

**SYLLABUS OF BACHELOR OF PHARMACY (B.Pharm) PROGRAMME AS
PER CHOICE BASED CREDIT SYSTEM**

Semester I

Course of study for semester I

| Course code | Name of the course | No. of hours | Tutorial | Credit points |
|----------------------|---|--|----------|--|
| BP101T | Human Anatomy and Physiology I-Theory | 3 | 1 | 4 |
| BP102T | Pharmaceutical Analysis – Theory | 3 | 1 | 4 |
| BP103T | Pharmaceutics – Theory | 3 | 1 | 4 |
| BP104T | Pharmaceutical Inorganic Chemistry – Theory | 3 | 1 | 4 |
| BP105T | Communication skills – Theory * | 2 | - | 2 |
| BP106RBT BP106RMT | Remedial Biology/ Remedial Mathematics – Theory* | 2 | - | 2 |
| BP107P | Human Anatomy and Physiology – I Practical | 4 | - | 2 |
| BP108P | Pharmaceutical Analysis – Practical | 4 | - | 2 |
| BP109P | Pharmaceutics – Practical | 4 | - | 2 |
| BP110P | Pharmaceutical Inorganic Chemistry – Practical | 4 | - | 2 |
| BP111P | Communication skills – Practical* | 2 | - | 1 |
| BP112RBP | Remedial Biology – Practical* | 2 | - | 1 |
| Total | | 32/34^{\$}/36[#] | 4 | 27/29^{\$}/30[#] |

Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

^{\$}Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.

* Non University Examination (NUE)

BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

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|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives:

Upon completion of this course the student should be able to

- Explain the gross morphology, structure and functions of various organs of the human body.
- Describe the various homeostatic mechanisms and their imbalances.
- Identify the various tissues and organs of different systems of human body.
- Perform the various experiments related to special senses and nervous system.
- Appreciate coordinated working pattern of different organs of each system

Course Content:

| | | |
|----------------|---|-----------------|
| Unit I | Introduction to human body <ul style="list-style-type: none">• Definition and scope of anatomy and physiology, levels of structural• organization and body systems, basic life processes, homeostasis, basic anatomical terminology. Cellular level of organization <ul style="list-style-type: none">• Structure and functions of cell, transport across cell membrane, cell• division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine Tissue level of organization <ul style="list-style-type: none">• Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues. | 10 hours |
| Unit II | Integumentary system <ul style="list-style-type: none">• Structure and functions of skin | 10 hours |

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| | Skeletal system <ul style="list-style-type: none"> Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction Joints <ul style="list-style-type: none"> Structural and functional classification, types of joints movements and its articulation | |
| Unit III | Body fluids and blood <ul style="list-style-type: none"> Body fluids, composition and functions of blood, hemopoiesis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system. Lymphatic system <ul style="list-style-type: none"> Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system | 10 hours |
| Unit IV | Reproductive system Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition Introduction to genetics Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance | 08 hours |
| Unit V | Cardiovascular system <ul style="list-style-type: none"> Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram. | 07 hours |

BP107P. HUMAN ANATOMY AND PHYSIOLOGY I (Practical)

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| Credit Points | 02 |
| Practical Hours per week | 04 |

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

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones
6. Introduction to hemocytometry.
7. Enumeration of white blood cell (WBC) count
8. Enumeration of total red blood corpuscles (RBC) count
9. Determination of bleeding time
10. Determination of clotting time
11. Estimation of hemoglobin content
12. Determination of blood group.
13. Determination of erythrocyte sedimentation rate (ESR).
14. Determination of heart rate and pulse rate.
15. Recording of blood pressure.

Recommended Books (Latest Editions)

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

Reference Books (Latest Editions)

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

BP102T. PHARMACEUTICAL ANALYSIS (Theory)

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|--------------------------|----|---------------------------|----|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of the course student shall be able to

- Understand the principles of volumetric and electro chemical analysis
- Carryout various volumetric and electrochemical titrations
- Develop analytical skills

Course Content:

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| Unit I | <p>(a) Pharmaceutical analysis- Definition and scope</p> <ul style="list-style-type: none">• Introduction to different techniques of analysis (Volumetric, gravimetric, Electrochemical)• Methods of expressing concentration (Molarity, Normality, Molality, Mole, Percentage, ppm ($\mu\text{g/ml}$))• Primary and secondary standards. (Definitions, ideal properties and examples)• Preparation and standardization of various molar and normal solutions-Oxalic acid, sodium hydroxide, hydrochloric acid, iodine, sodium thiosulphate, sulphuric acid, potassium permanganate, ceric ammonium sulphate, perchloric acid, lithium methoxide, disodium EDTA, silver nitrate, Ammonium thiocyanate. <p>(b)Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures</p> <p>(c)Pharmacopoeia, Sources of impurities in medicinal agents, limit tests.</p> | 10 hours |
| Unit II | <p>Acid base titration:</p> <ul style="list-style-type: none">• Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves. Applications Benzoic acid, Aspirin, Calcium Hydroxide, Lactic acid. <p>Non aqueous titration:</p> <ul style="list-style-type: none">• Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl | 10 hours |
| Unit III | <p>Precipitation titrations:</p> <p>Theory, Factors affecting solubility of precipitate, Mohr's</p> | 10 hours |

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| | <p>method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride and potassium chloride..</p> <p>Complexometric titration: Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.</p> <p>Gravimetry: Principle and steps involved in gravimetric analysis. Organic precipitants, Purity of the precipitate: co-precipitation and post precipitation, Estimation of Barium Sulphate, Aluminium by Oxime method</p> <p>Basic Principles, methods and application of diazotisation titration. Estimation of Sulfanilamide</p> | |
| Unit IV | <p>Redox titrations</p> <p>(a) Concepts of oxidation and reduction</p> <p>(b) Types of redox titrations (Principles and applications) Permanganometry, Cerimetry, Iodimetry, Iodometry, Bromometry, Dichrometry, Titration with potassium iodate and Potassium Bromate.</p> <p>Applications: Assay of Hydrogen Peroxide, Ferrous Sulphate, Ascorbic acid, Copper Sulphate, Potassium Iodide, Isoniazid.</p> | 08 hours |
| Unit V | <p>Electrochemical methods of analysis</p> <p>Conductometry- Introduction, Conductivity cell, Conductometric titrations, applications.</p> <p>Potentiometry - Electrochemical cell, construction and working of reference (Standard hydrogen electrode, Silver-silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration. Types and applications of Potentiometric titration.</p> <p>Polarography - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications</p> | 07 hours |

