic application of the following drugs – Liquorice, Asparagus, Dioscorea, Fenugreek, Brahmi, Ginseng • Introduction to cardiac glycosides with respect to their classification, chemistry & general chemical tests. Detailed study of drugs with respect source, chemistry cultivation and collection, preparation & biopotential of the following drugs – *Digitalis lanata*, *Digitalis purpurea*, Squill • Extraction, Identification and Analysis of Phytoconstituents – Liquorice constituents • Commercial application of Diosgenin **Interactive Session** • Potency, marketed preparation of all cardiac glycosides • Composition and indication of Fenugreek containing formulations	6 1
2	**Alkaloids** Introduction to alkaloids - Classification, properties, general methods of extraction. • Study of following drugs containing alkaloids with respect to their sources, chemistry (structures), salient features of extraction and specific tests for detection (if any) and therapeutic applications of: a. Alkaloidal Amines – Ephedra, colchicum b. Tropane - Datura, Coca, Ashwagandha c. Indole - Rauwolfia, Vinca, Ergot	8

	d. Steroidal –Kurchi e. Quinazoline – Vasaka f. Benzyl isoquinoline – Opium g. Isoquinoline - Ipecac, *Berberis aristata* h. Quinoline - cinchona i. Pyridine-Piperidine –Pepper, Tobacco j. Purine - Tea, Coffee, Cocoa k. Imidazole – Pilocarpus l. Glycoalkaloids- Solanum • Isolation, Identification and Analysis of Phytoconstituents Piperine, Caffeine **Interactive Session** • Market products and their therapeutic uses of Atropine, Pilocarpine, Vasaka, Kurchi, Ephedra, Pepper	 1 1
3	**Biosynthesis** of lysergic acid, tropane alkaloids, emetine, quinine,	2
4	**Glycoproteins** – Castor, Pea and Oats	2
5	**Glycosides** a) Anthracene derivative – Study of aloes, senna, rhubarb, with respect to Occurrence, chemistry, salient features of cultivation, collection, preparation, chemical test and uses. b) Source, chemistry and uses of Rubia, St. John`s wort **Occurrence, Chemistry, Test and Uses of** a) Isothiocyanate – Brassica, cabbage b) Cyanogenetic - bitter almond, wild cherry bark, Biosynthesis of amygdaline Isolation, Identification and Analysis of Phytoconstituents – Anthraquinone- Aloe emodin	3 2
6	**Detailed study of Flavonoids and Coumarins:** **a.** Introduction, classification, chemical tests occurrence & their biopotential as exemplified by Orange Peel, Soyabean, Buckwheat, Psoralea. b. Monomeric, dimeric and related phenylpropanoid derivatives e.g., lignans- Podophyllum • Isolation, Identification and Analysis of Phytoconstituents - Rutin	3
7	**Interactions with DONO :** **Concept of pharmacokinetic interaction and pharmacodynamic interactions** herb- drug interactions – 3 examples each of synergistic and antagonistic interactions herb- food interactions – 3 examples each of synergistic and antagonistic interactions eg . Hypercium, Liquorice, Coffee, Ginseng, Ginkgo biloba, Digitalis, Garlic, Pepper & Ephedra.	3
8	**Use of spectroscopy techniques in characterization of phytoconstituents**. a. Citral b. Rutin c. Gallic acid	2
9	**Standardization of herbal drugs using various type of markers with examples.** Application of various chromatographic techniques in standardization of herbal products with two examples. Stability testing of herbal medicines with respect to marker analysis. **Interactive session** Standardization of polyherbal formulation with respect to respective marker constituents emphasizing on simultaneous estimation.	3 1
10	**Monograph of herbal drugs & excipients** in Indian Pharmacopoeia (Two examples each) **Interactive session** Comparative study of herbal monographs in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia.	2 2
11	**Regulatory Issues - ASU formulations, patent and proprietary medicine and Phytopharmaceuticals** Schedule T & Y of Drugs & Cosmetics Act for ASU drugs and phytopharmaceuticals	2
12	**Study of herbal formulations & Ayurvedic formulations** a. Ayurvedic Formulations –Introduction to Ayurvedic formulations like aristas, asava, gutika,taila, churna, avaleha, bhasma, ghrita. b. Introduction to the concept of detoxification in Ayurveda (2eg). c. Herbal formulations: Challenges in the preparation and evaluation of Herbal tablets, capsules, liquid oral, semisolid dosage forms	3

	d. NDDS of Herbal medicine: Limitation of conventional formulations, challenges in development of NDDS of Herbal medicine, Phytosomes with one example each **Interactive session** Phytopharmaceuticals in the market: Study of any two formulations under each category with respect to their ingredients used and activities / claims of each ingredient used in them	1
	TOTAL	48

Books:

Latest editions of the following books to be adopted.

1. Trease D. & Evans W.C.: Text Book of Pharmacognosy: W.B. Saunders.
2. Tyler V. E. Brady L. R. & Robbers J. E.: Pharmacognosy; Lea Feibger, USA.
3. Wallis T. E.; Text Book of Pharmacognosy; CBS Publishers, Delhi.
4. Kokate C. K., Purohit A. P. & Gokhale S. B.: Pharmacognosy; Nirali Publications, Pune.
5. Harbone J. B.: Phytochemical Methods: A guide to modern techniques Analysis: Chapman & Hall, London.
6. Bruneton J.: Pharmacognosy, Phytochemistry, Medicinal Plants: Intercept Limited.
7. Vasudevan T. N. & Laddha K. S.: A Textbook of Pharmacognosy, Vrinda Publication House, Jalgaon.
8. The Indian Pharmacopeia: The Controller of Publication; Delhi.
9. R. S. Guad, S. J. Surana, G. S. Talele, S. G. Talele, Mr. S. B. Gokhale. Natural Excipients, Pragati Books Pvt. Ltd., 2006
10. Biren Shah, Avinash Seth, Textbook of Pharmacognosy and Phytochemistry , Elsevier Health Sciences,
11. Ashutosh Kar, Pharmacognosy And Pharmacobiotechnology, New Age International, 2003
12. Quality Control Methods for Medicinal Plant Materials, World Health Organization World Health Organization, 1998 - Botanical drug industry
13. WHO Monographs on Selected Medicinal Plants, World Health Organization World Health Organization, 1999
14. ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, ESCOP, European Scientific Cooperative on Phytotherapy, Thieme, 2003 -
15. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, Max Wichtl CRC Press, 2004 - Health & Fitness
16. Pulok K. Mukherjee Evidence-Based Validation of Herbal Medicine, Elsevier, 17-Feb-2015
17. Adverse Effects of Herbal Drugs 2, Springer Science & Business Media, 06-Dec-2012
18. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals, Pulok K. Mukherjee Business Horizons, 2002
19. Brain K. R. & Turner T. D.: The Practical Evaluation of Phytopharmaceuticals: Wright, Scientica, Bristol.
20. Iyengar M. A. & Nayak S. G.: Anatomy of Crude Drugs: Manipal Power Press, Manipal
21. Iyengar M. A.: Pharmacognosy of Powdered Drugs; Manipal Power Press, Manipal

BPH_C_703_T – Pharmaceutical Analysis III- (4 Hr/Wk)

Course Objectives

On completion of this course, the learner should be able to apply the principles of spectroscopy for multicomponent analysis and describe working principle, instrumentation and applications of chromatographic and characterization techniques.

Course Outcomes

The learner should be able to:

1. Explain various methods used for multicomponent analysis of drugs by UV spectroscopy.
2. Summarize chromatographic and hyphenated techniques used for the separation, identification and quantification of analytes.
3. Describe the working of proton ^{1}H NMR spectroscopy and mass spectrometry.
4. Interpret spectral data to predict structure of a given compound.
5. Summarize the parameters of ICH guidelines for analytical method validation.

No.	Details	Hours
1.0	**Multicomponent analysis by UV Spectroscopy**	**4**
1.1	• Assay as a single component sample • Corrected interference • Assay after solvent extraction • Simultaneous Equation method	4

	• Absorbance Ratio method • Difference Spectroscopy method • Derivative Spectroscopy	
2.0	**Concepts of Chromatography**	**7**
2.1	*Terminologies:* stationary phase, mobile phase, retention time, gradient and isocratic elution, normal and reverse phase chromatography, planar chromatography, retention factor, chromatogram, internal standard, reference standard, working standard, tailing factor (symmetry factor), asymmetry factor, resolution, signal to noise ratio, column chromatography, preparative chromatography, adsorption chromatography and partition chromatography.	3
2.2	• Classification of chromatographic methods ***(Self study-0.5 hr)*** • Quantitative analysis (Peak height, peak areas, calibration curve, internal standard, and area normalization) • Optimization of column performance (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)	3
2.3	Numericals and justification based problems related to column performance	1
3.0	**High Performance Liquid chromatography (HPLC)**	**4**
3.1	**Instrumentation:** • Mobile phase reservoir • Pumps (reciprocating, displacement, pneumatic) ***(Self study-0.5 hr)*** • 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, Phototodiode array, fluorescence, , Electrochemical, Evaporative Light Scattering), • Difference between UPLC and HPLC ***(Self study-0.5 hr)*** • Applications, Advantages and Limitations of HPLC ***(Self study-0.5 hr)***	4
4.0	**Gas chromatography (GC)**	**3**
4.1	• Introduction **Instrumentation** • Carrier gas supply • Sample injection system including Head space analysis • Columns (Packed, Open tubular columns, Capillary columns) and column ovens ***(Self study-0.5 hr)*** • Detectors (Thermal conductivity, Electron capture, Flame ionization) Applications, Advantages and Limitations of GC ***(Self study-0.5 hr)***	3
5.0	**Planar chromatography**	**3**
5.1	• **Paper chromatography**-Principle, Developmental techniques (Ascending, Descending, Radial and Two-dimensional), Spray reagents and Pharmaceutical applications ***(Self study-0.5 hr)*** • **TLC**-Principle, types of adsorbents, Developmental techniques ***(Self study-0.5 hr),*** Visualisation techniques, factors affecting resolution, Pharmaceutical applications of TLC and Preparative TLC. • **HPTLC:** Instrumentation- Applicator, photodensitometry, photodocumentation, • Advantages of HPTLC over TLC and HPLC ***(Self study-0.5 hr)***	3
6.0	**Ion exchange chromatography, Ion Pair and Size Exclusion chromatography**	**3**

