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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**

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

## Scheme Examination Semesters V to VIII

## &

## Syllabus Semesters V to VIII

## EXAMINATION SCHEME FOR THE

## CHOICE BASED CREDIT SYSTEM (CBCS)

### SEMESTER V

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

**SEMESTER VI**

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

**SEMESTER VII**

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

**SEMESTER VIII**

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

# SYLLABUS FOR T. Y. B. Pharm.

# SEMESTER-V

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

**Course Objective**

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

**Course Outcomes**

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

| No. | Details | Hours |
|---|---|---|
| 1 | **1 Heterocyclic Chemistry**<br>1.1<br>Nomenclature of mono, bi- and tri-cyclic hetero-aromatic, fused heterocyclic ring and bridge head system of the drug molecules along with drug examples.<br>Synthesis, Discussion of aromaticity, resonance, properties of heterocycles, acidity and basicity and reaction of the following heterocycles<br><br>1.2<br>**Five membered Heterocycles with One Heteroatom:**<br>a. Furan: Synthetic methods including synthesis using carbohydrates, Paal-Knorr synthesis<br>b. Pyrrole: Synthetic methods including synthesis using furan, Knorr synthesis, Paal-Knorr synthesis, Hantzsch synthesis.<br>c. Thiophene: Synthetic methods including synthesis using Paal-Knorr synthesis.<br>Reactions of Furan, Pyrrole and Thiophene: With acids, Electrophilic Aromatic Substitution (EAS), Nucleophilic Aromatic substitution (NAS) reaction, oxidizing and reducing agents.<br><br>1.3.<br>**Five membered heterocycles with Two heteroatoms**:<br>a. Imidazole: Synthetic methods including synthesis from imidazolines, α-haloketones, Radiszewskii reaction.<br>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)<br>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,.<br><br>1.4<br>**Six membered heterocycles with One and Two heteroatoms**:<br>a. Pyridine: Synthetic methods including synthesis using 1,5-diketones and Hantzsch synthesis.<br>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**<br><br>**4**<br><br>**5**<br><br>**4** |