BP108P. PHARMACEUTICAL ANALYSIS (Practical)

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| Credit Points | 02 |
| Practical Hours per week | 04 |

- I. **Calibration of volumetric glassware (Burette, Pipette, Volumetric Flask)**
- II. **Preparation and standardization of**
 - a. Sodium hydroxide
 - b. Sulphuric acid
 - c. Iodine
 - d. Sodium thiosulfate
 - e. Potassium permanganate
 - f. Ceric ammonium sulphate
 - g. Di sodium EDTA
 - h. Perchloric acid
 - i. Silver Nitrate (demonstration)
- III. **Assay of the following compounds along with Standardization of Titrant**
 - a. Ammonium chloride by acid base titration
 - b. Ascorbic acid by Iodometry
 - c. Copper sulphate by Iodometry
 - d. Calcium gluconate by complexometry
 - e. Hydrogen peroxide by Permanganometry
 - f. Sodium benzoate by non-aqueous titration
 - g. Sodium Chloride by precipitation titration (Demonstration)
 - h. Ferrous sulphate by cerimetry
- IV. **Determination of Normality by electro-analytical methods**
 - a. Conductometric titration of strong acid against strong base
 - b. Conductometric titration of strong acid and weak acid against strong base
 - c. Potentiometric titration of strong acid against strong base

Recommended Books: (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
5. John H. Kennedy, Analytical chemistry principles
6. Indian Pharmacopoeia.
7. Pharmaceutical Chemistry- Theory and applicatipons Volume I and II Chatten
8. Analytical Chemistry by Gary Christian.

BP103T. PHARMACEUTICS (Theory)

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|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

Objectives:

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

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

Course Content:

| | | |
|----------------|---|-----------------|
| Unit I | Historical background and development of profession of pharmacy: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia. Dosage forms: Introduction to dosage forms, classification and definitions Prescription: Definition, Parts of prescription, handling of Prescription and Errors in prescription. Posology: Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area. | 10 hours |
| Unit II | Pharmaceutical calculations: Weights and measures–Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight. | 10 hours |

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| | <p>Powders: Definition, classification, advantages and disadvantages, Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.</p> <p>Liquid dosage forms: Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques</p> | |
| Unit III | <p>Monophasic liquids: Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.</p> <p>Biphasic liquids:</p> <p>Suspensions: Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.</p> <p>Emulsions: Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.</p> | 10 hours |
| Unit IV | <p>Suppositories: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.</p> <p>Pharmaceutical incompatibilities: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.</p> | 08 hours |
| Unit V | <p>Semisolid dosage forms: Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosage forms</p> | 07 hours |

BP109P. PHARMACEUTICS (Practical)

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|--------------------------|----|
| Credit Points | 02 |
| Practical Hours per week | 04 |

1 . Syrups

- a. Syrup IP'66
- b. Compound syrup of Ferrous Phosphate BPC'68

2. Elixirs

- a. Piperazine citrate elixir
- b. Paracetamol pediatric elixir

3.Linctus

- a. Terpin Hydrate Linctus IP'66
- b. Iodine Throat Paint (Mandles Paint)

4. Solutions

- a. Strong solution of ammonium acetate
- b. Cresol with soap solution
- c. Lugol's solution

5. Suspensions

- a. Calamine lotion
- b. Magnesium Hydroxide mixture
- c. Aluminum Hydroxide gel

6. Emulsions

- a. Turpentine Liniment
- b. Liquid paraffin emulsion

7. Powders and Granules

- a. ORS powder (WHO)
- b. Effervescent granules
- c. Dusting powder d)Divided powders

8. Suppositories

- a. Glycero gelatin suppository
- b. Cocoa butter suppository
- c. Zinc Oxide suppository

8. Semisolids

- a. Sulphur ointment
- b. Non staining-iodine ointment with methyl salicylate
- c. Carbopol gel

9. Gargles and Mouthwashes

- a. Iodine gargle
- b. Chlorhexidine mouthwash

Recommended Books: (Latest Editions)

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

BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

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|--------------------------|----|---------------------------|----|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of course student shall be able to

- know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
- understand the medicinal and pharmaceutical importance of inorganic compounds

Course Content:

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| Unit I | Impurities in pharmaceutical substances: <ul style="list-style-type: none">• History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate• General methods of preparation, assay for the compounds superscripted with asterisk (*), properties and medicinal uses of inorganic compounds belonging to the following classes | 10 hours |
| Unit II | Acids, Bases and Buffers: Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity. Major extra and intracellular electrolytes: Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance. Dental products: Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement. | 10 hours |
| Unit III | Gastrointestinal agents <ul style="list-style-type: none">• Acidifiers: Ammonium chloride* and Dil. HCl• Antacid: Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture, Magnesium stearate | 10 hours |

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| | <ul style="list-style-type: none"> • Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite <p>Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations</p> | |
| Unit IV | <p>Miscellaneous compounds</p> <ul style="list-style-type: none"> • Expectorants: Potassium iodide, Ammonium chloride*. • Emetics: Copper sulphate*, Sodium potassium tartarate • Haematinics: Ferrous sulphate*, Ferrous gluconate • Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium nitrite • Astringents: Zinc Sulphate, Potash Alum | 08 hours |
| Unit V | <p>Radiopharmaceuticals:</p> <p>Radio activity, Measurement of radioactivity, Properties of α, β, γ radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I^{131}, Storage conditions, precautions & pharmaceutical application of radioactive substances.</p> | 07 hours |

BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

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| Credit Points | 02 |
| Practical Hours per week | 04 |

I Limit tests for following ions

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

II Identification test

Magnesium hydroxide Ferrous sulphate Sodium bicarbonate Calcium gluconate
Copper sulphate

III Test for purity

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

IV Preparation of inorganic pharmaceuticals

- Boric acid
- Potash alum
- Ferrous sulphate

Recommended Books (Latest Editions)

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

BP105T.COMMUNICATION SKILLS (Theory)

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|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 02 | Total Teaching Hours | 30 |
| No. of lectures per week | 02 | No. of tutorials per week | - |

Scope:

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

Objectives:

Upon completion of the course the student shall be able to

- Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
- Communicate effectively (Verbal and Non Verbal)
- Effectively manage the team as a team player
- Develop interview skills
- Develop Leadership qualities and essentials

Course content:

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|----------------|--|-----------------|
| Unit I | Communication Skills: Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context Barriers to communication: Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers Perspectives in Communication: Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment | 07 hours |
| Unit II | Elements of Communication: Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication Communication Styles: Introduction, The Communication Styles Matrix with example for each - Direct Communication Style, Spirited | 07 hours |