6.1	Principle, Stationary phases, Mobile phases and Applications ***(Self study-0.5 hr)***	3
7.0	**Nuclear Magnetic Resonance Spectroscopy (^{1}H-NMR)**	**8**
7.1	**^{1}H-NMR phenomenon-** spinning nucleus, precessional motion, precessional frequency, gyromagnetic ratio, energy transitions and relaxation processes, NMR Spectra, Chemical shift, shielding and deshielding, Vanderwaal's deshielding, Deuterium exchange, Chemical and magnetic equivalence , anisotropic effect (eg. Alkanes, alkenes, alkynes, carbonyl, aromatic and cyclohexane), Solvents, Reference compounds and internal standards.	2
7.2	**Measurement of chemical shift:** • Scales used. • Factors affecting chemical shift (Electronegativity-Shielding and Deshielding, Vanderwaal's deshielding, anisotropic effect) • Instrumentation of NMR Spectrometer (including schematic representation) ***(Self study-0.5 hr)*** • Principle of FT NMR (including representation of conversion of time domain spectra to frequency domain spectra)	3
7.3	**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). Information obtained from proton NMR-Chemical shift, splitting, coupling constant, integration. ***(Self study-0.5 hr)***	3
8.0	**Mass Spectrometry**	**4**
8.1	Principle & basic theory- Mass spectrum, relative abundance, mass to charge ratio, molecular ion, fragment ion (daughter ion), metastable ion, base peak, isotope peak, mass to charge ratio.	1
8.2	**Instrumentation:** • Basic components of mass spectrometer (including block diagram). • Ionisation methods: Electron Ionisation, Chemical Ionisation, Desorption Ionisation (MALDI), Fast Atomic Bombardment, Atmospheric Pressure Ionisation (Electrospray, APCI, APPI). • Analysers: Quadrupole, Ion Trap and Time of Flight.	2
8.3	Examples of different mass fragmentation pathways	1
9.0	**Hyphenated techniques**	**2**
	Significance, interfaces and applications of • LC-MS • GC-MS ***(Self study-1 hr)***	
10.0	**Structure Elucidation by spectral techniques using UV, IR, 1H-NMR and Mass spectrometry**	**8**
10.1	UV-Woodward Fieser rules for predicting λ_{max} (acyclic & cyclic dienes, and α, β unsaturated ketones (acyclic and 6 membered ring). (**Note**-only alkyl substituents to be studied). ***(Practice problems-Self study-0.5 hr)***	2
10.2	Elucidation of structure of a compound using IR and ^{1}H NMR data- Problems for simple organic compounds with molecular formula given ***(Practice problems-Self study-0.5 hr)***	3
10.3	Mass spectrometry:	3

	Fragmentation: Representation of fragmentation process, Basic types of fragmentation: • Fissions (homolytic and heterolytic, α and β fission). • Rearrangement (Mclafferty, Retro Diel-Alders, 4 membered cyclic rearrangement), • Nitrogen rule and Even electron rule. ***(Practice problems-Self study-0.5 hr)***	
11	**Analytical method Validation.** ***(Self study- 0.5 hr)***	**2**
11.1	Analytical method Validation as per ICH guidelines.	
	Total	**48**

Books:

1. D. A. Skoog, F. J. Holler and S. R. Crouch, Principles of Instrumental Analysis, Saunders College Publishing, USA.
2. K. A. Connors, A Textbook of Pharmaceutical Analysis, John Wiley and Sons, Canada.
3. A. H. Beckett and J. B. Stenlake, Practical Pharmaceutical Chemistry, ,Vol. 6, Part I and II, CBS Publishers and Distributors, India.
4. D. A. Skoog, D. M. West, F. J. Holler and S. R. Crouch, Fundamentals of Analytical Chemistry, Saunders College Publishing, USA.
5. G. D. Christian, Analytical Chemistry, John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd.
6. H.H. Willard, L. L. Merrit and J. A. Dean, Instrumental Method of Analysis, CBS Publishers & Distributors, New Delhi.
7. Ashutosh. Kar, Pharmaceutical Drug Analysis, New Age International (P) Ltd. Publishers, India.
8. S. S. Mahajan, Instrumental Methods of Analysis, Popular Prakashan Pvt Ltd., India.
9. G. R. Chatwal and S. K. Anand, Instrumental methods of chemical analysis, Himalaya Publishing House Pvt. Ltd.
10. Indian Pharmacopoeia, The Indian Pharmacopoeia Commission, Ghaziabad, Government of India.
11. United States Pharmacopeia
12. J. Mendham, R. C. Denney, J. D. Barnes, M. J. K. Thomas, Vogel's Textbook of Quantitative Chemical Analysis, Pearson Education Ltd.
13. D. G. Watson, Pharmaceutical Analysis –A textbook for pharmacy students and pharmaceutical chemists. Churchill Livingstone Elsevier.
14. J. W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, Marcel Dekker, New York, USA.
15. R. Kellnar, J. M. Mermet, M. Otto, M. Valcarceland, H. M. Widmer, Analytical Chemistry: A modern approach to analytical science, Wiley-VCH, USA.
16. J. W. Munson, Pharmaceutical Analysis: Modern methods (in two parts), Marcel Dekker Inc., USA.
17. W. Kemp, Organic Spectroscopy, Palgrave Publishers Ltd., New York, USA.
18. R. M. Silverstein, F. X. Webster and D. J. Kiemle, Spectrometric identification of organic compounds, John Wiley & Sons, Inc. (Indian edition), New Delhi.
19. D. B. Troy and P. Beringer, Remington-The Science and Practice of Pharmacy, Vol-I & II, Wolters Kluwer/ Lippincott Williams & Wilkins (Indian edition), New Delhi.
20. 20 J. W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, Marcel Dekker, New York, USA.
21. J. R. Dyer, Applications Of Absorption Spectroscopy Of Organic Compounds, Prentice- Hall of India Pvt Ltd, New Delhi, India.
22. D. L. Pavia, G. M. Lampman, G. S. Kriz and J. R. Vyvyan, Introduction to Spectroscopy, Brooks/Cole Cengage Learning, Australia.
23. Y. R. Sharma, Elementary organic spectroscopy-Principles and Chemical Applications, S. Chand & Company Ltd, New Delhi, India.
24. L. R. Snyder, J. J. Kirkland, J. L. Glajch, Practical HPLC Method Development, Wiley-Interscience publication, John Wiley & Sons, Inc., Canada.
25. S. Ahuja and M. W. Dong, Handbook of Pharmaceutical Analysis by HPLC, Volume 6 of Separation Science and Technology, Elsevier Academic Press, Indian edition.

BPH_C_704_T – Pharmacology III- (4 Hr/Wk)

Course prerequisites

- Knowledge of anatomy, physiology and pathophysiology of diseases/disorders of central nervous system and gastrointestinal system
- Concept of Inflammation
- Information on endogenous receptors in the human body

Course objectives

1. To educate on different drugs acting on central nervous system and its associated diseases.
2. To educate on pharmacology of anti-inflammatory drugs.
3. Impart knowledge on pharmacology of drugs used in inflammatory disorders like asthma and gout.
4. Educate on autacoids and drugs impacting autacoids' actions.
5. To provide understanding about drugs used in GIT associated disorders.
6. To convey principles of toxicity with briefing on common toxicants.

Course outcomes

1. Explain pharmacology of drugs acting on central nervous system and associated diseases.
2. Classify and explain pharmacology of anti-inflammatory drugs, make use of knowledge of these drugs to justify their use in asthma and gout.
3. Discuss the pharmacology of drugs used in gastrointestinal disorders.
4. Know the toxic effects of heavy metals, drugs and environmental toxicants.

No	Details	Hours
1	Drugs acting on Central Nervous System	24
1.1	Aliphatic alcohols	2
1.2	General and Local anaesthetics	4
1.3	Sedatives, Hypnotic and anxiolytic agents	3
1.4	Antiepileptic drugs	2
1.5	Drugs Used in Parkinson's disease	2
1.6	Drugs used in Alzheimer's disease	2
1.7	Antipsychotic, antidepressant, anti-mania drugs	4
1.8	Opioid analgesics	3
1.9	CNS stimulants	2
2	Autacoids; Drug therapy of inflammation	13
2.1	Histamine, bradykinin and their antagonists	2
2.2	Serotonin, agonists and antagonists	2
2.3	Lipid derived autacoids, Eicosanoids and platelet activating factor	2
2.4	NSAIDs	3
2.5	Pharmacotherapy of Asthma	2
2.6	Pharmacotherapy of Gout	2
3	Drugs acting on gastrointestinal tract	8
3.1	Antacids and Drugs for peptic ulcers	3
3.2	Emetics, anti-emetics and Prokinetics	2
3.3	Drugs for constipation and diarrhoea	2
3.4	Drugs for Inflammatory Bowel Diseases	1
4	Principles of Toxicology	3
4.1	Heavy metals (Lead, Mercury, Arsenic) Poisoning,	2
4.2	Pesticide and Opioid Poisoning and treatment	1
	TOTAL	**48**

Books:
Latest editions of following books to be adopted

1. Goodman & Gilman's Pharmacological Basis of Therapeutics, McGraw Hill Companies Inc.
2. Satoskar R.S. Bhandarkar S.D. & Rege N.N. Pharmacology & Therapeutics, Popular Prakashan.
3. Rang & Dale Pharmacology, Churchill Livingstone.
4. Lippincott's Illustrated Reviews: Pharmacology- Lippincott-Raven Howland & Nyeets Publishers NY.
5. Laurence D.R. & Bennett Clinical Pharmacology, Elsevier NY.
6. Kulkarni S.K. Handbook of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
7. B.G.Katzung-Basic and Clinical Pharmacology, Appleton and Lange publications.
8. Ghosh M.N. Fundamental of Experimental Pharmacology. Hilton and company, Kolkata

BPH_C_705_T – Pharmaceutical Jurisprudence- (3 Hr/Wk)

Course Objectives

To impart knowledge on important legislations related to the profession of Pharmacy

Course Outcomes

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

1. Interpret Pharmaceutical Legislation
2. Understand pricing of drugs & pharmaceuticals
3. Summarize offences & penalties concerned with laws for drugs and pharmaceuticals
4. Gain an insight into Drug Regulatory Affairs

No.	Details	Hours
1	Pharmaceutical Legislation – A brief review of Historical perspectives, Study of Drugs Enquiry Committee (Chopra Committee), Hathi Committee, Dr Mashelkar Committee	**1**
2	**PHARMACY ACT 1948**	
2.1	Definitions	**0.5**
2.2	Pharmacy Council of India and State Councils: Composition and Functions	
2.3	Registration of Pharmacists: Preparation of registers and qualifications for entry into registers	**2**
2.4	Educational Regulations and Approval of Courses and Institutions	
2.5	Offences and Penalties	
2.6	Pharmacy Practice Regulations, 2015	**1**
3	**DRUGS AND COSMETICS ACT 1940 AND RULES 1945**	
3.1	Definitions	**0.5**
3.2	Advisory Bodies: DTAB and DCC: Composition and Function	**2**
3.3	Analytical Bodies: Drug control Laboratories and Government Analyst	
3.4	Executive Bodies: Licensing Authorities, Controlling Authorities, Drug Inspectors and Customs Collectors	
3.5	Provisions regarding Import of Drugs	**3**
3.6	Provisions regarding Manufacture of Drugs	
3.7	Provisions regarding Sale of Drugs	
3.8	Labeling and Packing of Drugs	**1**
3.9	Provisions applicable to Manufacture, Sale, labeling and Packing of Ayurvedic Drugs	**1**

3.10	Provisions applicable to Import, Manufacture, Sale, labeling and Packing of Homeopathic Drugs	**1**
3.11	Provisions applicable to Import, Manufacture, Sale, labeling and Packing of Cosmetics	**1**
3.12	Offences and penalties	**1**
3.13	Schedules to the Drugs and Cosmetics Act & Rules (in brief), Schedule M and Schedule Y in moderate details	**1**
3.14	Self-study: Case Studies	
4.0	**DRUGS AND MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENTS) ACT 1954 & RULES 1955**	**2**
4.1	Definitions	
4.2	Prohibited Advertisements, Savings	
4.3	Self-study: Case Studies	
5	**NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT & RULES 1985**	**2**
5.1	Definitions	
5.2	Narcotics Commissioner and other Officers	
5.3	Illicit Traffic and measures to prevent illicit traffic of opium	
5.4	Essential Narcotic Drugs, Recognized Medical Institutions	
5.4	Offences and penalties	
6	**DRUGS PRICES CONTROL ORDER 2013**	**2**
6.1	Definitions	
6.2	Calculation, fixation, revision of ceiling / retail price for a scheduled formulation and its monitoring	
6.3	Display of prices of non-scheduled formulations and price list thereof and Sale of splitSS quantities of formulations	
6.4	Manufacturer, distributor or dealer not to refuse sale of drug	
6.5	National List of Essential Medicines and Schedule I	
6.6	Draft Pharmaceutical Policy – 2017	
7	**MEDICINAL AND TOILET PREPARATIONS (EXCISE DUTIES ACT) 1955**	**2**
7.1	Definitions, restricted and unrestricted preparations	
7.2	Manufacturing in bond and outside bond	
8	**FOOD SAFETY AND STANDARDS ACT 2006 AND RULES 2011**	**3**
8.1	Definitions: Food, Adulterant and Food additive	
8.2	Authorities and bodies: Food Safety and Standards Authority of India, Central Advisory Committee, Food safety Officer, Commissioner of Food Safety in the State, Analytical Laboratories and Food Analysts	
8.3	Different Food Safety and Standards Regulations	
8.4	Food Safety and Standards (Packaging and Labeling) Regulation, 2011	