| | | |
|---|---|---|
| | substitution (NAS), Hetaryne formation, oxidizing and reducing agents and Reactions of pyridine-N-oxide<br><br>1.5<br>**Fused heterocycles with One heteroatoms**<br>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<br>b. Isoquinoline: Synthetic methods including Bischler-Napieralski and Pomeranz-Fritsch, Reactions including EAS, nucleophiles, oxidizing and reducing agents.<br>c. Indole: Synthesis by Fischer indole synthesis, Madelung synthesis. Reactions with acids, EAS, Metallic K, Mannich reaction, oxidizing and reducing agents.<br><br>1.6<br>**Non-aromatic heterocyclic chemistry**: Synthesis and properties of the following heterocycles- Morpholines, Piperazines, Piperidine | **5**<br><br>**4** |
| **2** | **Biomolecules:**<br><br>**I. Chemistry of Steroids**<br>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.<br>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.<br><br>**II. Peptides:**<br>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.<br><br>**III. DNA:** Merrifield solid phase synthesis of DNA<br><br>**IV. Polymers**<br>Chain growth polymers (free radical polymerization)<br>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**<br><br>**5**<br><br>**3**<br><br>**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<br>Definition, advantages and disadvantages, desirable features and pharmaceutical dispersions | 1 |
| 1.2 | **Suspensions**<br>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<br>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**<br>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.<br>Quality evaluation, Examples of Official formulations. | 3 |
| **3** | **Suppositories** | **6** |
| 3.1 | Suppositories:<br>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.<br>Containers – Tin Plate, Aluminium, Glass, Plastics<br>Valve and Actuator, Metered dose valve<br>Product concentrate - Different formulation systems- solution, dispersions, foams.<br>Dry Powder Inhalations-concept. | 6 |
| 4.3 | Manufacture of Aerosols-Cold filling and Pressure filling.<br>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<br>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<br>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.<br>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.<br>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<br>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.<br>b) Factors affecting pathogenicity and infection,<br>c) Innate defense mechanism – first line of body defense, physiological phenomena-inflammatory response, fever, cellular, mediators; soluble (humoral) mediators, phagocytosis.<br>d) Specific defense Mechanism – Characteristics, Antigen, Cell-mediated immunity, humoral immunity.<br>e) Antibody structure and types, pathways of immune response, clonal selection theory.<br>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.<br>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)<br>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**<br>10.1 | **Introduction to Bioinformatics**<br>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**<br>1. Paracetamol Paediatric Oral Suspension IP<br>2. Dry suspension for reconstitution (any one)<br>3. Antacid Suspension<br>5. Liquid Paraffin Emulsion IP<br>6. White Liniment BPC/ Turpentine Liniment IP<br>7. Evaluation of any one suspension & one emulsion<br>Evaluation Parameters: Organoleptic Properties, Particle/droplet size, Sedimentation/Creaming volume , pH, stability studies, rheology of any one preparation |
| **2** | **Semisolids**<br>1. Compound Benzoic acid Ointment IP<br>2. Aqueous Calamine Cream IP<br>3. Cetrimide Cream IP<br>4. Diclofenac Gel BP<br>Evaluation of any one Ointment / Cream |
| **3** | **Suppositories**<br>1. Glycerin Suppositories USP<br>2. Paracetamol Suppositories BP/Indomethacin Suppositories IP /<br>Bisacodyl suppositories IP/ Aspirin Suppositories USP<br>Evaluation of any one suppository |
| **4** | **Pharmaceutical Aerosols**<br>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**<br>1. Toothpaste<br>2. Clear liquid Shampoo<br>3. Lipstick/ Nail lacquer<br>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**<br>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.<br>Self-study: Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community, Limitations of Nutraceuticals | 3<br><br><br><br><br>1 |
| 2 | **Phytochemicals as Nutraceuticals**:<br>Occurrence, Structure, Properties, Metabolism and Pharmacokinetics, Therapeutic uses, Recommended Doses and Marketed Preparations of following<br>a) **Carotenoids**- Lycopene, Lutein, Zeaxanthene, Astaxanthene<br>b) **Phenolics and Polyphenolics as Antioxidants** - - Reservetrol , Grapeseed extract, Tea, Pycnogenol, Avenanthramides from Oats, Rutin, Soy Isoflavones, Curcumin<br>c) **Sulphur Compounds**- Glucosinates<br>d) **Prebiotics / Probiotics**-Fructo-oligosaccharides, Lactobacillum.<br>e) **Dietary fibres** – Soluble and insoluble any two examples each.<br>f) **Lignans** – Flax Lignans<br>g) **Essential Fatty acids**- Fish oils, α- Linolenic acid from Flax.<br>h) **Quinones**- Tocopherol.<br>i) **Proteins and Minerals**- Melatonin, Glutathione, Shilajit, Carnitine.<br>j) **Marine nutraceuticals** – Collagen from fish skin | 9 |
| 3 | **Formulations and Challenges**<br>Challenges involved in processing, extraction and concentration of nutraceutical constituents, formulations and delivery systems, safety, storage and stability evaluation of formulations.<br>Labeling of Nutraceuticals | 4 |
| 4 | **Safety and Toxicity of Nutraceuticals**<br>Adverse Effects, Interactions, Adulteration- Intentional, counterfeiting, undeclared labeling, toxic contaminants | 3 |
| 5 | **Regulatory issues of Nutraceuticals and Dietary Supplements**<br>a) EU, US and Indian guidelines.<br>b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.<br>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**<br>i. Introduction and History<br>ii. Types of transformation in prokaryotes--Natural transformation in Streptococcus pneumoniae, Haemophilus influenzae, and Bacillus subtilis<br>iii. Mapping of bacterial genes using transformation.<br>iv. Problems based on transformation. | 3 |
| | **1.2. Conjugation**<br>i. Discovery of conjugation in bacteria<br>ii. Properties of F plasmid/Sex factor<br>iii. The conjugation machinery<br>iv. Hfr strains, their formation and mechanism of conjugation<br>v. F' factor, origin and behavior of F' strains, Sexduction.<br>vi. Mapping of bacterial genes using conjugation<br>(Wolman and Jacob experiment).<br>vii. Problems based on conjugation | 3 |
| | **1.3. Transduction**<br>i. Introduction and discovery<br>ii. Generalised transduction<br>iii. Use of Generalised transduction for mapping genes<br>iv. Specialised transduction v. Problems based on transduction | 3 |
| | **1.4. Recombination in bacteria**<br>General/Homologous recombination<br>i. Molecular mechanism<br>ii. Holliday model of recombination<br>Site –specific recombination | 3 |
| 2 | **PLASMIDS, TRANSPOSONS & OPERONS (REGULATION)** | **12** |
| | **2.1. Plasmids**<br>a. Physical nature<br>b. Detection and isolation of plasmids<br>c. Plasmid incompatibility and Plasmid curing<br>d. Cell to cell transfer of plasmids<br>e. Types of plasmids<br>i. Resistance Plasmids,<br>ii. Plasmids encoding Toxins and other Virulence characteristics | 3 |