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| | Communication Style, Systematic Communication Style, Considerate Communication Style | |
| Unit III | Basic Listening Skills: Introduction, Self-Awareness, Active Listening, Becoming anActive Listener, Listening in Difficult Situations Effective Written Communication: Introduction, When and When Not to Use WrittenCommunication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication Writing Effectively: Subject Lines, Put the Main Point First, Know Your Audience,Organization of the Message | 07 hours |
| Unit IV | Interview Skills: Purpose of an interview, Do's and Dont's of an interview Giving Presentations: Dealing with Fears, Planning your Presentation, Structuring YourPresentation, Delivering Your Presentation, Techniques of Delivery | 05 hours |
| Unit V | Group Discussion: Introduction, Communication skills in group discussion, Do's andDont's of group discussion | 04 hours |

BP111P.COMMUNICATION SKILLS (Practical)

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|--------------------------|----|
| Credit Points | 01 |
| Practical Hours per week | 02 |

The following learning modules are to be conducted using wordsworth® English language lab software

Basic communication covering the following topics

- a. Meeting People
- b. Asking Questions
- c. Making Friends
- d. What did you do?
- e. Do's and Don'ts

Pronunciations covering the following topics

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

Advanced Learning

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

Recommended Books: (Latest Edition)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1st Edition, Oxford Press, 2011
3. Organizational Behaviour, Stephen .P. Robbins, 1st Edition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1st Edition, Pearson Life, 2011

5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5thEdition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2ndEdition, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1stEdition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1stEdition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4thEdition, Pan Mac Millan, 2009
12. Bringing out the best in people, Aubrey Daniels, 2ndEdition, Mc Graw Hill, 1999

BP 106RBT.REMEDIAL BIOLOGY (Theory)

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| Credit Points | 02 | Total Teaching Hours | 30 |
| No. of lectures per week | 02 | No. of tutorials per week | - |

Scope:

To learn and understand the components of living world, structure and functional system of plant and animal kingdom.

Objectives:

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

- know the classification and salient features of five kingdoms of life
- understand the basic components of anatomy & physiology of plant
- know understand the basic components of anatomy & physiology animal with special reference to human

Course content:

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| Unit I | Living world: <ul style="list-style-type: none">• Definition and characters of living organisms• Diversity in the living world• Binomial nomenclature• Five kingdoms of life and basis of classification. Salient features of Monera, Protista, Fungi, Animalia and Plantae, Virus, Morphology of Flowering plants <ul style="list-style-type: none">• Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.• General Anatomy of Root, stem, leaf of monocotyledons & Dicotyledones. | 07 hours |
| Unit II | Body fluids and circulation <ul style="list-style-type: none">• Composition of blood, blood groups, coagulation of blood• Composition and functions of lymph• Human circulatory system• Structure of human heart and blood vessels• Cardiac cycle, cardiac output and ECG Digestion and Absorption <ul style="list-style-type: none">• Human alimentary canal and digestive glands• Role of digestive enzymes• Digestion, absorption and assimilation of digested food Breathing and respiration <ul style="list-style-type: none">• Human respiratory system• Mechanism of breathing and its regulation• Exchange of gases, transport of gases and regulation of respiration | 07 hours |

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| | <ul style="list-style-type: none"> Respiratory volumes | |
| Unit III | <p>Excretory products and their elimination</p> <ul style="list-style-type: none"> Modes of excretion Human excretory system- structure and function Urine formation Rennin angiotensin system <p>Neural control and coordination</p> <ul style="list-style-type: none"> Definition and classification of nervous system Structure of a neuron Generation and conduction of nerve impulse Structure of brain and spinal cord Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata <p>Chemical coordination and regulation</p> <ul style="list-style-type: none"> Endocrine glands and their secretions Functions of hormones secreted by endocrine glands <p>Human reproduction</p> <ul style="list-style-type: none"> Parts of female reproductive system Parts of male reproductive system Spermatogenesis and Oogenesis Menstrual cycle | 07 hours |
| Unit IV | <p>Plants and mineral nutrition:</p> <ul style="list-style-type: none"> Essential mineral, macro and micronutrients Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation <p>Photosynthesis</p> <ul style="list-style-type: none"> Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis. | 05 hours |
| Unit V | <p>Plant respiration:Respiration, glycolysis, fermentation (anaerobic).</p> <p>Plant growth and development</p> <ul style="list-style-type: none"> Phases and rate of plant growth, Condition of growth,Introduction to plant growth regulators <p>Cell - The unit of life</p> <ul style="list-style-type: none"> Structure and functions of cell and cell organelles.Cell division <p>Tissues</p> <ul style="list-style-type: none"> Definition, types of tissues, location and functions. | 04 hours |

Text Books

1. Text book of Biology by S. B. Gokhale
2. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

1. A Text book of Biology by B.V. Sreenivasa Naidu
2. A Text book of Biology by Naidu and Murthy
3. Botany for Degree students By A.C.Dutta.
4. Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.

5. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

BP112RBP.REMEDIAL BIOLOGY (Practical)

| | |
|--------------------------|----|
| Credit Points | 01 |
| Practical Hours per week | 02 |

1. Introduction to experiments in biology
 - a) Study of Microscope
 - b) Section cutting techniques
 - c) Mounting and staining
 - d) Permanent slide preparation
2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues pertinent to Stem, Root Leaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Reference Books

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

BP 106RMT.REMEDIAL MATHEMATICS (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 02 | Total Teaching Hours | 30 |
| No. of lectures per week | 02 | No. of tutorials per week | - |