9	**INDIAN PATENTS ACT 2005**	**4**
9.1	Intellectual Property and its types, PCT, Different Laws related to Intellectual Property in India	
9.2	Definitions, features of a patent	
9.3	Criteria for patentability and inventions not patentable in India	
9.4	Process of patenting in India	
9.5	Working of Patents, Compulsory Licences	
9.5	Self-study: Case Studies	
10	**BOMBAY SHOPS AND ESTABLISHMENTS ACT**	
10.1	Definitions of Shops and Commercial Establishments and Provisions under the Act in Brief	**1**
11	**FACTORIES ACT 1954**	
11.1	Definitions	**1**
11.2	Provisions under the Act in Brief	
12	**INDIAN PENAL CODE AND CODE OF CRIMINAL PROCEDURES**	
12.1	Provisions pertaining to different courts, jurisdiction and power	**1**
12.2	Provisions governing entry, search, arrest, bailable and non-bailable offences, cognizable and non-cognizable offences	
13	**INTRODUCTION TO DRUG REGULATORY AFFAIRS**	**2**
13.1	Brief overview of Drug Regulatory Agencies of US, Australia, Europe, UK, Japan	
13.2	Introduction to USFDA, European, ICH and WHO guidelines	
	TOTAL	**38**

Books:

Latest editions of the following

1. Kuchekar B. S., Khadtare A. M., Itkar S. C., Pharmaceutical Jurisprudence, Nirali Prakashan.
2. N.K. Jain, Pharmaceutical Jurisprudence, Vallabh Prakashan.
3. Mittal B. M., Forensic Pharmacy, Vallabh Prakashan
4. Deshpande S. W. & Nilesh Gandhi, Drugs & Cosmetics Act; 9th Edition;2018
5. Government of India Publications of above Acts and Rules
6. www.fda.gov
7. www.tga.gov.au
8. www.ema.europa.eu
9. www.mhra.gov.uk
10. www.ich.org
11. www.who.int

BPH_C_706_L – Pharmacognosy Lab II- (4 Hr/Wk)

Course Objectives

1. To study crude drugs representative to major parts of plants for their morphological features and microscopic characters including histology, powder characteristics.
2. To apply the knowledge of microscopic characters of the crude drugs in ascertaining genuinely of powdered formulations.
3. To extract and perform qualitative chemical tests belonging to various classes of phytoconstituents viz. Anthraquinone Glycosides, Cardiac Glycosides, Flavonoids, Cyanogenetic Glycosides, Alkaloids, Triterpenoid and Steroidal Glycosides, Saponins, Tannins.

4. To apply knowledge of analytical procedures in quantitative determination of total Aldehyde content / Phenol content / total alkaloids from crude drugs
5. To understand principles involved and carry out extraction of active constituents
6. To identify crude drugs based on the morphological characters and quote some formulations available in market with their therapeutic utility

Course outcomes

At the end of the course the learner will be able to

1. Identify crude drugs based on morphological characters, microscopic characters and give biological source with the chemical constituents and therapeutic uses
2. Apply the knowledge of microscopic characters in ascertaining the genuinely of powdered formulations.
3. Extract and perform qualitative chemical rests on the crude drugs containing Anthraquinone Glycosides, Cardiac Glycosides, Flavonoids, Cyanogenetic Glycosides, Alkaloids, Triterpenoid and Steroidal Glycosides, Saponins, Tannins
4. Apply analytical procedures and principles for quantitative determination of total Aldehyde content / Phenol content / total alkaloids from crude drugs
5. Understand principles involved apply these for carrying out extraction of active constituents
6. Identify crude drugs based on the morphological characters and quote some formulations available in market with their therapeutic utility

No.	Details	Hours
1	Study of morphology, histology, powder characteristics, Extraction Chemical test, and TLC. (TLC of any 5 drugs) Clove, Fennel, Senna, Cinnamom bark, Ephedra, Kurchi, Liquorice	20
2	To ascertain the authenticity of the powder formulation using microscopy containing drugs listed in topic 1. Qualitative Phytochemical Tests of all phytoconstituents – Anthraquinone Glycosides, Cardiac Glycosides, Flavonoids, Cyanogenetic Glycosides, Alkaloids, Triterpenoid and Steroidal Glycosides, Saponins, Tannins,	8
3	Monograph analysis of 1 herbal drug or 1 herbal excepient from IP	4
4	Estimation of Aldehyde content / Phenol content / total alkaloids from crude drug (Beckett)	4
5	Exercise involving isolation & detection of active principles of any two – Piperine / Caffeine/ eugenol / embelin / rutin)	8
6	To study morphological characters and one marketed formulation of Arjuna, Vasaka, Brahmi, Fenugreek, Garlic, Guggul, Asafoetida, Pepper, Ergot, Mint, Jatamansi, Lemon grass, Digitalis, Vinca, Aloe vera, Vidang, Myrobalans, Dill, Cumin, Lemon grass.	4
	TOTAL	**48**

Books:

1. Trease D. & Evans W. C.: Textbook of Pharmacognosy: W. B. Saunders.
2. Tyler V.E., Brady L.R. & Robbers J. E.: Pharmacognosy; Lea Febiger, USA.
3. Wallis T. E.; Textbook of Pharmacognosy; CBS Publishers, Delhi.
4. Kokate C.K., Purohit A. P. &Gokhale S. B.: Pharmacognosy; Nirali Publications, Pune.
5. Harborne J. B.: Phytochemical Methods: A guide to modern techniques Analysis: Chapman& Hall, London.
6. Bruneton J.: Pharmacognosy, Phytochemistry, Medicinal Plants: Intercept Limited.
7. Vasudevan T.N. & Laddha K.S.: A Textbook of Pharmacognosy, Vrinda Publication House, Jalgaon.
8. The Indian Pharmacopeia: The Controller of Publication; Delhi.
9. Brain K.R. & Turner T. D.: The Practical Evaluation of Phytopharmaceuticals: Wright, Scientica, Bristol.

BPH_C_707_L – Pharmaceutical Analysis Lab III- (4 Hr/Wk)

Course Objectives

On performing the following experiments, the learner should be able 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

The learner should be able to:

1. Record, calculate and interpret data obtained by UV spectrophotometric analysis for pK_a determination and concentration determination by multicomponent analysis techniques.
2. Apply ICH guidelines to validate an analytical method by UV spectroscopy and interpret results obtained.
3. Develop and optimize mobile phase composition for qualitative analysis by TLC and interpret qualitative analysis data by TLC and paper chromatography.
4. Outline working and application of column chromatography, HPLC and GC.

No.	Details
1.	UV spectrophotometric estimation of two components formulation by simultaneous equation method, Eg- Caffeine and Sodium benzoate injection.
2.	UV spectrophotometric estimation of two components formulation by absorbance ratio method, Eg- Caffeine and Sodium benzoate injection.
3.	UV spectrophotometric estimation of formulation by Difference spectroscopy: Eg: Phenylephrine HCl ophthalmic solution.
4.	Assay of Trimethoprim in cotrimoxazole tablets
5.	Determination of concentration of sample by UV spectroscopy (Construction of calibration curve using linear regression analysis). Eg-Ibuprofen.
6.	Determination of validation parameters by UV spectroscopy: Eg-Ibuprofen, Paracetamol. • Linearity • Precision • Accuracy
7.	Separation and identification of compounds by TLC
8.	Determination of pKa by UV spectroscopy eg. Phenylephrine HCl
9.	Demonstration experiments: • Separation and identification of amino acids by paper chromatography. • Development of mobile phase for TLC • Working of HPLC, GC and HPTLC. • Separation of compounds by column chromatography

Note: Examples of drugs are provided for reference purpose only. Any other suitable drug can also be used.

Books:

1. A.H. Beckett and J.B. Stenlake, *Practical Pharmaceutical Chemistry*, 4th Edn., Part I and II, CBS Publishers and Distributors, India.
2. G. D. Christian, *Analytical Chemistry*, 6th Edn., John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd.
3. Indian Pharmacopoeia, The Indian Pharmacopeia Commission, Ghaziabad, Government of India.
4. United States Pharmacopeia.
5. J. Mendham, R. C. Denney, J. D. Barnes, M.J. K. Thomas, Vogel's Textbook of Quantitative Chemical Analysis, Pearson Education Ltd.
6. D.G. Watson, *Pharmaceutical Analysis –A textbook for pharmacy students and pharmaceutical chemists*. 3rd Edn., Churchill Livingstone Elsevier.
7. L. R. Snyder, J. J. Kirkland, J. L. Glajch, *Practical HPLC Method Development*, 2nd Edn., Wiley-Interscience publication, John Wiley & Sons, Inc., Canada.
8. S. Ahuja and M. W. Dong, Handbook of Pharmaceutical Analysis by HPLC, Volume of Separation Science and Technology, Elsevier Academic Press, Indian edition.

BPH_C_708_L– Pharmacology Lab II- (4 Hr/Wk)

Course prerequisites:

- Ability to perform *in vitro* "dose response" experiments using cock ileum.

Course objectives:

1. Practical training on performing Bioassay of acetylcholine and atropine using cock ileum.
2. Demonstration of oxytocin bioassay and behavioural experiments using interactive CDs.
3. Information on Regulatory and toxicity guidelines.

Course outcomes:

1. Define Bioassay, list the types, methods and applications of bioassay and perform *in vitro* bioassay using cock ileum and record, calculate and interpret unknown concentration of agonist/antagonist/drug.

2. Observe preclinical models which provide evidences on drug/lead pharmacological activity.
3. Relate to and apply the ethical, regulatory and toxicity guidelines/rules (ICH, OECD, CPCSEA, Schedule Y) in drug/lead testing using preclinical animals.

No.	Details
1.	**Experiments:** 1. Bioassay of Acetylcholine using suitable isolated tissue preparation e.g. Cock ileum 2. Bioassay of Atropine using suitable isolated tissue preparation e.g. Cock ileum
2.	**Demonstrations: (with kymograph recordings or audio-visual aids)** 1. Bioassay of oxytocin 2. Behavioral Pharmacology Demonstrations/ Simulated experiments (CDs). • To study effect of drugs on locomotor activity in rodents using actophotometer. • To study the muscle relaxant property of drug using Rota-rod. • To study analgesic activity of drug using an analgesiometer. • To study anticonvulsant activity of drugs using maximal electroshock/ chemically induced seizures. • To study phenothiazines induced catalepsy using suitable animal model.
3.	**Toxicity studies** • Introduction to CPCSEA, OECD guidelines • Introduction to acute, sub-acute and chronic toxicity studies

Books:

Latest editions of the following books to be adopted:

1. Kulkarni S. K. Handbook of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
2. Ghosh M.N. Fundamentals of Experimental Pharmacology Hilton & Company, Kolkata.
3. S. B. Kasture. A handbook of Experiments in Pre-Clinical Pharmacology, Career Publications.
4. W. L. M. Perry, Pharmacological Experiments on isolated preparations, E & S Livingstone, Edinburg & London.
5. Patil C. R. X-cology (Software), Pragati Book Co. Pvt. Ltd, Pune.