| | | |
|---|---|---|
| | iii. col factor<br>iv. Degradative plasmids<br><br>**2.2. Transposable Elements in Prokaryotes**<br>a. Insertion sequences<br>b. Transposons<br>i. Types<br>ii. Structure and properties<br>iii. Mechanism of transposition<br>iv. Transposon mutagenesis<br>c. Integrons<br><br>**2.3. Lac operon and problems on Lac operon, Trp operon** | 3<br><br>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.<br>DNA Replication in Eukaryotes and differences with respect to prokaryotes.<br>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<br>a. Order of events<br>b. Reversal of polarity<br>c. Protecting groups | 4 |
| 3.<br>3.1<br><br>3.2<br>3.3 | <br>Disconnection of simple alcohols, alkyl halide, ethers, olefins, esters, carboxylic acids, aldehydes, ketones and amines.<br>Two group disconnections – 1,2-, 1,3-, 1,4- difunctionalized compounds<br>Strategies for synthesis of aromatic heterocycles pyrrole, thiophene, furan, pyridine, pyrimidine | 8<br>3<br><br>3<br>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<br>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-<br>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<br>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.<br>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<br>and Quality control, Common defects | 1 |
| 3.0 | Ancillary materials in packaging- | 1 |

| | | |
|---|---|---|
| | Cushioning materials-applications for impact, vibration, temperature & humidity protection<br>Fasteners, tapes | |
| 4.0 | Sterilization of containers and closures | 1 |
| 4.0 | **Labels and labelling**:<br>Types of labels, adhesives,<br>Printing of labels- printing inks, toxicity and safety of printing inks, inject and bar coding and printing of labels,<br>Quality control and common defects in printing of labels | 2 |
| 5.0 | **Stability of Packages**<br>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 –<br>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<br>Monoclonal Antibodies, Peptides<br>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<br>Penicillins (natural and semisynthetic penicillins like Penicillins G, Penicillins V, ampicillin*, amoxicillin, cloxacillin*, oxacillin, naficillin, methicillin and ampicillin prodrugs like bacampicillin and hetacillin);<br>β-lactamase inhibitors like clavulinic acid, (self study – tazobactam)<br>Cephalosporins (cephalexin, cefadroxil, cefazolin, cefamandole, cefoxitin, cefuroxime, cefotaxime, ceftriaxone, cefpodoxime proxetil)<br>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);<br>Only highlight the structures of the following compounds: Carbapenems (Emepenem, Meropenem) Monobactams (Aztreonam, Tigemonam) Linezolid, | |
| 5.3 | Fluoroquinolones<br>Norfloxacin, ciprofloxacin*, sparfloxacin, gatifloxacin, levofloxacin, lomefloxacin | **2** |
| 6 | Antiparasitic Agents | |
| 6.1 | Antimalarial Agents<br>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<br>Combination therapy. | **3** |
| 6.2 | Drugs for treatment of amoebiasis, giardiasis and trichomoniasis (Self Study)<br>Metronidazole*, tinidazole, secnidazole, diloxanide furoate*, nitazoxanide | **1** |
| 6.3 | Anthelmintics (Self Study)<br>Albendazole, Mebendazole*, Thiabendazole, Diethylcarbamazine, Ivermectin, Praziquantel, Pyrantel Pamoate | **1** |
| 7 | AntiMycobacterial Agents<br>Antitubercular drugs<br>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<br>Natural products like griseofulvin, amphotericin B and nystatin (later two only general aspects of structure related to activity)<br>Antifungal azoles like clotrimazole*, ketoconazole, fluconazole, and itraconazole<br>Allyl amines like naftifine, and terbinafine,<br>Flucytosine<br><br>Miconazole, econazole, flutrimazole, sulconazole, sertaconazole, voriconazole, butenafine and tolnaftate (Self-Study) | **3**<br><br>**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<br>preformulation aspects;<br>Types of tablets-Effervescent, buccal, chewable, sublingual,<br>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-<br>• Direct compression, wet granulation, dry granulation;<br>Characterization and evaluation of granules<br>• Large scale manufacturing process and equipment for: Mixing, drying,<br>wet granulation, slugging and roller compaction. Tablet tooling<br>• Compression – (Single station tablet press and Rotary press), physics of tablet<br>compression (brief. Only the steps. No equations)<br>• 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<br>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<br>Materials, and processes employed | 3 |