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

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

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

Course Content:

| | | |
|-----------------|---|-----------------|
| Unit I | <p>☐ Partial fraction Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction, Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics</p> <p>☐ Logarithms Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.</p> <p>☐ Function: Real Valued function, Classification of real valued functions,</p> <p>Limits and continuity :Introduction, Limit of a function, Definition of limit of a function (☐ ☐ ☐ ☐ definition)</p> $\lim_{x \rightarrow a} \frac{x^n - a^n}{x - a} = na^{n-1}, \quad \lim_{\theta \rightarrow 0} \frac{\sin \theta}{\theta} = 1,$ | 06 hours |
| Unit II | <p>Matrices and Determinant: Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants, Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix, Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley-Hamilton theorem, Application of Matrices in solving Pharmacokinetic equations</p> | 06 hours |
| Unit III | Calculus: | 06hours |

| | | |
|----------------|---|-----------------|
| | <p>Differentiation : Introductions, Derivative of a function, Derivative of a</p> <p>Derivative of a product of a constant and a function , constant, Derivative of the sum or difference of two functions, Derivative of the product of two functions (productDerivative of quotient of two formula), the functions</p> <p>(Quotient formula) – WithoutDerivative of x^n w.r.t x, where n is any</p> <p>Proof, rational of of $\log_e x$, number, Derivative e^x, Derivative Derivative of a^x, Derivative of trigonometric functions from first principles(withoutProof), Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point. Application</p> | |
| Unit IV | <p>Analytical Geometry</p> <ul style="list-style-type: none"> • Introduction: Signs of the Coordinates, Distance formula, • Straight Line : Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line • Integration: • Introduction, Definition, Standard formulae, Rules of integration , Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application | 06 hours |
| Unit V | <p>☐ Differential Equations : Some basic definitions, Order and degree, Equations in separable form , Homogeneous equations, Linear Differential equations, Exact equations, Application in solving</p> <p>Pharmacokinetic equations</p> <p>☐ Laplace Transform : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, Application in solving Chemical kinetics and Pharmacokinetics equations</p> | 06 hours |

Recommended Books (Latest Edition)

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

Semester II

Course of study for semester II

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

*Non University Examination (NUE)

BP 201T. HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives:

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

- Explain the gross morphology, structure and functions of various organs of the human body.
- Describe the various homeostatic mechanisms and their imbalances.
- Identify the various organs of different systems of human body.
- Appreciate coordinated working pattern of different organs of each system
- Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Course Content:

| | | |
|----------------|---|-----------------|
| Unit I | Nervous system Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters. Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity) | 10 hours |
| Unit II | Digestive system Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients | 06 hours |

| | | |
|-----------------|---|-----------------|
| | <p>and disorders of GIT</p> <p>Energetics Formation and role of ATP, Creatinine Phosphate and BMR.</p> | |
| Unit III | <p>Respiratory system Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.</p> <p>Urinary system Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.</p> | 10 hours |
| Unit IV | <p>Endocrine system Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.</p> | 10 hours |
| Unit V | <p>Peripheral nervous system:</p> <ul style="list-style-type: none"> • Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system. • Origin and functions of spinal and cranial nerves. <p>Special senses</p> <ul style="list-style-type: none"> • Structure and functions of eye, ear, nose and tongue and their disorders. | 09 hours |

BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY II (Practical)

| | |
|--------------------------|----|
| Credit Points | 02 |
| Practical Hours per week | 04 |

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

1. To study the integumentary and special senses using specimen, models, etc.,
2. To study the nervous system using specimen, models, etc.,
3. To study the endocrine system using specimen, models, etc
4. To demonstrate the general neurological examination
5. To demonstrate the function of olfactory nerve
6. To examine the different types of taste.
7. To demonstrate the visual acuity
8. To demonstrate the reflex activity
9. Recording of body temperature
10. To demonstrate positive and negative feedback mechanism.
11. Determination of tidal volume and vital capacity.
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
13. 13. Recording of basal mass index .
14. Study of family planning devices and pregnancy diagnosis test.
15. Demonstration of total blood count by cell analyser
16. Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

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

6. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
7. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books:

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

BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

Objectives:

Upon completion of the course the student shall be able to

- write the structure, name and the type of isomerism of the organic compound
- write the reaction, name the reaction and orientation of reactions
- account for reactivity/stability of compounds,
- identify/confirm the identification of organic compound

Course Content:

| | | |
|-----------------|--|-----------------|
| Unit I | Classification, nomenclature and isomerism <ul style="list-style-type: none">• Classification of Organic Compounds• Common and IUPAC systems of nomenclature of organic compounds• (up to 10 Carbons open chain and carbocyclic compounds) Structural isomerisms in organic compounds | 07 hours |
| Unit II | Alkanes*, Alkenes* and Conjugated dienes* <ul style="list-style-type: none">• sp^3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins. Stabilities of alkenes, sp^2 hybridization in alkenes• E_1 and E_2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E_1 verses E_2 reactions, Factors affecting E_1 and E_2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.• Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement | 10 hours |
| Unit III | Alkyl halides* | 10 |

| | | |
|----------------|---|-----------------|
| | <p>SN₁ and SN₂ reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.</p> <p>SN₁ versus SN₂ reactions, Factors affecting SN₁ and SN₂ reactions</p> <p>Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.</p> <p>Alcohols*- Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol</p> | hours |
| Unit IV | <p>Carbonyl compounds* (Aldehydes and ketones)</p> <p>Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde.</p> | 10 hours |
| Unit V | <p>Carboxylic acids*</p> <p>Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids, amide and ester</p> <p>Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid</p> <p>Aliphatic amines* - Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine</p> | 08 hours |

BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)

| | |
|--------------------------|----|
| Credit Points | 02 |
| Practical Hours per week | 04 |

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

Recommended Books (Latest Editions)

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

BP203 T. BIOCHEMISTRY (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

Objectives:

Upon completion of course student shall be able to

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

Course Content:

| | | |
|----------------|--|-----------------|
| Unit I | Biomolecules Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins. Bioenergetics Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential. Energy rich compounds; classification; biological significances of ATP and cyclic AMP | 08 hours |
| Unit II | Carbohydrate metabolism Glycolysis – Pathway, energetics and significance Citric acid cycle- Pathway, energetics and significance HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency Glycogen metabolism Pathways and glycogen storage diseases (GSD) Gluconeogenesis- Pathway and its | 10 hours |

| | | |
|-----------------|---|-----------------|
| | <p>significance</p> <p>Hormonal regulation of blood glucose level and Diabetes mellitus</p> <p>Biological oxidation</p> <p>Electron transport chain (ETC) and its mechanism. Oxidative phosphorylation & its mechanism and substrate level phosphorylation</p> <p>Inhibitors ETC and oxidative phosphorylation/Uncouplers</p> | |
| Unit III | <p>Lipid metabolism</p> <ul style="list-style-type: none"> • β-Oxidation of saturated fatty acid (Palmitic acid) • Formation and utilization of ketone bodies; ketoacidosis • De novo synthesis of fatty acids (Palmitic acid) • Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D • Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity. <p>Amino acid metabolism</p> <ul style="list-style-type: none"> • General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders • Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenylketonuria, Albinism, alcaptonuria, tyrosinemia) • Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline • Catabolism of heme; hyperbilirubinemia and jaundice | 10 hours |
| Unit IV | <p>Nucleic acid metabolism and genetic information transfer</p> <p>Biosynthesis of purine and pyrimidine nucleotides</p> <p>Catabolism of purine nucleotides and Hyperuricemia and Gout disease Organization of mammalian genome</p> <p>Structure of DNA and RNA and their functions DNA replication (semi conservative model) Transcription or RNA synthesis</p> <p>Genetic code, Translation or Protein synthesis and inhibitors</p> | 10 hours |
| Unit V | <p>Enzymes</p> <p>Introduction, properties, nomenclature and IUB classification of enzymes Enzyme kinetics</p> | 07 hours |

| | | |
|--|--|--|
| | <p>(Michaelis menton plot, Line Weaver Burke plot)</p> <p>Enzyme inhibitors with examples</p> <p>Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation</p> <p>Therapeutic and diagnostic applications of enzymes and isoenzymes Coenzymes –Structure and biochemical functions</p> | |
|--|--|--|