ANY ONE SUBJECT FROM THE FOLLOWING 2 CREDIT SUBJECTS TO BE CHOSEN AS ELECTIVE FOR A TOTAL OF 2 CREDITS

BPH_E_709_T – Intellectual Property Rights- (2 Hr/Wk)

Course Objectives

The course is framed to impart knowledge to the learners so that they get conversant with the Fundamentals of Intellectual property Rights (IPR), their types and governing laws.

Course Outcomes

1. Correlate the knowledge of IPR with respect to pharmaceutical products.
2. Apply knowledge of IPR in designing strategy for pharmaceutical product development.

No.	Details	Hours
1	Intellectual Property Rights (IPR) – Introduction, definition, need history	2
2	Patents – Introduction, Indian Patent Act (1970), Patent and claim drafting, Process of filing and prosecution, Rights achieved, Patentability with respect to Regional/ country's Requirement, Opposition of Patent Self-Study - Case Study Presentations	8 1
3	Industrial Design – Introduction, filing and prosecution	2
4	Geographical Indication - Introduction, filing and prosecution	1
5	Natural biodiversity Act and Depository Bodies – Introduction and filing procedure	1
6	Patent Filing under PCT (Paris Convention Treaty/Patent Convention Treaty) - Introduction, filing and prosecution, territorial specificity	3
7	Trademark – Introduction, filing and prosecution, opposition to trademark	3
8	Copyright – Introduction, filing and prosecution	1
9	Role of IPR in pharmaceutical product launch	1
10	IPR infringement and remedies	1
	TOTAL	24

Books:

1. Intellectual Property Law, P. Narayanan, , Eastern Law House, Revised Edition, 2017.
2. www.wipo.int (World Intellectual Property Organization)
3. Indian Patent Act (www.ipindia.nic.in)

BPH_E_710_T – Green Chemistry and Catalysis- (2 Hr/Wk)

Course Objective

1. To introduce the learner with principles of green chemistry.
2. To study the source, disposal and prevention of chemical waste.
3. To learn basic level environmental management system.
4. To learn and select various kinds of catalysis with respect to industrial case studies.

Course Outcomes

The learner should be able to:

1. Know the terms involved in green chemistry.
2. Understand the concept and techniques of waste management.
3. Know various guidelines of environmental management system.
4. Outline type of catalysis and their uses.
5. Learn greener process designing.

No.	Details	Hours
1	Principles and Concepts of Green Chemistry	**2**
1.1	Introduction and Twelve principles	
1.2	Sustainable development and green chemistry	
1.3	Atom economy, Atom economic reactions like rearrangement and addition reactions, Atom uneconomic reactions like substitution, elimination	
1.4	Reducing and measuring toxicity, E-Factor	
2	Waste: Production, problems and prevention	**3**
2.1	Introduction, Problems caused by waste	
2.2	Sources of waste from chemical industry, cost of waste	
2.3	Waste minimization techniques: Approach, Process design, minimizing waste from existing resources	
2.4	Treatment of waste: Physical, Chemical, Biotreatment	
2.5	Design for degradation: Degradation and surfactants, DDT, Polymer	
2.6	Polymer recycling: Separation and sorting, Incineration, Mechanical and chemical recycling of monomers	
3	Environmental Management Systems (EMS) ISO 4000, The European Eco-Management and Audit Scheme (EMAS)	**2**
3.1	Introduction to Life Cycle assessment system (LCA): Four stages, carbon foot printing	
3.2	Eco labels, Integration Pollution Prevention and Control (IPPC), REACH	
4	Catalysis and Green Chemistry	**4**
4.1	Introduction to catalysis, comparison of catalyst types	
4.2	Heterogeneous catalysts: Basics, Zeolites and bulk chemical industry, heterogeneous catalyst in Fine chemicals and pharmaceutical Industry, Catalytic converters	
4.3	Homogeneous catalysts: Basics, Transition metal catalysts, Greener lewis catalyst, asymmetric catalyst	
4.4	Phase transfer catalysis: Basics, hazard reduction, C-C bond formation, oxidation using H_2O_2	
4.5	Biocatalysis, Photocatalysis	
5	Use of solvents	**4**
5.1	Organic solvents and volatile organic compounds, solvent free system, Supercritical fluids, $scCO_2$,scH_2O	
5.2	Water as reaction solvent	
5.3	Ionic liquids as solvent and catalyst, Fluorous biophase solvents,	
5.4	Greenness of solvent a comparison	
6	Renewable resources	**2**
6.1	Biomass as renewable resource, Energy: from biomass, solar power, fuel cells	
6.2	Chemicals from renewable feedstock: from fatty acids, polymers, natural resources	
7	Emerging Greener technology	**3**
7.1	Photochemical reactions: Advantages and challenges, examples	
7.2	Microwave assisted chemistry: Microwave heating and examples	

7.3	Sonochemistry, Electrochemistry with examples	
8	Designing green process	**2**
8.1	Conventional reactors: Batch reactors, continuous reactors	
8.2	Inherently safer design using concept of minimization, simplification, substitution, moderation, limitation	
8.3	Process intensification: PI equipment with examples of intensified processes	
8.4	In-process monitoring, Process safety	
9	Industrial case studies: Methyl Methcrylate, acetic acid manufacturing, Vitamin C, Dyes, Naproxen, Ibuoprofen	**2**
	TOTAL	**24**

Books:

1. Green Chemistry: An Introductory Text, Mike Lancaster, 2nd edition, RSC publishing.
2. Green Chemistry: Theory and Practice, Anastas P T and Warner J C, Oxford University Press.
3. Introduction to Green Chemistry, Ryan M. A., Tinnesand M., American Chemical Society (Washington).
4. Handbook of Green Chemistry and Technology, Clarke J and Macquarrie D, Blackwell.

BPH_E_711_T – Preformulation Studies- (2 Hr/Wk)

Course Objectives

On completion of the course the learner will be able to understand the importance of physicochemical properties of a drug candidate in design and development of an effective, stable, acceptable and safe formulation

Course Outcomes

At the end of the course the learners will be able to:

1. Explain physicochemical principles relevant to pharmaceutical dosage forms.
2. Comprehend the importance of solubility, stability and compatibility of drug substances with different excipients
3. Understand the role of preformulation studies in drug discovery, drug and product development

No	Details	Hours
1	**Drug Discovery and Development Process in the Pharmaceutical Industry-** Need, Hurdles faced, Scheme of Steps in New Drug Development Process. **The concept of preformulation -**Goals and scope of preformulation, Basic information for designing preformulation studies. **Principal areas of Preformulation research**	**3**
2	**Bulk Characterization**	**10**
2.1	Organoleptic properties: Appearance, odour and taste, Hygroscopicity	1
2.2	Crystallinity & Polymorphism: Crystal morphology & Crystal habit, Pseudopolymorphism (solvates), True polymorphism. Methods to characterize polymorphs-Melting point determination, Hot-stage microscopy, Differential scanning calorimetry and thermal analysis, PXRD (basic principles of the methods only)	3
2.3	Fine particle characterization - Particle size distribution measurements, Microscopy, sieve analysis. Laser diffraction method (basic principle) Particle Size Reduction, effect of milling and micronization,	3
2.4	Powder flow and Compression properties**:** Bulk density, void volume, Carr's compressibility, Hausner's ratio, Angle of repose. Deformation behaviour of particles under the influence of applied forces-Elastic & Plastic deformation, Fragmentation, Punch filming (sticking).	3
3	**Solubility**	**7**
3.1	Aqueous solubility: Intrinsic solubility (K_0), pK_a determination, pH solubility profile and Common ion effect, effect of temperature, Techniques of solubilization-Co solvents, Chelating agents, Surfactants Complexation.	4
3.2	Dissolution: Intrinsic dissolution rate, Measurement of intrinsic dissolution rate Partition coefficient ($K_{o/w}$): Significance in preformulation studies as predictor of *in vivo* absorption, methods to determine partition coefficient	3
4	**Stability** Temperature, Order of reaction, Hydrolysis, Oxidation, photolysis **(Self-study with follow up)** Solid-state stability: bulk stability, effect of high humidity Compatibility in presence of excipients Solution phase stability: pH stability profile	**3**

5	Preformulation aspects for development of Tablets and Monophasic liquid dosage forms	**1**
	TOTAL	**24**

Books:

1. M.E. Aulton. Pharmaceutics: The Design and manufacture of medicines. Third edition. 2007. Churchill Livingstone Elsivier.
2. David B. Troy, Paul Beringer. Remington's - The Science and Practice of Pharmacy. Twenty first Edition. 2006. Lippincot Williams & Wilkins.
3. Mark Gibson. Pharmaceutical Preformulation and Formulation: A Practical Guide from candidate selection to commercial dosage form. Second edition. Informa Healthcare.
4. Leon Lachman, Herbert A. Lieberman. Theory and Practice of Industrial Pharmacy. Special Indian edition. 2009; CBS Publishers.
5. Herbert Lieberman, Leon Lachman, Joseph B. Schwartz. Pharmaceutical Dosage Forms: Tablets, Volume 1. 1989. Second Edition. Marcel Dekker Inc. NY

SEMESTER-VIII

BPH_C_801_T – Pharmaceutical Chemistry III- (4 Hr/Wk)

Course Objectives

1. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of CNS active drugs like sedatives/hypnotics, anticonvulsants, antidepressants, anxiolytics and antipsychotics
2. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of ANS active drugs like adrenergic and cholinergic agents
3. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of testosterons and adrenocorticoids

Course Outcome

Students will gain knowledge in the thurst areas of CNS, ANS active drugs, analgesic agents and male female hormones. They will be apply this knowledge in research areas.