| 2.3 | Coating equipment – Conventional & modified pans, coating columns (fluidized bed coating), Spray equipmen<br>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.<br>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<br>of empty shells. | 1 |
| 3.3 | Hard capsule fill formulation aspects: , types of fill and excipients;<br>Large scale manufacturing steps with detailed study of Filling of hard capsule shells;<br>Filling equipments : classification-volumetric, dosator type and tamping type.<br>(one example of each type of equipment-schematic representation only).<br>Problems in capsule filling & remedies<br>Layout of capsule section. Humidity control in capsule manufacturing and filling area.<br>Quality control aspects of hard capsules. | 4 |
| 3.4 | Soft gelatin capsules: Properties, nature of shell and contents,<br>Formulation aspects- types of fills and excipients, Concept (minim/gm)<br>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<br>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:**<br>• Concepts of Quality Assurance & Quality Control, Responsibilities of Q.A. department.<br>• Raw material control, actives and inactive, Q.C. standards for raw materials. (identity, purity, quality and potency<br>• Sanitization, environmental and microbiological control, packaging and labeling control, finished product control,<br>• Statistical Quality control-concept, Q.C. charts, sampling & Sampling Plans, Sampling tools. | **6** |
| 6.0 | **Documentation**<br>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.<br>• Beer-Lambert's law-statement, derivation of mathematical expression, limitations<br>• Choice of solvents<br>• Chemical derivatization | 2 |

| | | |
|---|---|---|
| 1.3 | ***Instrumentation of UV-VIS spectrophotometer:***<br>• Sources of UV-VIS radiation<br>• Monochromators (Filters, prisms, gratings)<br>• Sample cells<br>• Detectors<br>• Colorimeter and UV-VIS spectrophotometer (single beam and double beam with diagram) | 3 |
| 1.4 | ***Applications of UV-VIS spectrophotometry:***<br>• 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<br>• Measurement of Equilibria constant.<br>• 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<br>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:***<br>• Filter fluorimeter and Spectrofluorimeter (including Block diagram)<br>• Sources of radiation<br>• Monochromators (Filters, gratings)<br>• Sample cells<br>• Detectors<br>***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:***<br>• 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<br>Instrumentation of FTIR | 2 |
| 3.2 | ***Sample preparation & applications of I.R. spectroscopy:***<br>• Sample preparation for I.R spectroscopy -Solids (mulling, pelleting and thin film deposition, and in solution form), Liquids (Neat and in solution form).<br>• Sample handling: Attenuated Total Reflectance and Diffuse Reflectance.<br>• 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)<br>Pharmaceutical applications of Near IR spectroscopy including PAT (Process Analytical Techniques) | 4 |
| **4** | **Raman Spectroscopy** | **4** |
| 4.1 | • Principle of Raman scattering<br>• Comparison between I.R Spectroscopy and Raman Spectroscopy<br>• Raman instrumentation-Sources of light, Sample illumination system (Liquid, solid and fiber optic sampling), Block diagram of Raman spectrometer.<br>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:***<br>• For AAS: Radiation sources (Hollow cathode lamp, Electrode discharge lamps)<br>• Plasma sources: Inductively coupled plasma and Direct current plasma source<br>For AES- Flame atomization (types of flames, flame structure, flame atomizers) | 1.5 |
| 5.3 | ***Interferences & Applications:***<br>• Cationic, Anionic and Physical interferences in Flame photometry<br>• Spectral Interferences and Chemical Interferences in AAS.<br>Pharmaceutical applications | 2 |