BP 209 P. BIOCHEMISTRY (Practical)

| | |
|--------------------------|----|
| Credit Points | 02 |
| Practical Hours per week | 04 |

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity/ β amylase.
11. Study the effect of Temperature on Salivary amylase / β amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity/ β amylase.

Recommended Books (Latest Editions)

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

BP 204T.PATHOPHYSIOLOGY (THEORY)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes. This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

Objectives:

Upon completion of the subject student shall be able to–

- Describe the etiology and pathogenesis of the selected disease states;
- Name the signs and symptoms of the diseases; and
- Mention the complications of the diseases

Course Content:

| | | |
|----------------|--|-----------------|
| Unit I | Basic principles of Cell injury and Adaptation: <ul style="list-style-type: none"> • Introduction, definitions, Homeostasis, Components and Types of Feedback systems, • Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance Basic mechanism involved in the process of inflammation and repair: <ul style="list-style-type: none"> • Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism • of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis | 10 hours |
| Unit II | Cardiovascular System: | 10 |

| | | |
|-----------------|--|-----------------|
| | <p>Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis)</p> <p>Respiratory system: Asthma, Chronic obstructive airways diseases.</p> <p>Renal system: Acute and chronic renal failure</p> | hours |
| Unit III | <p>Haematological Diseases:</p> <p>Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia</p> <p>Endocrine system: Diabetes, thyroid diseases, disorders of sex hormones</p> <p>Nervous system: Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.</p> <p>Gastrointestinal system: Peptic Ulcer, Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.</p> | 10 hours |
| Unit IV | <p>Disease of bones and joints: Rheumatoid arthritis, osteoporosis and gout</p> <p>Principles of cancer: classification, etiology and pathogenesis of cancer</p> <p>Diseases of bones and joints: Rheumatoid Arthritis, Osteoporosis, Gout</p> | 08 hours |
| Unit V | <p>Infectious diseases: Meningitis, Typhoid, Leprosy, Tuberculosis</p> <p>Urinary tract infections</p> <p>Sexually transmitted diseases: AIDS, Syphilis, Gonorrhea</p> | 07 hours |

Recommended Books (Latest Editions)

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore; 1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders

- Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
 9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
 10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

Recommended Journals

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

BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 02 | Total Teaching Hours | 30 |
| No. of lectures per week | 02 | No. of tutorials per week | - |

Scope:

This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

Objectives:

Upon completion of the course the student shall be able to

- know the various types of application of computers in pharmacy
- know the various types of databases
- know the various applications of databases in pharmacy

Course content:

| | | |
|-----------------|--|---------------------|
| Unit I | Operating Systems Purpose of an Operating System, Types & functions Communications and connectivity Overview of Computer Networks, LAN, MAN, WAN, Internet , Intranet, Network topology, Network Architecture , Network Protocols Internetworking: Bridges, Repeaters and Routers Concept of Information Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project | 08 hours |
| Unit II | Web technologies: Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database | 06 hours |
| Unit III | Application of computers in Pharmacy –Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System | 06 hours |
| Unit IV | Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in | 06 hours |

| | | |
|---------------|--|-----------------|
| | VaccineDiscovery | |
| Unit V | Computers as data analysis in Preclinical development: Chromatographic dada analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMs) | 04 hours |

BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

| | |
|--------------------------|----|
| Credit Points | 01 |
| Practical Hours per week | 02 |

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

Recommended books (Latest edition):

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002
5. Introduction to database management system by Kahate
6. Computer Applications and Biostatistics By Bhise & Dias.

BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 02 | Total Teaching Hours | 30 |
| No. of lectures per week | 02 | No. of tutorials per week | - |

Scope:

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

Objectives:

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

- Create the awareness about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the environment.
- Motivate learner to participate in environment protection and environment improvement.
- Acquire skills to help the concerned individuals in identifying and solving environmental problems.
- Strive to attain harmony with Nature.

Course content:

| | | |
|-----------------|--|-----------------|
| Unit I | The Multidisciplinary nature of environmental studies Natural Resources Renewable and non-renewable resources: Natural resources and associated problems a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources. | 10 hours |
| Unit II | Ecosystems ☐ Concept of an ecosystem. ☐ Structure and function of an ecosystem. ☐ Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries) | 10 hours |
| Unit III | Environmental Pollution: Air pollution; Water pollution; Soil pollution | 10 hours |

Recommended Books (Latest edition):

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

Semester III

Course of study for semester III

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

BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

This subject deals with general methods of preparation and reactions of someorganic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

Objectives:

Upon completion of the course the student shall be able to

- write the structure, name and the type of isomerism of the organic compound
- write the reaction, name the reaction and orientation of reactions
- account for reactivity/stability of compounds,
- prepare organic compounds

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

| | | |
|----------------|---|-----------------|
| Unit I | Benzene and its derivatives A. Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule B. Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation. C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction D. Structure and uses of DDT, Saccharin, BHC and Chloramine | 10 hours |
| Unit II | Phenols* - Acidity of phenols, effect of substituents on acidity, qualitativetests, Structure and uses of phenol, cresols, | 10 hours |

| | | |
|-----------------|---|-----------------|
| | <p>resorcinol, naphthols</p> <p>Aromatic Amines* - Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts</p> <p>Aromatic Acids* -Acidity, effect of substituents on acidity and important reactions of benzoic acid.</p> | |
| Unit III | <p>Fats and Oils</p> <ul style="list-style-type: none"> Fatty acids – reactions. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination. | 10 hours |
| Unit IV | <p>Polynuclear hydrocarbons:</p> <ul style="list-style-type: none"> Synthesis, reactions Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives | 08 hours |
| Unit V | <p>Cyclo alkanes*</p> <p>Stabilities – Baeyer’s strain theory, limitation of Baeyer’s strain theory, Coulson and Moffitt’s modification, Sachse Mohr’s theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane.</p> | 07 hours |

BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

| | |
|--------------------------|----|
| Credit Points | 02 |
| Practical Hours per week | 04 |

I Experiments involving laboratory techniques

- ☐ Recrystallization
- ☐ Steam distillation

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

- ☐ Acid value
- ☐ Saponification value
- ☐ Iodine value

III. Preparation of compounds

Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.