No.	Details	Hours
	Discussion of the following classes of drugs including classification, chemical nomenclature, structure including stereochemistry, generic names, SAR and metabolism, molecular mechanism of action, synthesis(*) and rational development if any	
1	**CNS Drugs**	
1.1	Sedatives – Hypnotics Benzodiadepines: chlordiazepoxide, diazepam, nitrazepam*, temazepam, alprazolam, estazolam; zolpidem, eszopiclone, ramelteon (last 3 for self study – 1 hr).	3
1.2	Anticonvulsants Types of seizures (Self study- 1 hr) phenytoin, mephenytoin, ethotoin, trimethadione, diazepam, clonazepam, carbamazepine*, valproic acid, vigabatrine, progabide, lamotrigine, tiagabine	3 1
1.3	Antidepressants imipramine*, chlorimipramine, amitriptyline, nortriptyline, doxepine* fluoxetine*, paroxetine, sertraline, escitalopram, amoxapine	3
1.4	Anxiolytics Oxazepam, buspirone	1
1.5	Antipsychotics chlorpromazine*, triflupromazine, thioridazine, fluphenazine, trifluperazine, chlorprothixen(self study), droperidol , pimozide, risperidone, loxapine, clozapine, sulpiride	4
1.6	Antiparkinson's carbidopa, levodopa, selegiline, amantadine, benztropine, procyclidine, orphenadrine (last 3 for self study- 1 hr)	1
2	**ANS Drugs**	
2.1	Adrenergic Drugs Alpha adrenergic agonists: phenylephrine*, naphazoline, xylometazoline, oxymetazoline, methyldopa, clonidine, guanabenz, guanafacine Beta agonists : Isoproterenol, colterol, metaproterenol, terbutaline*, albuterol, isoxsuprine, ritodrine Alpha antagonist : tolazoline, phentolamine, phenoxybenzamine, prazosin, doxazosin Beta Antagonists : pronethalol, propranolol*, sotalol, timolol, atenolol, metoprolol, esmolol, acebutolol, carvedilol, labetalol* (last two for self study, including synthesis of labetalol) Other adrenergic agents (Self study-2 hrs) : pseudoephedrine, ephedrine, guanethidine, propylhexedrine, reserpine	7
2.2	Cholinergic Drugs Muscarinic agonists : methacholine, carbachol, bethanechol, pilocarpine Acetylcholineesteraseinhibitors : physostigmine, neostigmine*, pyridostigmine, edrophonium, echothiophate, malathion, parathion, pralidoxime AntiAlzheimer's :Tacrine*, donepezil, rivastigmine	7

	Cholinergic antagonists : Atropine, scopolamine, homatropine, ipratropium cyclopentolate*, dicyclomine*, benztropine, procyclidine, isopropamide, tropicamide Neuromuscular blockers :(Self study) tubocurarine, gallamine, succinylcholine, decamethonium	
3.	**Analgesic Drugs**	
3.1	Opioid peptides(Self study) Different types of opioid receptors, Potuguese and Becket Casy model, agonists, partial agonists and antagonists of these receptors Morphine, codeine, levorphanol, buprenorphine, phenazocine, pentazocine, meperidine*, alpha and beta prodine, pheniridine, anileridine, fentanyl, methadone, dextropropoxyphene*, tramadol, nalorphine, naloxone, naltrexone, flupirtine Antidiarrhoeals (Self study-1 hr) : loperamide, diphenoxylate	6
3.2	NSAIDS paracetamol, aspirin, indomethacin, sulindac, mefenamic acid, ibuprofen, naproxen*, nabumetone, diclofenac*, piroxicam*, nimesulide, celecoxib, valdecoxib. Cytokine inhibitors :(Self study-1 hr) infliximab, rituximab, anakinra, abatacept Drugs in Gout : colchicine, probenecid, sulfinpyrazone, allopurinol, febuxostat	5
4	**Drugs affecting Male and Female Health (Steroids)**	
4.1	Testosterone, 17-alphamethyltestosterone, oxymesterone, fluoxymesterone, stanazolol, danazol (Self study) estradiol, ethinyl estradiol, mestranol, medroxyprogesterone acetate, megestrol acetate, norethindrone, norgestrel, diethylstilbestrol*(Synthesis for self study), clomiphene (Self study), tamoxifen, anastrozole, letrozole, exemestane (Self study-1 hr) medroxy progesterone acetate, megesterol acetate, norethindrone and norgestrel	3
4.2	Adrenocorticosteroids cortisone, hydrocortisone, prednisone, prednisolone, dexamethasone and betamethasone, flurometholone, fluocinolone, triamcinolone, aldosterone, fludrocortisone	2
	TOTAL	**48**

Books:
Same as prescribed for Pharm. Chem. – III

BPH_C_802_T – Pharmaceutics IV- (4 Hr/Wk)

Course Objectives

To provide detailed insights into formulation and technology of sterile products including parenterals and ophthalmic dosage form, to orient students about oral sustained and controlled release systems, to introduce important pharmacokinetics models and parameters and to familiarize students with the concept of Pilot plant, Validation, cGMP etc. as important quality management systems in the pharmaceutical industry.

Course Outcomes

Upon completion of the course, the learner shall be able to:
1. Apply the knowledge of sterile technology in designing safe and effective injectables and ophthalmic products
2. Study the rationale for oral SR/CR products, principles of design, development and evaluation of SR formulations
3. Understand the concepts of validation and pilot plant scale up for large scale manufacturing operations
4. Understand the concept of biopharmaceutics and significance of various pharmacokinetic parameters

No.	Details	Hours
1	**Introduction to sterile dosage forms - Parenteral products**	**12**
1.1	Various routes of parenteral administration, pyrogens, vehicle, Water for Injection (WFI) - preparation, purity, storage and distribution, vehicles other than WFI, additives in parenteral products.	3
1.2	Containers - glass and plastics- types and evaluation, rubber closures – characteristics and testing.	2
1.3	Personnel, Manufacturing facilities- layout, environmental control, cleanliness classes, air handling (HVAC systems), HEPA filters, laminar flow	2
1.4	SVP: formulation considerations- solutions, suspensions, product procedures, freeze drying.	2
1.5	LVP – types, formulation aspects, packaging, FFS technology.	2
1.6	QA & QC- sterility test, pyrogen/ endotoxin test, particulate evaluation, leaker test.	1

2	**Ophthalmic Products**	**5**
2.1	Physiology of eye, lachrymal system, tears, precorneal tear film, cornea, ocular bioavailability	1
2.2	a) Formulations - additives and packaging of various ophthalmic products - solutions, suspension, ophthalmic ointments and gels, preservatives and efficacy test b) Contact lens solutions: types of lenses, cleaning solution, disinfection solution, lubricants, multipurpose solutions and packages	3
2.3	QA and QC - sterility test, clarity, particle size for suspension, tests on ointments and collapsible tubes	1
3	**Oral sustained and controlled release systems**	**6**
	Need, definitions, Advantages of SR & CR systems, biopharmaceutical considerations; Properties of drug with reference to the design of oral SR systems Dose calculation of drug, calculation for dose- loading and maintenance	2
3.2	Matrix and reservoir type of systems, dissolution-controlled systems, diffusion-controlled systems, ion exchange-controlled systems	3
3.3	Evaluation of sustained release systems	1
4	**Microencapsulation**	**5**
4.1	Definition, need/ reasons, concepts of core and coat	1
4.2	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 Evaluation of microcapsules	4
5	**Introduction to Industrial Pharmacy**	**6**
5.1	Pilot plant scale up techniques: Need, components, Factors considered while scaling up of formulations: Mention the points for tablets, liquids (suspension, solutions, emulsions) and semisolids	2
5.2	Validation: Definition, Types- Prospective, concurrent, Retrospective and revalidation. Qualification of equipment-design, installation, operational, performance	2
5.3	Factory Layout: schedule M - general considerations/ steps, Examples of Typical layout schemes for Tablets, capsule, liquids, sterile formulations manufacturing areas **(Individual layouts- Assignment with follow up)**	2
6	**Introduction to NDDS**	**8**
6.1	Advantages of NDDS, concept of targeting-Active & Passive targeting	1
6.2	Concept, design and one suitable application of a typical system of following NDDS: a) Floating gastro-retentive systems, b) Colon targeted drug delivery systems, c) Mucoadhesive drug delivery systems, d) Osmotic systems, e) Transdermal DDS (membrane permeation systems), f) Ocular inserts, g) Colloidal DDS (liposomes, nanoparticles, microemulsions),	7 **1 hour for each system**
8	**Introduction to Pharmacokinetics**	**6**
8.1	Definitions: Pharmacokinetics, ADME, bioavailability absolute and relative, bioequivalence. Emphasis on the importance in drug discovery, development and clinical pharmacy	1
8.2	Pharmacokinetics: Introduction to compartmental and physiological models. Introduction to the one compartmental open model and its assumptions	1
8.3	One compartment open model: IV bolus dosing: importance of volume of Distribution. Clearance, elimination rate constant, half-life, area under the curve (trapezoidal rule)	2
8.4	One compartment open Model: Extra-vascular dosing. Absorption rate constant, absorption half -life, bioavailability. Introduction of the Concept of Cmax, T_{max}, area under the curve, the trapezoidal rule and the method of Residuals.	2
	TOTAL	**48**

Books:
Latest Editions

1. The theory and practice of Industrial Pharmacy, Ed. Leon Lachman, H. A. Liberman, J. L. Kanig; Varghese Publishing House.
2. Remington, The science and practice of Pharmacy, Vols. I and II, B. L. Publications Pvt. Ltd.
3. Cole Graham, Pharmaceutical Production Facilities, Design and Applications.
4. Pharmaceutical Process Validation, Nash Robert A., Berry Ira R., Volume 57, Marcell Dekker INC, New York.

5. Pharmaceutical Dosage Forms: Parenteral medications. Vols. I, II, III, Ed Kenneth A. Avis, Leon Lachman and H. A. Liberman, Marcel Dekker INC.
6. Pharmacetuical Technology, Vols. I, II, R S R Murthy, Ashutosh Kar, New Age Int. Ltd.
7. Pharmaceutical dosage forms: Parental medications, Vol. I, II, III, ed. by Kenneth A. Avis, Leon Lachman and H. A. Liberman, Marcel Dekker Inc., 1986.
8. Pharmaceutics. The Science of dosage form design ed. by M. E. Aulton, 2 nd ed., Churchill Livingstone, 2002.
9. Modern Pharmaceutics, 4 th ed. Revised and Expanded ed. by Gilbert S. Banker and Christopher T. Rhodes, Marcel Dekker INC., 2002.
10. The theory and practice of industrial pharmacy, ed. by Leon Lachman, H. A. Liberman, J. I. Kanig, 3 rd ed., Verghese Publishing house, 1987.
11. Ophthalmic drug delivery, ed. by Ashim K. Mitra, 1993, Marcel Dekker INC.
12. Turco and Kings, Sterile Dosage forms, 3 rd Edn., Lea & Febiger, Philadelphia, 1985.
13. Michael J. Akers, Quality Control of Parenterals, Marcel Dekker
14. Controlled drug delivery – Fundamentals and Applications", Robinson Joseph R., Lee Vincent H., Vol. 29, Marcel Dekker Inc
15. Leon Shargel, Susanna Wu – Pong, Andrew B.C, Applied Biopharmaceutics and Pharmacokinetics, Singapor
16. Brahmankar D.M and Jaiswal Sunil B, Biopharmaceutics and Pharmacokinetics – A Treatise, Vallabh Prakashan.

Note: References to latest amendments of Schedule M and Schedule U of Drugs and Cosmetics Act 1940 to be made wherever it is appropriate

BPH_C_803_L – Pharmaceutical Chemistry Lab II- 4 Hr/Wk)

Course Objectives

1) To introduce the learner to various hands-on experimental organic synthetic techniques including column chromatography and thin layer chromatography.
2) To learn characterization of intermediates and final products by TLC and IR
3) To review important topics such as cyclization, reduction, rearrangement, condensation reactions.
4) To introduce the learner to the concepts of green chemistry.
5) To study the source, disposal and prevention of chemical waste.

Course Outcomes

The learner should be able to

1) Design and perform various unit operations of organic synthetic reactions
2) Characterize reaction intermediates and final products.
3) Know the theoretical concepts behind organic synthesis.
4) Understand the concept and techniques of waste management.