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| **6** | **X-Ray Diffraction Technique** | **4** |
| 6.1 | ***Fundamentals & Applications:***<br>• Fundamentals- Origin of X-ray, Bragg's law and its mathematical derivation, Bravais lattices and Miller indices<br>Pharmaceutical applications- Crystal structure determination, polymorphism | 2 |
| 6.2 | ***Instrumentation & working principle:***<br>• X-Ray source (X-ray tube source)<br>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<br>• Relative biological effectiveness, Radionuclidic purity, Radiochemical purity<br>Safety aspects of radiopharmaceutical laboratory | 1 |
| 7.2 | • Measurements of radioactivity- Geiger-Muller Counting, liquid Scintillation Counting<br>• Requirements of radiopharmaceuticals- Properties of radionuclides, Pharmaceutical properties, chemical properties<br>• Radionuclide generator- $^{99m}$Tc generator<br>• Quality control of radiopharmaceuticals: Physical, Chemical (Radionuclidic purity, Radiochemical purity)<br>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)<br>• Indicator electrode (only glass electrode to be studied)<br>• Rejuvenation of glass electrodes<br>• 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)<br>• Calibration of pH meter and measurement of pH<br>Determination of pKa by potentiometric titration | 3 |
| **9** | **Thermal methods of analysis** | **4** |
| 9.1 | ***Principle, Instrumentation, working and applications of:***<br>a) Thermogravimetry (TG)<br>b) Differential thermal analysis (DTA)<br>c) Differential scanning calorimetry (DSC)<br>Factors affecting the above thermal methods of analysis | 4 |
| **10** | **Statistical data handling** | **5** |
| 10.1 | ***Normal Distribution numerical based on:***<br>• Confidence limits and Tests of significance (F-test, Student t-test-paired and unpaired)<br>• Linear regression analysis and correlation coefficient<br>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, 6$^{th}$ 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.**<br>Adulteration &Substitution of drugs of natural origin.<br>**Case Studies: Adulteration & Substitution with 4 examples**<br>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.<br>• Introduction and application of terpeneless volatile oils.<br>a. Umbelliferous fruits (Dill, Fennel, Coriander, Cumin, Caraway).<br>b. Alcohol – Peppermint, Cardomom<br>c. Aldehyde volatile oil –Lemongrass, Vanillin<br>d. Ketone volatile oil - Spearmint (mint oils)<br>e. Ester volatile oil - Oil of Wintergreen | 8 |