2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/ Acetanilide by halogenation (Bromination) reaction.

5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.

Benzoic acid from Benzyl chloride by oxidation reaction.

Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.

1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.

Benzil from Benzoin by oxidation reaction.

Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction

Cinnamic acid from Benzaldehyde by Perkin reaction

P-Iodo benzoic acid from *P*-amino benzoic acid

Recommended Books (Latest Editions)

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

BP302T. PHYSICAL PHARMACEUTICS-I (Theory)

| | | | |
|--------------------------|----|---------------------------|----|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

The course deals with the various physical and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation forms.

Objectives:

Upon the completion of the course student shall be able to

- Understand various physicochemical properties of drug molecules in the designing the dosage forms
- Know the principles of chemical kinetics & use them for stability testing and determination of expiry date of formulations
- Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Content:

| | | |
|-----------------|--|-----------------|
| Unit I | Solubility of drugs: Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications | 10 hours |
| Unit II | States of Matter and properties of matter: State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols – inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism. Physicochemical properties of drug molecules: Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations and applications | 11 hours |
| Unit III | Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions, Surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface. | 08 hours |

| | | |
|----------------|--|-----------------|
| Unit IV | Complexation and protein binding: Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants. | 08 hours |
| Unit V | pH, buffers and Isotonic solutions: Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions. | 08 hours |

BP306P. PHYSICAL PHARMACEUTICS – I (Practical)

| | |
|--------------------------|----|
| Credit Points | 02 |
| Practical Hours per week | 04 |

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

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin
2. Experimental Pharmaceutics by Eugene, Parott.
3. Tutorial Pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C and ManavalanR.
8. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
9. Physical Pharmaceutics by C.V.S. Subramanyam
10. Test book of Physical Pharmacy, by Gaurav Jain &Roop K. Khar
11. Physical Pharmacy and Pharmaceutical Science Sinko by Alfred Martin
12. Physical Pharmaceutics by AnantParadkar and UmeshHadkar

BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

Study of all categories of microorganisms especially for the production of alcohol antibiotics, vaccines, vitamins enzymes etc.

Objectives:

Upon completion of the subject student shall be able to;

- Understand methods of identification, cultivation and preservation of various microorganisms
- To understand the importance and implementation of sterilization in pharmaceutical processing and industry
- Learn sterility testing of pharmaceutical products.
- Carry out microbiological standardization of Pharmaceuticals.
- Understand the cell culture technology and its applications in pharmaceutical industries.

Course Content:

| | | |
|-----------------|---|-----------------|
| Unit I | Introduction, history of microbiology, its branches, scope and its importance. Introduction to Prokaryotes and Eukaryotes Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count). Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy. | 10 hours |
| Unit II | Identification of bacteria using staining techniques (simple, Gram's & Acid fast staining) and biochemical tests (IMViC). Study of principle, procedure, merits, demerits and applications of physical, chemical, gaseous, radiation and mechanical method of sterilization. Evaluation of the efficiency of sterilization methods. Equipments employed in large scale sterilization. Sterility indicators. | 10 hours |
| Unit III | Study of morphology, classification, reproduction/replication | 10 |

| | | |
|----------------|---|-----------------|
| | and cultivation of Fungi and Viruses. Classification and mode of action of disinfectants. Factors influencing disinfection, antiseptics and their evaluation for bacteriostatic and bactericidal actions. Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP. | hours |
| Unit IV | Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification. Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic. | 08 hours |
| Unit V | Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage. Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations. Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures. Application of cell cultures in pharmaceutical industry and research. | 07 hours |

BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)

| | |
|--------------------------|----|
| Credit Points | 02 |
| Practical Hours per week | 04 |

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

Recommended Books (Latest edition)

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

BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of the course student shall be able:

- To know various unit operations used in Pharmaceutical industries.
- To understand the material handling techniques.
- To perform various processes involved in pharmaceutical manufacturing process.
- To carry out various test to prevent environmental pollution.
- To appreciate and comprehend significance of plant lay out design for optimum use of resources.
- To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

Course Content:

| | | |
|----------------|---|-----------------|
| Unit I | <p>Flow of fluids: Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer.</p> <p>Size Reduction: Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.</p> <p>Size Separation: Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.</p> | 10 hours |
| Unit II | <p>Heat Transfer: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.</p> <p>Evaporation: Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator,</p> | 10 hours |

| | | |
|-----------------|--|-----------------|
| | <p>climbing film evaporator, forced circulation evaporator, multiple effect evaporator & Economy of multiple effect evaporator.</p> <p>Distillation: Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation</p> | |
| Unit III | <p>Drying: Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.</p> <p>Mixing: Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier</p> | 10 hours |
| Unit IV | <p>Filtration: Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.</p> <p>Centrifugation: Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.</p> | 08 hours |
| Unit V | <p>Materials of pharmaceutical plant construction, Corrosion and its prevention: Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. Ferrous and nonferrous metals, inorganic and organic non metals, basic of material handling systems.</p> | 07 hours |

BP308P - PHARMACEUTICAL ENGINEERING (Practical)

| | |
|--------------------------|----|
| Credit Points | 02 |
| Practical Hours per week | 04 |

1. Determination of radiation constant of brass, iron, unpainted and painted glass.
2. Steam distillation – To calculate the efficiency of steam distillation.
3. To determine the overall heat transfer coefficient by heat exchanger.
4. Construction of drying curves (for calcium carbonate and starch).
5. Determination of moisture content and loss on drying.
6. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
7. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
8. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.
9. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
10. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.
11. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity)
12. To study the effect of time on the Rate of Crystallization.
13. To calculate the uniformity Index for given sample by using Double Cone Blender.