Synthesis of the following Drugs and Drug Intermediates

1. Synthesis of Benzilic Acid: Conventional Method and Green Modification as in Green Chemistry DST Monograph
2. Three Component Synthesis of Pyrimidone using Ethylacetoacetate, Benzaldehyde and Urea as per Green Chemistry DST Monograph
3. Hofmann rearrangement: Anthranilic acid from Phthalimide.
4. Reduction reaction: PABA from *p*-nitrobenzoic acid.
5. Pechmann condensation for coumarin synthesis using clay catalyst (Clay catalyzed solid state synthesis of 7-hydroxy-4-methylcoumarin).
6. Synthesis of resacetophenone (Ref. Vogel page 983)
7. Synthesis of 4-methylcarbostyryl (old syllabus experiment)
8. Synthesis of Phenytoin
9. Synthesis of Hippuric Acid (https://www.linfield.edu/assets/files/chem/Courses/CHEM%20322/3bAmide_synthesis_2015.pdf)

Or Synthesis of adipic acid (Ref. DST Monograph pg. 38)

Monitoring the progress of any two reactions by using TLC: Aim is to only monitor the completion of the reaction under consideration. Student can comment on status of the reaction (completion/ incompletion) using TLC; they must develop the solvent system

Books:

1. Vogel's A Text book of Practical Organic Chemistry by Vogel, Longman group limited, London.
2. Practical Organic Chemistry by Mann FC & Saunders BC, Longman Group Limited, London.
3. Laboratory Techniques in Organic Chemistry, Ahluwalia V.K. I.K. Publishers.
4. Green Chemistry, V. K. Ahluwalia.

5. New Trends in Green Chemistry, V K Ahluwalia and M Kidwai, KluwerAcademic Publishers
6. Monograph on Green laboratory Experiments, Grenn Chemistry Task Force Committee, DST.
7. Practical Organic Synthesis: A Student's Guide - Reinhart Keese, Martin Brändle, Trevor Toube.
8. Advanced practical Medicinal Chemistry by Ashutosh Kar, New Age International Publications.

BPH_C_804_L – Pharmaceutics Lab IV- (4 Hr/Wk)

Course Objectives

To train the learner with the practical aspects of formulation, manufacturing and quality control tests of parenteral and ophthalmic products.

Course Outcomes

Upon completion of the course, the learner shall be able to:
1. Demonstrate the intricacies of formulation and development of parenterals and ophthalmic products.
2. Understand and know about quality control and documentation of a manufacturing process.
3. Know about the pharmacopoeial tests for these products and their packaging materials.
4. Explain the concept of dissolution testing as an important quality control tool and relate to its importance from regulatory point of view.
5. Apply pharmacokinetic principles of oral routes of administration.
6. Demonstrate oral and written communication skills and ability to plan the experimentation with proper time management

EXPERIMENTS

No.	Details
1	Preparation & Testing of WFI as per IP
2	Processing and monographic testing of Glass containers and rubber closures as per IP.
3	Preparation and documentation of the following injections: a. Calcium Gluconate injection IP b. Ascorbic acid injection IP. c. Sodium chloride & Dextrose Injection IP
4	Preparation and documentation of following ophthalmic products: a. Sulphacetamide eye drops, IP b. Official antibiotic eye ointment (any one)
5	Preparation and *in vitro* release evaluation of sustained release oral tablets (matrix type)
6	Dissolution testing of marketed formulations of conventional tablets containing poorlywater soluble drug (selection of medium)
7	Calculations of pharmacokinetic parameters -i.v. administration (plasma samples provided).
8	Microencapsulation of solid/liquid core using phase separation coacervation technique
9	Preparation and evaluation of mucoadhesive buccal formulation (tablet/film)
10	Validation of process- mixing/milling
11	Assignment on SOP's of dissolution apparatus/tablet press/coating equipment
12	Assignment on excipient/API specifications. (One example of each)

Books:
All books listed in the theory syllabus as well as Current editions of IP, BP and USP.

BPH_E_805_D– Project- (12 Hr/Wk)

ANY TWO SUBJECTS FROM THE FOLLOWING 4 CREDIT SUBJECTS TO BE CHOSEN AS ELECTIVES FOR A TOTAL OF 8 CREDITS

BPH_E_806_T – Phytopharmaceutical Technology- (4 Hr/Wk)

Course Objectives

1. To make learners aware of various terms used in Phytopharmaceuticals and understand the concept of standardization of natural products utilized in cosmetics, medicine and as nutraceuticals.
2. To understand industrial preparation of standardized extracts and isolation of phytoconstitutents.
3. To give an insight towards various Conventional and Novel Drug Delivery Systems (NDDS) of Herbal medicines and the challenges faced along with the bioavailability aspects of Herbal formulations.
4. To introduce the concepts of QC and QA of Phytopharmaceuticals.
5. To learn role of herbs as Nutraceutical remedies for common disorders and in cosmeticeuticals.
6. To study the regulatory requirements for phytopharmaceuticals and Traditional Digital Knowledge Library (TKDL)

Course Outcomes

Upon completion of the course learners will be able to –
1. Understand terms related to phytopharmaceuticals and standardization of Natural Products.
2. Explain industrial preparation of standardized extracts, isolation of phytoconstitutents and their applications.
3. Discuss the challenges faced in formulation of conventional and NDDS of herbal medicines.
4. Explain the applications of QC and QA of Phytopharmaceuticals.
5. To suggest the use of herbs as nutraceuticals in common disorders and cosmeticeuticals.
6. Describe the regulatory requirements for phytopharmaceuticals.

No	Topics	Hours
1	**Introduction to the terms** Phytopharmaceutical Technology – Phytopharmaceuticals, Active ingredient, Botanical Drug Substance, Ethnomedicine, Herbal Medicine, Phytomedicine, Phytopharmaceutical Science, Regulatory affairs, Traditional medicine, Folklore medicine, Herbal medicine, Finished herbal product, Pharmaco-vigilance of herbals, Phytopharmacoepidemology and Phytopharmacoeconomics.	3
2	**Herbal Extracts** Processing and authentication, Introduction to Preparation and Types of extracts with suitable examples – liquid, solid, semisolid, dried and powdered Large scale industrial method for preparation of extracts, Process and equipment: Names of equipment and their uses, merits and demerits in the unit operations of size reduction, Extraction, Filtration, Evaporation/ Distillation, Drying of Extracts	8
3	**Formulations and drug delivery system** A) Methods of preparations and evaluation of Herbal Tablets, Capsules, topical and liquid oral dosage forms. Study of any two examples of formulations under each dosage form with respect to their formulae and activities / claims of each ingredient used in them. B) NDDS of Herbal medicine: Limitation of Conventional, Challenges in Development of NDDS of Herbal medicine, Phytosomes, Nanocarriers, Transdermal with one example each. Use of Bio-enhancers in formulation development of herbal products. Labeling of Phyto-pharmaceuticals. Preservation of Phyto-pharmaceuticals	8
4	**Quality Assurance and Quality Control of Phytopharmaceuticals** A) For Herbal Extracts: Q.A by cultivation and Breeding, Standardized extracts –Quantitative standardization using different types of Marker Compound. Stability testing of Herbal extracts. B) For Formulations: Stability of herbal formulation, Bioavailability of Phytoconstituents from Herbal Formulations – Factors affecting bioavailability and pharmacokinetics of some herbal drugs and phytoconstituents.	4
5	**Herbs as Phytopharmaceutical Products** Occurrence, Structure, Pharmacology, Metabolism and Pharmacokinetics, Therapeutic uses, Recommended doses and Marketed preparations, Toxicity and Regulatory status of the following – Ephedra Alkaloids, Ginger, Garlic, Kava kava, Ginkgo Biloba, Valerian, Chammomile, Echinacea, Panax Ginseng, Cranberry, Acoruscalamus, Comfrey, Tomato, Liquorice, Senna, Cascara.	8
6	**Non-Nutritive Sweeteners from Natural sources** Preparation, evaluation and salient features of Steveosides, Thaumatin, Glycyrrhizin.	2
7	**Herbal Cosmeceuticals** Role of Herbs and phytoconstituents in the following categories of cosmetic preparations. Formulation aspects of the following cosmetic preparations and their market potential • Skin cosmetics – herbs used as Fairness agents- Turmeric (Curcumin), Uvaursi (Arbutin) Moisturizers – Aloe vera (mannans), Coriander seed oil (SELENOL)	8

	Anti-ageing agents- **Rose and rosehip** (*Rosa canina*), **Chamomile** (*Matricariachamomilla*) Face packs -Apricot, Orange peel • Colour cosmetics advantages of natural dyes and colourants– Onosmaechioides, Carthamine, Bixin - their use in lipsticks, rouges, eye shadows • Cosmetic products for eyes – Butcher's broom, Chammomile • Hair cosmetics – Colouring of hair- Tea extracts, Amla, Henna Herbs used in improving health of hair -shampoos, oils, conditioners. (Any two examples) • Dental hygiene Products: *Salvadorepersica*, clove, neem	
8	**Industrial production and estimation of the following phytoconstituents** Preparation of their derivatives and products Alkaloids -Berberine Carotenoids- Capsanthin Flavonoids- Naringenin, Hesperidin Terpenoids- Citral, Forskolin, Gymnemic acid Steroids -Diosgenin Carbohydrates-Pectin	**4**
9	**Regulatory issues in Phytomedicine** Indian and International requirements. TKDL (Traditional Knowledge Digital Library), Certification of Phytodrug industry. (DSHE) Dietary Supplement Health and Education. Acts related to banned or restricted phytoingredients. Standardization Regulation for labeling purpose.	**3**
	TOTAL	**48**

References:

1. Evidence-Based Validation of Herbal Medicine edited by Pulok K. Mukherjee Business Horizons Publishers
2. Phytotherapies: Efficacy, Safety, and Regulation. Ed Iqbal Ramzan John Wiley and Sons
3. Contemporary Phytomedicines. Amritpal Singh Saroya, CRC press
4. Journal of Ethnopharmacology 140 (2012) 513–518: www.elsevier.com/locate/jethpharm Pharmacovigilance of herbal medicine Shaw Debbiea,, Ladds Graeme B, Duez Pierrec, Williamson Elizabeth D, Chan Kelvine,F
5. Textbook of Pharmacognosy by Trease & Evans.
6. Textbook of Pharmacognosy by Tyler, Brady & Robber.
7. Pharmacognosy by Kokate, Purohit and Gokhale
8. Essential of Pharmacognosy by Dr. S.H. Ansari
9. Pharmacognosy & Phytochemistry by V.D.Rangari
10. Pharmacopoeial standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
11. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002
12. Toxicology and Clinical Pharmacology of Herbal Products,Steven B. Karch, Humana Press
13. Herbal Principles in Cosmetics Properties and Mechanisms of Action, Bruno Burlando, Luisella Verotta, Laura Cornara, and Elisa Bottini-Massa, CRC Press.

BPH_E_807_T – Clinical Pharmacy- (4 Hr/Wk)

Course Prerequisites

- Understanding of Pharmacology and its applications.

Course Objectives

1. Introduction to clinical pharmacy, Role of clinical pharmacist, patient case history, presentation of cases and counselling.
2. Educate on personalized drug therapy taking into consideration general and special population.
3. Teach basics of ADRs and pharmacovigilance.
4. Introduce the concept of therapeutic drug monitoring and its importance in therapy areas like epilepsy, cardiovascular disorders, and others
5. Introduce the concepts of pharmacoepidemiology and pharmacoeconomics

Course Outcomes

1. Relate to the role of pharmacist in different setups like clinics, pharmacies and in the community and appraise the crucial role of pharmacists in patient counselling and eventually in drug adherence and compliance to therapy.
2. Discuss the types, risk factors, classification, methods of detection, monitoring and reporting of ADRs, drug interactions, pharmacovigilance and TDM in normal as well as special populations.
3. Outline the process of drug discovery and development, Ethical Guidelines/Schedules, Role of Ethics Committee, essential documents in clinical trials/research, BA-BE studies and, apply and appreciate the role of GCP in conduct of clinical research.
4. Identify and analyze the trends in drug use to optimize health outcomes.