| | | |
|---|---|---|
| | f. Ether volatile oil - Eucalyptus oil<br>g. Miscellaneous - Sandalwood, Jatamansi.<br>h. Phenylpropanoids - Cinnamon, Clove, Nutmeg.<br>• Salient features of cultivation, collection, preparation of Umbelliferous fruits, Clove, Cinnamon<br>• Isolation, Identification and Analysis of Phytoconstituents<br>Terpenoids: Menthol, Citral<br>**Interactive session**<br>• *Comparative study of Umbelliferous fruits* (Dill, Fennel, coriander, cumin, caraway).<br>• Commercially significant volatile oils, eg. Palmarosa Oil, Citrus Peel Oil, Patchouli Oil, Primrose Oil, Tea Tree Oil. | <br><br><br><br><br><br><br>1<br>1 |
| 4 | **Biosynthetic Pathways:** Acetate mevalonate pathway, shikimic acid pathway,<br>Biosynthesis of Menthol, citral, cinnamaldehyde | 3 |
| 5 | **Resins and resin combinations**<br>Study of occurrence, preparation, composition, uses and specific tests for identification of the following<br>a. Natural resins - Colophony, Benzoin, Asafoetida, Boswellia<br>b. Prepared resins - Turmeric, Ginger,<br>• Separation, Identification and Analysis of Phytoconstituents –<br>Resin – Curcuminoids<br>**Interactive Session:**<br>• Processing and Preparations for market - Ginger, Turmeric and Asafoetida | 3<br><br><br><br><br>1<br><br>1 |
| 6 | **Study of the following Classes of Phytoconstituents with respect to sources, chemistry and therapeutic uses.**<br>a. Iridoids<br>Study of piccrohiza, gentian<br>b. Sesquiterpenes and Diterpenes<br>Artemisia, Andrographis.<br>c. Tetraterpenoids- carotenoids - lutein, crocin,<br>d. Organo sulphur- *Allium cepa, Allium sativa*<br>e. Quinones: Napthoquinones - Chitrak , Henna and Benzoquinone - Vidang | 5 |
| 7 | **Tannins**<br>Introduction of tannins and their definition, classification, Study of sources, composition, extraction and applications of<br>Galls, Amla, Harda, Behra, Catechu (Pale & Black, Arjuna, Green Tea, Pomegranate Peel.<br>• **I**solation, Identification and Analysis of Phytoconstituents<br>Ellagic acid from Myrobalan<br>**Interactive Session**<br>• Preparation containing tannins in healthcare with suitable examples<br>Commercial Application of tannins in synthesis of drugs eg. Trimethoprim<br>• Abuse of Tannins | 4<br><br><br><br><br>1<br><br>1 |
| 8 | **Plant Tissue Culture**:<br>Different methods of manipulation of secondary metabolites<br>Introduction and application of transgenic plants with special reference to<br>Edible vaccines | 4 |
| 9 | **Excipients of natural origin** – Significance of substances of natural origin as excipients<br>a. colorants – bixin, saffron,<br>b. Sweeteners- thaumatin, stevia<br>c. binders, diluents, viscosity builders, disintegrants<br>d. Flavors & Perfumes with two suitable examples each from the class of volatile oils.<br>**Interactive Session**<br>Study of two examples of each type of excipient (binders, diluents, viscosity builders, disintegrants) from natural sources and its applications in pharmaceutical formulations. | 3<br><br><br><br><br>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<br>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.<br>b. Disintegrating agents-Swelling index<br>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:<br>a) Direct compression technique<br>b) Non-aqueous wet granulation technique<br>c) Aqueous wet granulation technique |
| **3.** | Preparation and evaluation of any one formulation of the following types of tablets:<br>a) Mouth dissolving tablet<br>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)-**<br>Minimum assay of 5 formulations:<br>• Paracetamol tablets<br>• Propranolol tablets<br>• Atenolol tablets<br>• Hydrochlorothiazide tablets<br>• Frusemide tablets<br>• Albendazole tablet<br>• Rifampicin capsules |
| **2** | **Assay of drug by UV spectroscopy.**<br>• Use of single point and double point standardization method e.g. Paracetamol |
| **3** | **Colorimetric assay**<br>(Construction of calibration curve using linear regression analysis)<br>**A.** Assay of streptomycin injection<br>**B.** Assay of salicylic acid. |
| **4** | **Fluorimetric analysis**<br>**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**<br>(All experiments must be performed by use of titration curve and calculations based on equivalence point determination)<br>**A.** Determination of pKa and normality of phosphoric acid (First & Second end-point)<br>**B.** Determination of normality of individual acids in a mixture of acids. (e.g: HCl and $H_3PO_4$)<br>**C.** Determination of normality of strong acid (HCl)Vs standard solution of strong base (NaOH) as a titrant<br>**D.** Determination of Normality of weak acid (acetic acid) Vs standard solution of strong Base (NaOH) as a titrant |