Recommended Books: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
3. Unit operation of chemical engineering – McCabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceuticals- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.
9. Pharmaceutical Engineering: G.K. Jani
10. Pharmaceutical Engineering: Anant Narayan & Umesh B. Hadkar

Semester IV

Course of study for semester IV

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

BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

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

- understand the methods of preparation and properties of organic compounds
- explain the stereo chemical aspects of organic compounds and stereo chemical reactions
- know the medicinal uses and other applications of organic compounds

Course Content:

Note: To emphasize on definition, types, mechanisms, examples, uses/applications

| | | |
|----------------|---|-----------------|
| Unit I | Stereo isomerism Optical isomerism – Optical activity, enantiomerism, diastereoisomerism, meso compounds Elements of symmetry, chiral and achiral molecules DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers Reactions of chiral molecules Racemic modification and resolution of racemic mixture. Asymmetric synthesis: partial and absolute | 10 hours |
| Unit II | Geometrical isomerism Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems) Methods of determination of configuration of geometrical isomers. Conformational isomerism in Ethane, n-Butane and Cyclohexane. Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity. | 10 hours |

| | | |
|-----------------|--|-----------------|
| | Stereospecific and stereoselective reactions | |
| Unit III | Heterocyclic compounds: Nomenclature and classification Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrrole, Furan, and Thiophene Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene | 06 hours |
| Unit IV | Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrazole, Imidazole, Oxazole and Thiazole. Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives | 12 hours |
| Unit V | Reactions of synthetic importance Metal hydride reduction (NaBH_4 and LiAlH_4), Clemmensen reduction, Birch reduction, Wolff Kishner reduction. Oppenauer-oxidation and Dakin reaction. Beckmanns rearrangement and Schmidt rearrangement. Claisen-Schmidt condensation | 07 hours |

Recommended Books (Latest Editions)

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry by Morrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist

BP402T. MEDICINAL CHEMISTRY – I (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of the course the student shall be able to

- understand the chemistry of drugs with respect to their pharmacological activity
- understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- know the Structural Activity Relationship (SAR) of different class of drugs
- write the chemical synthesis of some drugs

Course Content:

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

| | | |
|----------------|---|-----------------|
| Unit I | Introduction to Medicinal Chemistry History and development of medicinal chemistry Physicochemical properties in relation to biological action Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism. Drug metabolism Drug metabolism principles- Phase I and Phase II. Factors affecting drug metabolism including stereo chemical aspects | 10 hours |
| Unit II | Drugs acting on Autonomic Nervous System Adrenergic Neurotransmitters: | 10 hours |

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| | <p>Biosynthesis and catabolism of catecholamine.</p> <p>Adrenergic receptors (Alpha & Beta) and their distribution.</p> <p>Sympathomimetic agents: SAR of Sympathomimetic agents</p> <p>Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine, Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.</p> <p>☐ Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.</p> <p>☐ Agents with mixed mechanism: Ephedrine, Metaraminol.</p> <p>Adrenergic Antagonists:</p> <p>Alpha adrenergic blockers: Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.</p> <p>Beta adrenergic blockers: SAR of beta blockers, Propranolol*, Metipranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol</p> | |
| Unit III | <p>Cholinergic neurotransmitters:</p> <p>Biosynthesis and catabolism of acetylcholine.</p> <p>Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.</p> <p>Parasympathomimetic agents: SAR of Parasympathomimetic agents</p> <p>Direct acting agents: Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.</p> <p>Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible): Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorophate, Echothiophate iodide, Parathion, Malathion.</p> <p>Cholinesterase reactivator: Pralidoxime chloride.</p> <p>Cholinergic Blocking agents: SAR of cholinolytic agents</p> <p>Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyaminesulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*.</p> | 10 hours |

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| | <p>Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolatehydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride</p> | |
| Unit IV | <p>Drugs acting on Central Nervous System</p> <p>A. Sedatives and Hypnotics:</p> <p>Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem</p> <p>Barbiturates: SAR of barbiturates, Barbitol*, Phenobarbital, Mephobarbital, Amobarbital, Butobarbital, Pentobarbital, Secobarbital</p> <p>Miscellaneous:</p> <p>Amides & imides: Glutethimide.</p> <p>Alcohol & their carbamate derivatives: Meprobamate, Ethchlorvynol.</p> <p>Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.</p> <p>B. Antipsychotics</p> <p>Phenothiazines: SAR of Phenothiazines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.</p> <p>Ring Analogues of Phenothiazines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.</p> <p>Fluoro buterophenones: Haloperidol, Droperidol, Risperidone.</p> <p>Beta amino ketones: Molindone hydrochloride.</p> <p>Benzamides: Sulpieride.</p> <p>C. Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action</p> <p>Barbiturates: Phenobarbital, Methobarbital. Hydantoins: Phenytoin*, Mephentyoin, Ethotoin Oxazolidine diones: Trimethadione, Paramethadione Succinimides: Phensuximide, Methsuximide, Ethosuximide* Urea and</p> | 08 hours |

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| | <p>monoacylureas: Phenacemide, Carbamazepine*</p> <p>Benzodiazepines: Clonazepam</p> <p>Miscellaneous: Primidone, Valproic acid , Gabapentin, Felbamate</p> | |
| Unit V | <p>Drugs acting on Central Nervous System</p> <p>General anesthetics:</p> <p>Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.</p> <p>Ultra short acting barbiturates: Methohexital sodium*, Thiamylalsodium, Thiopental sodium.</p> <p>Dissociative anesthetics: Ketamine hydrochloride.*</p> <p>Narcotic and non-narcotic analgesics</p> <p>Morphine and related drugs: SAR of Morphine analogues, Morphinesulphate, Codeine, Meperidine hydrochloride, Anilerdine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate.</p> <p>Narcotic antagonists: Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.</p> <p>Non-Steroidal Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepirac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.</p> | 07 hours |

BP406P. MEDICINAL CHEMISTRY – I (Practical)

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| Credit Points | 02 |
| Practical Hours per week | 04 |

I Preparation of drugs/ intermediates

- 1 1,3-pyrazole
- 2 1,3-oxazole
- 3 Benzimidazole
- 4 Benztriazole
- 5 2,3- diphenyl quinoxaline
- 6 Benzocaine
- 7 Phenytoin
- 8 Phenothiazine
- 9 Barbiturate

II Assay of drugs (Any six)

- 1 Chlorpromazine
- 2 Phenobarbitone
- 3 Atropine
- 4 Ibuprofen
- 5 Aspirin
- 6 Furosemide
- 7 Hexamine
- 8 Thiamine HCl
- 9 Benzoic Acid
- 10 Quinine Sulfate

III Determination of Partition coefficient for any two drugs

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.