No.	Details	Hours
1	**Introduction to Clinical Pharmacy:** Concept of Clinical Pharmacy, Community pharmacy and hospital pharmacy (Definition, scope and objectives)	**4**
2	**Pharmacist-Patient Interaction**	**4**
2.1	Patient Counselling: Role of Pharmacist in patient counselling	2
2.2	Patient Compliance, Methods of assessment of compliance, Reason for patient noncompliance, Strategies to improve compliance, Precaution and directions for medication, Administration instructions	2
3	**Adverse Drug reactions:** Epidemiology, Classification, Risk factors, Monitoring, Detecting and reporting of ADR	**5**
4	**Drug interactions:** Types, General Considerations and Mechanisms	**3**
5	**Drug use in special population**	**6**
5.1	Drugs used in Geriatrics	2
5.2	Drugs used in Paediatrics	2
5.3	Drugs used in Pregnancy	2
6	**Therapeutic Drug Monitoring:** Definition, indications and strategies	**2**
7	**Drug discovery & development**	**14**
7.1	Preclinical development	2
7.2	Clinical development-	5
	a. History, terminologies, types of clinical research, phases of clinical trials, role of clinical trial in new drug developments. Ethical issues in clinical trials: Principle of regulatory requirements, responsible conduct, supervision of ethics, (Informed Consent, Independent Ethics Committee, Institutional Review Board)	
7.3	Good Clinical Practice (GCP): Concept and importance	1
7.4	Definitions of essential documents; SOP, protocol, Investigator's brochure,	2
7.5	Introduction to BA/BE studies	2
7.6	Pharmacovigilance: Definition, scope and aims of Pharmacovigilance	2
8	**Pharmacoepidemiology:** Definition, types, methods, factors affecting drug utilization, applications of pharmacoepidemiology	**4**
9	**Pharmacoeconomics and outcomes Research:** Theories and methodologies of pharmacoeconomics and outcomes research, applications to pharmacotherapy and managed health care	**6**
	Total	**48**

Books:

Latest editions of the following books to be adopted

1. Clinical Pharmacy and Therapeutics, Roger Walker, Clive Edwards, Churchill Livingstone.
2. Clinical Pharmacy, H. P. Tipnis, A. Bajaj, Career Publications.
3. Clinical Pharmacology, P.N. Benett, M. J. Brown, Churchill Livingstone.
4. Text Book of Clinical Pharmacy Practice, G. Parthisarathi, Karin Nyfort Hansen, Milap C. Nahata, Orient Longman.
5. Strom BI, Limmel SE. Textbook of Pharmacoepidemiology. Chichester, West Sussex, England: John Wiley & Sons Ltd; 2006.
6. Rascati, Karen L. Essentials of Pharmacoeconomics. Philadelphia, Pa.: Lippincott Williams and Wilkins, 2009.

7. M. F. Drummond, M. J. Sculpher and G. W. Torrance, Methods for the economic evaluation of health care programmes. Oxford University Press, USA, 2005.
8. Brenda Waning; Michael Montagne; William W McCloskey, Pharmacoepidemiology: Principles and practice, New York, McGraw-Hill, 2001.

BPH_E_808_T – Pharmacovigilance- (4 Hr/Wk)

Course Prerequisites

- Basic/core courses in Pharmacology.

Course Objectives

1. Provide an opportunity for the student to learn about development of pharmacovigilance.
2. Learn the basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance.
3. Train students on establishing pharmacovigilance programme in an organization.
4. Various methods that can be used to assess adverse drug reactions generate safety data and signal detection.
5. Regulatory aspects of pharmacovigilance.

Course Outcomes

1. Relate to the role of pharmacovigilance and its prevalence in different setups.
2. Discuss the different facets of ADRs in normal as well as special populations with their relation to pharmacovigilance methods.
3. Integrate knowledge of resources of drug information, safety data and drug utilization.
4. Outline the regulatory processes in pharmacovigilance.
5.

No.	Details	Hours
1	**Introduction to Pharmacovigilance**	**6**
1.1	History and development of Pharmacovigilance	0.5
1.2	Importance of safety monitoring of Medicine	0.5
1.3	WHO international drug monitoring programme	1
1.4	Pharmacovigilance Program of India (PvPI)	1
1.5	Vaccine safety surveillance	1
	Vaccine Pharmacovigilance, Vaccination failure	
1.6	Establishing pharmacovigilance programme	2
	Establishing in a hospital	
	Establishment & operation of drug safety department in industry	
	Contract Research Organizations (CROs)	
	Establishing a national programme	
2	**Adverse drug reactions**	**9**
2.1	Definitions and classification of ADRs	1
2.2	Detection and reporting	3
2.3	Methods in Causality assessment	2
2.4	Severity and seriousness assessment	1
2.5	Predictability and preventability assessment	1
2.6	Management of adverse drug reactions	1
3	**Pharmacogenomics of adverse drug reactions: Drug safety evaluation in special population**	**6**
3.1	Pediatrics	2
3.2	Pregnancy and lactation	2
3.3	Geriatrics	2
4	**Pharmacovigilance methods**	**10**
4.1	Passive surveillance – Spontaneous reports and case series	7

	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	
4.2	Communication in pharmacovigilance	3
	Effective communication in Pharmacovigilance	
	Communication in Drug Safety Crisis management	
	Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media	
5	**Drug dictionaries and coding in pharmacovigilance**	**10**
5.1	WHO adverse reaction terminologies	2
	MedDRA and Standardized MedDRA queries	
	WHO drug dictionary	
5.2	Information resources in pharmacovigilance	2
	drug information resources	
	Specialized resources for ADRs	
5.3	Basic terminologies used in pharmacovigilance	1
	Terminologies of adverse medication related events	
	Regulatory terminologies	
5.4	Drug utilization:	2
	Need, types of drug utilization studies	
	Drug use evaluation	
5.5	Medication safety data: Safety data generation	3
	Pre-clinical phase	
	Clinical phase	
	Post approval phase	
6	**Regulatory Aspects of Pharmacovigilance**	**7**
6.1	ICH Guidelines for Pharmacovigilance	4
	Organization and objectives of ICH	
	Expedited reporting	
	Individual case safety reports	
	Periodic safety update reports	
	Post approval expedited reporting	
	Pharmacovigilance planning	
	Good clinical practice in pharmacovigilance studies	
6.2	CIOMS	1
	CIOMS Working Groups	
	CIOMS form	
6.3	CDSCO (India) and Pharmacovigilance	2
	D & C Act and Schedule Y	
	Differences in Indian and global pharmacovigilance requirements	
	TOTAL	**48**

Books:

Latest editions of the following books to be adopted

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.

2. Practical Drug Safety from A to Z, Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiology, Eds Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: Concept and Practice by GP Mohanta and PK Manna, PharmaMed Press/BSP Books.
12. http://www.cioms.ch/
13. http://cdsco.nic.in/
14. http://www.who.int/vaccine_safety/en/
15. http://www.ipc.gov.in/PvPI/pv_home.html
16. http://apps.who.int/medicinedocs/pdf/s4876e/s4876e.pdf

BPH_E_809_T – Pharmaceutical Regulatory Affairs- (4 Hr/Wk)

Course Objectives

The course is framed to impart knowledge to the learners so that they get conversant with drug regulatory practices and procedures followed at national and international level for registration and approval.

Course Outcomes

The learner should be able to:
1. Understand the basics of new drug and generic product development.
2. Apply knowledge of regulatory requirements for preparing the documents for registration of pharmaceutical product in India and overseas.
3. Understand various harmonized practices and integrate the knowledge required for various certifications.

No.	Details	Hours
1	**Drug Regulatory Affairs**	**4**
	1.1 Introduction to Drug Regulatory Affairs(DRA)	1
	1.2 DRA in Pharmaceutical Industry	1
	1.3 Regulatory bodies across the world and different markets and brief introduction of registration process in UK, Australia, Brazil, Canada, Japan, ASEAN countries, Commonwealth of Independent States, -Russian Commonwealth (CIS)	2
2	**Indian Regulations**	**9**
	2.1 Indian Pharmacopoeia (IP) commission - Introduction, IP review process with mentioning monograph and IP reference substances (RS)	3
	2.2 Pharmacovigilance Programme of India (PVPI)	1
	2.3 Central Drug Standard Control Organization (CDSCO), Drug Controller General of India (DCGI), Food and Drugs Administration (FDA), Centre Drugs Laboratory(CDL)- Structure, role, function and strategies of these organizations	3
	2.4 Procedure for obtaining test license (Form 29 and form 11), Export NOC, Loan License/Contract manufacturing	2
3	**US Regulations**	**11**
	3.1 USFDA - Structure, role and function	1
	3.2 Drug price competition and patent term restoration act (Hatch Waxman Act 1984)- scope and objective	3
	3.3 Type of filings- Type of application and relevant forms - Investigational New Drug (IND), New Drug Application (NDA), Supplemental new drug application (SNDA), Abbreviated NDA (ANDA), Biologic License Application (BLA)	2
	3.4 Orange book Therapeutic Equivalent (TE) codes, Patent term and exclusivity	
	3.5 21 CFR- Brief introduction and mention of 21 CFR Part 11	2
	3.6 Post Approval changes and SUPAC guidelines - Brief introduction	1
	3.7 Drug master file (DMF) and different types	1
		1
4	**European Regulations (EU)**	**10**
	4.1 EMEA- Structure role and function	2

	4.2 Types of filing- Centralized, Decentralized, Mutual recognition procedure, National 4.3 Type of applications for marketing authorization - New drug, Hybrid drug, Generic, similar biologic, Fixed combination 4.4 Active Substance master file (ASMF) – Brief introduction, Certificate of suitability (COS) 4.5 Post Approval changes and handling variations	3 2 2 1
5	International Council for Harmonization (ICH) 5.1 Introduction- Composition, Role and responsibilities 5.2 ICH guidelines- Quality (Q), Safety (S), Efficacy (E), Multidisciplinary (M) 5.3 ICH quality guidelines – Terminologies 5.4 Introduction of ICH , multidisciplinary M4 guidelines	**4** 1 1 1 1
6	GMP certification and ISO	**3**
7	Clinical Trials 7.1 Regulatory perspective of clinical trials and brief overview of schedule Y and amendments 7.2 ICMR guidelines, Institutional Ethics committee for biomedical research (IRB/IEC) 7.3 Bioavailability and bioequivalence study, Biowaiver- Regulatory requirement	**4** 1 1 2
8	Intellectual Property rights and type Patent Act 1970, TRIPS, WTO, GATT and PCT- Definition and Goals	**3**
	TOTAL	48

Books:

1. New Drug Approval: Accelerating Global Registrations by Richard A Guarino, MD, 5th Edition, Drugs and the Pharmaceutical Sciences, Vol.190.
2. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143.
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.
4. Intellectual Property Law, P. Narayanan, , Eastern Law House, Revised Edition, 2017.
https://www.ich.org
https://www.fda.gov
https://www.ema.europa.eu
https://www.cdsco.nic.in
https://www.icmr.nic.in
https://www.gov.uk

BPH_E_810_T – Lead Optimization – Strategies and Methods- (4 Hr/Wk)

Course Objectives

1. To introduce the learner to the concepts of druggability and physicochemical/ADME/Toxicity property optimization in new drug discovery.
2. To study the fundamentals, structure modification strategies and methods of determination of various physicochemical and pharmacokinetic properties of lead compounds.

