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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

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**

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.