| **6** | **Demonstration experiments:**<br>**A.** Determination of Na+/K+ by Flame photometry.<br>**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<br>Concepts of Quality Assurance & Quality Control, Responsibilities of Q.A. department.<br>Raw material control, actives and inactive, Q.C. standards for raw materials. (identity, purity, quality and potency)<br>QA before start up- environmental and microbiological control, manufacturing working formula procedures, cleaning, sanitization, in process control packaging and labelling control, finished product control.<br>Specimen documents-formats<br>cGMP<br>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<br>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,<br>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.<br>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 $t_{max}$.<br>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<br>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:**<br>1.1 Historical background. Advantages of Tissue Culture, Limitations, Major Types of Tissue Culture - Primary and secondary cell culture.<br>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<br>1 |
| 2 | **Media and reagents:**<br>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,<br>2.2 Selection of medium and serum.<br>2.3 Preparation and sterilization of cell culture media, serum and other reagents. | 2<br>1<br>1 |
| 3 | **Cell culture Techniques:**<br>3.1 Different types of cell cultures, Trypsinization, Cell separation, Continuous cell lines, Suspension culture, Organ culture.<br>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.<br>3.3 Primary Culture: Initiation of a Primary Cell Culture, Isolation of the Tissue, Types of Primary Culture, Subculture and Development of Cell Lines.<br>3.4 Common cell culture contaminants.<br>3.5 Scale-up & Automation. | 2<br>3<br>1<br>1<br>1 |
| 4 | **Applications of Cell and Tissue Culture:**<br>4.1 Stem cell Culture, Embryonic Stem Cell Culture: Current status and application in medicine, Cell based therapies, Nanomedicine.<br>4.2 Application of animal cell culture for *in vitro* testing of drugs.<br>4.3 Application of cell culture technology in production of human and animal viral vaccines and pharmaceutical proteins.<br>4.4 Production of recombinant hemoglobin, blood substituents, Artificial blood, General account of *in vitro* regulation of blood cells production.<br>4.5 Antibody Engineering and Large-scale Production of Pharmaceutical Products. | 2<br>2<br>2<br>2<br>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:<br>• Definitions: process, process control, Process variables and set point and<br>• Importance of process control | |
| **2** | **Process development** | **5** |
| 2.1 | Process development: Definition, steps involved with examples | 1 |
| 2.2 | Process equipment/ production plants<br>Dedicated plants, multipurpose and mixed plants<br>Typical equipment: reactors, filters, centrifuge, driers, extractors and evaporators | 2 |
| 2.3 | Chemical process kinetics:<br>Factors affecting chemical processes,<br>Reactor shape and effect of back mixing | 2 |
| **3** | **Unit processes** | **12** |
| 3.1 | Nitration:<br>• Nitrating agents, Aromatic nitration,<br>• Kinetics and mechanism of aromatic nitration,<br>• Process equipment for technical nitration, mixed acid nitration<br>• Examples to be covered: Nitrobenzene, p-nitroacetanilide | 2 |
| 3.2 | Amination by reduction:<br>• Reduction methods for amines<br>• Iron/acid reduction: Mechanism, chemical, physical factors, equipment<br>• Sulfide reduction with example of manufacture of m-Niroaniline by $Na_2S$: Zinnin reduction | 2 |
| 3.3 | Halogenation:<br>• Kinetics of halogenations, types of halogenations, catalytic halogenations.<br>• Case study on industrial halogenation process: Chloral | 2 |
| 3.4 | Oxidation:<br>• Introduction, types of oxidative reactions,<br>• Liquid phase oxidation with oxidizing agents<br>• Non-metallic Oxidizing agents: $H_2O_2$, sodium hypochlorite, Oxygen gas | 2 |
| 3.5 | Esterification:<br>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,<br>Equipment for hydrolysis, Case study | 2 |
| **4** | **API technology** | **2** |
| | • Impurities in API: Types and sources including genotoxic impurities<br>• Brief overview of guidelines in API manufacturing<br>• 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.<br>• Fire hazards, types of fire & fire extinguishers<br>• Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and<br>• 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:<br>Lactose, Starch, Magnesium stearate, Talc, Bentonite, Glycerol, Paraffins, Sodium Lauryl Sulphate, Sodium saccharin, Tweens and Spans, Arachis oil, Wool fat, Glyceryl mono stearate<br>**Self-study with follow up** | 4 |
| 3.0 | **Organoleptive additives-** colours, flavours and sweeteners-sources, mechanism/basic principles and examples<br>**Self-study with follow up** | 2 |
| 4.0 | **Excipients for solubility/dissolution and permeation enhancement**-Need, basic principles and examples<br>**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.<br>**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,<br>**Self-study with follow up**-of following polymers-HPMC, Gelatin, Carbopol and Eudragits | 3 |
| | **TOTAL** | **24** |