Course Outcomes

The learner should be able to:

1. Understand the importance of druggability and physicochemical/ADME/Toxicity property optimization in new drug discovery.
2. Understand the fundamentals of various physicochemical and pharmacokinetic properties and their significance in lead optimization.
3. Know various strategies for structure modification for optimizing druggability of lead molecules.
4. Describe different methods of determination of various physicochemical and pharmacokinetic properties of lead compounds.

No.	Details	Hours
1	**Drug-like Properties**	**4**
1.1	Introduction, drug-likeness and Drug Discovery	
1.2	Property profiling and optimization	
1.3	Rules for rapid property profiling from structure	
1.4	Lead-like compounds	
1.5	Strategies for integrating drug-like properties into Drug Discovery	
2	**Lipophilicity and pKa**	**4**
2.1	Fundamentals, effects and structure modification strategies	
2.2	Lipophilicity determination Methods: in silico lipophilicity methods, experimental lipophilicity methods, in-depth lipophilicity methods	

2.3	pKa determination methods: in silico methods, experimental methods, in-depth methods	
3	**Solubility**	**4**
3.1	Fundamentals of solubility, dissolution rate, structural properties affecting solubility, kinetic solubility and thermodynamic solubility	
3.2	Effects of solubility, IV formulations, solubility classification, effects of physiology on solubility and absorption	
3.3	Structure modification strategies to improve solubility, strategies for improving dissolution rate, salt forms	
3.4	Methods for solubility determination: solubility calculation methods and commercial software, kinetic solubility methods, thermodynamic solubility methods	
4	**Permeability**	**4**
4.1	Permeability fundamentals: passive diffusion permeability, endocytosis permeability, active uptake permeability, paracellular permeability, efflux permeability, combined permeability	
4.2	Permeability effects: effect of permeability on bioavailability, effect of permeability on cell-based activity assays	
4.3	Permeability structure modification strategies	
4.4	Methods for permeability determination: in silico permeability methods, in vitro permeability, in depth permeability methods	
5	**Transporters**	**4**
5.1	Transporter fundamentals	
5.2	Transporter effects, efflux transporters: p-glycoprotein (MDR1, ABCB1) , breast cancer resistance protein (BCRP, ABCG2), multidrug resistance protein 2 (MRP2, ABCC2) , efflux transporters in the BBB	
5.3	Uptake transporters, structure modification strategies	
5.4	Methods: in silico transporter methods, in vitro transporter methods, in vivo methods for transporters	
6	**Blood Brain Barrier**	**4**
6.1	BBB fundamentals: BBB permeation mechanisms, brain distribution mechanisms, brain–CSF barrier, interpreting data for brain penetration	
6.2	Effects of brain penetration	
6.3	Structure–BBB penetration relationships, structure modification strategies to improve brain penetration	
6.4	Methods for determining BBB: in silico methods, in vitro methods, in vivo methods,	
7	**Metabolic Stability, Plasma Stability, Solution Stability**	**6**
7.1	Metabolic stability fundamentals: Phase I metabolism, Phase II metabolism, metabolic stability effects	
7.2	Structure modification strategies for metabolic stability: Phase I, Phase II, consequences of chirality on metabolic stability	
7.3	Plasma Stability: fundamentals, effects, structure modification strategies to improve plasma stability	
7.4	Solution Stability: fundamentals, effects, structure modification strategies to improve solution stability	
7.5	Methods: *In silico* metabolic stability methods, in vitro metabolic stability methods, plasma stability methods, solution stability methods	
8	**Plasma Protein Binding**	**3**
8.1	Plasma Protein Binding Fundamentals: consequences of chirality on PPB	
8.2	Plasma Protein Binding Effects: Impact of PPB on distribution, clearance and pharmacology	
8.3	Structure modification strategies for PPB	
8.4	Methods for determining PPB: in silico methods, in vitro Methods	
9	**Cytochrome P450 inhibition**	**4**
9.1	CYP inhibition fundamentals and effects	
9.2	Structure modification strategies to reduce CYP inhibition	
9.3	Reversible and irreversible CYP inhibition	
9.4	Methods for determining CYP inhibition: in silico methods, in vitro methods	
10	**hERG Blocking**	**3**
10.1	hERG Fundamentals, hERG blocking effects	

10.2	hERG Blocking Structure–Activity Relationship, structure modification strategies for hERG	
10.3	hERG methods: In silico hERG methods, in vitro hERG methods, in vivo hERG methods	
11	**Toxicity**	**4**
11.1	Toxicity Fundamentals: toxicity terms and mechanisms	
11.2	Structure modification strategies to improve safety	
11.3	Methods: in silico toxicity methods, in vitro toxicity assays, in vivo toxicity	
12	**Pharmacokinetics**	**4**
12.1	Pharmacokinetic parameters: volume of distribution, Area Under the Curve, clearance, half-life, bioavailability	
12.2	Effects of plasma protein binding on PK parameters, tissue uptake	
12.3	Using PK data in drug discovery	
12.4	Pharmacokinetic methods: PK dosing (single-compound dosing, cassette dosing), PK sampling and sample preparation, instrumental analysis	
	Total Hours	**48**

Books:

1. Drug-like Properties: Concepts, Structure Design and Methods from ADME to Toxicity Optimization, Li Di, Edward Kerns, Academic Press.
2. Lead Optimization for Medicinal Chemists: Pharmacokinetic Properties of Functional Groups and Organic Compounds, Florencio Zaragoza Dörwald, Wiley-VCH.
3. Pharmacokinetics and Metabolism in Drug Design, Volume 31, Dennis A. Smith, Han van de Waterbeemd, Don K. Walker, Series Editors - Raimund Mannhold, Hugo Kubinyi and Gerd Folkers, Wiley-VCH.

BPH_E_811_T – Novel Drug Delivery Systems- (4 Hr/Wk)

Course Objectives

To provide the learner with knowledge of basic principles and the different types of Novel Drug Delivery Systems

Course Outcomes

Upon completion of the course, the learner shall be able to:
1. Understand the basic concept of NDDS
2. Discuss the different NDDS for different routes-oral, transdermal, ocular, transmucosal and implantable
3. Explain the need and concepts of targeting and active & passive targeting
4. Elaborate on principles and targeting systems for brain, colon, lymphatics and tumors
5. Discuss the various multiparticulate systems for targeting

No.	Details	Hours
1.0	Fundamentals of Novel drug delivery systems: Basic Concepts, Advantages and Disadvantages, Limitations of conventional dosage forms	1
2.0	Polymers: Introduction, classification, Role and applications in NDDS, Biodegradable and biocompatible polymers.	3
3.0	**Particulate NDDS:** Microspheres, liposomes, nanoparticles, aquasomes, niosomes, dendrimers-Classification, components & design, methods of preparation, characterization and applications of each system.	4
3.0	**Oral Controlled Drug Delivery Systems:** a) Matrix and reservoir systems- Diffusion and dissolution-controlled systems b) Multiparticulate drug delivery systems (Pellets)- need and significance of pelletization, techniques- pan coating, extrusion and spheronization, equipments, evaluation c) Osmotic Systems- Basic principles, classification- Implantable osmotic pumps, oral osmotic pumps, applications & evaluation d) Gastroretentive drug delivery systems (GRDDS)- Regional variability in intestinal absorption and concept of absorption window, Design of GRDDS technologies- low density (Floating systems), Swelling and expanding systems, Mucoadhesive systems, high density systems. Evaluation of GRDDS.	8
4.0	**Ocular drug delivery systems:**	4

	Limitations of conventional systems, *in situ* gelling systems, Ocular inserts: Non-erodible and Erodible inserts, Particulate systems for ocular delivery-liposomes & nanoparticles, ocular iontophoresis, evaluation. One example of each system	
5.0	**Transdermal Drug Delivery Systems (TDDS):** Permeation through skin, factors affecting permeation, Advantages and disadvantages of TDDS, basic components of TDDS, Different types of TDDS and release control mechanism, pressure sensitive adhesives, Evaluation	4
6.0	**Transmucosal drug delivery systems**: Concept of bioadhesion/ mucoadhesion, Advantages and disadvantages of transmucosal drug delivery, Bioadhesive polymers, Theories of mucoadhesion, Factors affecting mucoadhesion, transmucosal permeability, Formulation considerations: emphasis on buccal drug delivery, Evaluation of mucoadhesive strength	4
7.0	**Parenteral Controlled drug delivery systems**- Need and Various approaches, Details of Implantable Systems – Characteristics desired, routes employed, diffusion-controlled systems, activation-controlled systems and feedback-regulated systems. One example of each. Biocompatibility issues of implantable systems	5
8.0	**Nasal and Pulmonary Drug Delivery Systems**-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); Delivery systems (nebulised, systems, pMDIs and DPIs), Active and Passive devices, Evaluation methods.	7
9.0	. **Targeted drug delivery systems:** a) Introduction to targeting, concepts of active and passive targeting. b) Particulate systems for targeting- microspheres, aquasomes, niosomes, dendrimers, and solid lipid nanoparticles, liposomes c) Targeting to colon: Difficulties in colonic targeting, Approaches of colon targeting, Evaluation d) Targeting to Brain: Blood brain barrier (BBB), transport through BBB, factors affecting drug permeation through BBB, strategies for brain drug delivery e) Lymphatic targeting-need and approaches- f) Targeting to tumor – EPR effect, ligand-based active targeting with two examples	8
	TOTAL	**48**

Books:

Latest editions

1. Advances in controlled and novel drug delivery, ed. by N. K. Jain, CBS publishers and distributors, 2001.
2. Modern Pharmaceutics, 4th ed. Revised and Expanded, ed. by Gilbert S. Banker and Christopher T. Rhodes, Marcel Dekker INC., 2002
3. Targetted and controlled drug delivery, Novel carrier systems, S. P. Vyas and R. K. Khar, CBS publishers and distributors, 2002.
4. Controlled and novel drug delivery, ed. by N. K. Jain, CBS publishers and distributors, 1997.
5. Controlled drug delivery, concepts and advances, S. P. Vyas and R. K. Khar, Vallabh Publishers, 2002.
6. The theory and practice of industrial pharmacy, ed. by Leon Lachman, H. A. Liberman, J. L. Kanig, 3rd ed., Verghese Publishing house, 1987.
7. The science and practice of pharmacy, 21st ed., Remington, Vol I and II, B. L. Publications Pvt. Ltd., 2005.
8. Bioadhesive Drug Delivery Systems – Fundamentals, Novel Approaches, and Development, Mathiowitz Edith, Chickering III, Donald E., Lehr Claus-Michael, Volume 98, Marcel Dekker Inc., New York, 1995.
9. Nanoparticulate Drug Delivery Systems, Thassu Deepak, Dellers Michael, Pathak Yashwant, Volume 166, Marcel Dekker Inc., New York, 2007.
10. Microencapsulation – Methods and Industrial Applications", Benita Simon, 2nd Edition, Marcel Dekker Inc., New York, 2006.
11. Controlled and Novel Drug Delivery, Jain N. K., 1st Edition, CBS Publishers and Distributors, New Delhi, 2004.
12. Targeted and Controlled Drug Delivery- Novel Carrier Systems", Vyas S. P., Khar R. K., 1st Edition, CBS Publishers and Distributors, New Delhi, 2002.
13. Ophthalmic Drug Delivery Systems, Mitra, Ashim K., Volume 58, Marcel Dekker Inc., New York, 1993.
14. Encyclopedia of Pharmaceutical Technology, Swabrick, Boylan, Volumes 1,6,8,9,10,12,13,14,15,16,17,18,19,20, Marcel Dekker Inc., New York.