**Books:**

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

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

# SYLLABUS FOR Final. Y. B. Pharm.

## SEMESTER-VII

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

**Course Objective**

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

**Course Outcome**

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

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

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

*Synthesis to be taught

Latest editions of the following books to be adopted.

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

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

## BPH_C_702_T – Pharmacognosy III- (4 Hr/Wk)

**Course Objectives**

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

**Course Outcomes**

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

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

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

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

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

**Books:**

**Latest editions of the following books to be adopted.**


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


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

### Course Objectives

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

### Course Outcomes

The learner should be able to:

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

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

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

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

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

**Books:**


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

# BPH_C_704_T – Pharmacology III- (4 Hr/Wk)

## Course prerequisites

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

## Course objectives

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

## Course outcomes

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

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

**Books:**
**Latest editions of following books to be adopted**

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

## BPH_C_705_T – Pharmaceutical Jurisprudence- (3 Hr/Wk)

**Course Objectives**

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

**Course Outcomes**

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

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

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

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

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

**Books:**

**Latest editions of the following**


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


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

**Course Objectives**

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

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

**Course outcomes**

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

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

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

**Books:**


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


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

**Course Objectives**

On performing the following experiments, the learner should be able to operate the instruments, understand their functioning, prepare solutions accurately, conduct analysis using appropriate instrument, calculate, report and interpret the results of analysis.

**Course Outcomes**

The learner should be able to:

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

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

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

**Books:**


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


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

**Course prerequisites:**

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

**Course objectives:**

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

**Course outcomes:**

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

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

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

**Books:**

**Latest editions of the following books to be adopted:**


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


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

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

### Course Objectives

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

### Course Outcomes

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

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

**Books:**

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

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

### Course Objective

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

### Course Outcomes

**The learner should be able to**:

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

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

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

**Books:**


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


## BPH_E_711_T – Preformulation Studies- (2 Hr/Wk)

**Course Objectives**

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

**Course Outcomes**

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

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

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

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

**Books:**

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

# SEMESTER-VIII

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

**Course Objectives**

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

**Course Outcome**

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

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

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

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

## BPH_C_802_T – Pharmaceutics IV- (4 Hr/Wk)

**Course Objectives**

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

**Course Outcomes**

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

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

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

**Books:**
**Latest Editions**


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

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

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

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

**Course Objectives**

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

**Course Outcomes**

The learner should be able to

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

Synthesis of the following Drugs and Drug Intermediates

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

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

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

**Books:**

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

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

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

**Course Objectives**

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

**Course Outcomes**

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

**EXPERIMENTS**

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

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

## BPH_E_805_D– Project- (12 Hr/Wk)

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

## BPH_E_806_T – Phytopharmaceutical Technology- (4 Hr/Wk)

**Course Objectives**

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

**Course Outcomes**

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

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

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

**References:**


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


## BPH_E_807_T – Clinical Pharmacy- (4 Hr/Wk)

**Course Prerequisites**

- Understanding of Pharmacology and its applications.

**Course Objectives**

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

**Course Outcomes**

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

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

**Books:**

**Latest editions of the following books to be adopted**


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

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

## BPH_E_808_T – Pharmacovigilance- (4 Hr/Wk)

**Course Prerequisites**

- Basic/core courses in Pharmacology.

**Course Objectives**

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

**Course Outcomes**

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

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

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

**Books:**

**Latest editions of the following books to be adopted**

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

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

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

### Course Objectives

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

### Course Outcomes

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

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

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

**Books:**

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

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

**Course Objectives**

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

**Course Outcomes**

**The learner should be able to**:

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

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

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

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

**Books:**

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

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

**Course Objectives**

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

**Course Outcomes**

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

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

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

**Books:**

**Latest editions**


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