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

BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory)

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|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

The course deals with the various physical and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

Objectives:

Upon the completion of the course student shall be able to

- Understand various physicochemical properties of drug molecules in the designing the dosage forms
- Know the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations
 - Demonstrate use of physicochemical properties in the formulation
- development and evaluation of dosage forms.

Course Content:

| | | |
|-----------------|---|-----------------|
| Unit I | Colloidal dispersions: Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization & protective action. | 07 hours |
| Unit II | Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers Deformation of solids: Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus | 08 hours |
| Unit III | Coarse dispersion: Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of flocculated and deflocculated suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formulation by HLB method | 10 hours |

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| Unit IV | Micromeretics: Particle size and distribution, mean particle size, number and weight distribution, particle number, methods for determining particle size by different methods, counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties. | 10 hours |
| Unit V | Drug stability: Reaction kinetics: zero, pseudo-zero order, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention | 10 hours |

BP 407P. PHYSICAL PHARMACEUTICS- II (Practical)

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| Credit Points | 02 |
| Practical Hours per week | 04 |

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

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.
8. Physical Pharmaceutics. Anant Paradkar, Umesh B. Hadkar
9. Physical Pharmaceutics: CVS Subramanyam & Thimmasetty
10. Physical Pharmaceutics by Patrick Sinko

BP 404 T. PHARMACOLOGY-I (Theory)

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|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

Objectives:

Upon completion of this course the student should be able to

- Understand the pharmacological actions of different categories of drugs
- Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
- Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
- Observe the effect of drugs on animals by simulated experiments
- Appreciate correlation of pharmacology with other bio medical sciences

Course Content:

| | | |
|----------------|--|-----------------|
| Unit I | General Pharmacology a. Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists(competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy. b. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination | 08 hours |
| Unit II | General Pharmacology a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein-coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action. | 12 hours |

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| | b. Adverse drug reactions. c. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance. | |
| Unit III | Pharmacology of drugs acting on peripheral nervous system a. Organization and function of ANS. b. Neurohumoral transmission, co-transmission and classification of neurotransmitters. c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics. d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral). e. Local anesthetic agents. Drugs used in myasthenia gravis and glaucoma | 10 hours |
| Unit IV | Pharmacology of drugs acting on central nervous system a. Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine. b. General anesthetics and pre-anesthetics. c. Sedatives, hypnotics and centrally acting muscle relaxants. d. Anti-epileptics Alcohols and disulfiram | 08 hours |
| Unit V | Pharmacology of drugs acting on central nervous system a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens. b. Drugs used in Parkinsons disease and Alzheimer's disease. c. CNS stimulants and nootropics. d. Opioid analgesics and antagonists Drug addiction, drug abuse, tolerance and dependence. | 07 hours |

BP 408 P.PHARMACOLOGY-I (Practical)

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| Credit Points | 02 |
| Practical Hours per week | 04 |

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods
16. DRC of Acetylcholine using chick ileum

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

Recommended Books (Latest Editions)

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

8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan

BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)

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| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of the course, the student shall be able

- to know the techniques in the cultivation and production of crude drugs
- to know the crude drugs, their uses and chemical nature
- know the evaluation techniques for the herbal drugs
- to carry out the microscopic and morphological evaluation of crude drugs

Course content:

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| Unit I | Introduction to Pharmacognosy: (a) Definition, history, scope and development of Pharmacognosy (b) Sources of Drugs – Plants, Animals, Marine Mineral & Tissue culture (c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum - resins). <u>(d) Systematic description of crude drugs.</u> Classification of drugs: Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs <u>with merits and demerits.</u> Quality control of Drugs of Natural Origin: (a) Adulteration of drugs of natural origin. <u>Definition, causes of adulteration and different methods adopted in drug adulteration.</u> (b) Evaluation by organoleptic, microscopic, physical, chemical and biological methods <u>including quantitative microscopy.</u> | 13 hours |
| Unit II | Cultivation, Collection, Processing and storage of drugs of natural origin: Exogenous- Altitude, climate, temperature, rainfall, soil and soil fertility, pest & pest control, growth hormones. Endogenous- Mutation, Hybridisation, polyploidy and chemodensities). <u>Detailed method of cultivation and processing of the following drugs: Senna, Cinchona, Isabgol, Opium & Rauwolfia.</u> Conservation of medicinal plants: | 07 hours |

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| | <u>In situ and Ex situ Conservation of medicinal plants</u> | |
| Unit III | Plant tissue culture: Historical development of plant tissue culture, types of cultures including <u>callus, suspension, embryo, protoplast and hairy root cultures, Nutritional requirements, types of media, preparation and their maintenance.</u> Applications of plant tissue culture in pharmacognosy. Edible vaccines | 06 hours |
| Unit IV | <u>Cell Biology:</u> <u>(a) Cell wall constituents and cell inclusions (Ergastic substances – organic and inorganic substances).</u> <u>(b) Study of simple plant tissues – parenchyma, collenchyma, sclerenchyma, complex tissues – xylem and phloem.</u> <u>(c) Study of stomata and trichomes.</u> | 04 hours |
| Unit V | Study of biological source, chemical nature, <u>tests</u> and uses of drugs of natural origin containing following drugs Plant Products: Fibers - Cotton, Jute, Hemp Hallucinogens- <u>Fungi and Lysergic acid derivatives.</u> Teratogens,- <u>Nicotine and Lobelia</u> Natural allergens- <u>Pollen and Rhus species</u> Primary metabolites: General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites: Carbohydrates: Acacia, Agar, Tragacanth, Honey Proteins and Enzymes : Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin). Lipids(Waxes, fats, fixed oils) : Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax Marine Drugs: Novel medicinal agents belonging to the class of <u>Cardiovascular, Cytotoxic, Antimicrobial,from</u> marine sources | 15 hours |

BP409 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

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| Credit Points | 02 |
| Practical Hours per week | 04 |

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

Recommended Books: (Latest Editions)

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

Semester V

Course of study for semester V

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

BP501T. MEDICINAL CHEMISTRY – II (Theory)

| | | | |
|--------------------------|----|---------------------------|----|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of the course the student shall be able to

- Understand the chemistry of drugs with respect to their pharmacological activity
- Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- Know the Structural Activity Relationship of different class of drugs
- Study the chemical synthesis of selected drugs

Course Content:

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

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|---------------|--|-----------------|
| Unit I | Antihistaminic agents: Histamine, receptors and their distribution in the human body H₁-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartrate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine, Cromolyn sodium H₂-antagonists: Cimetidine*, Famotidine, Ranitidine. Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, | 10 hours |
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| | <p>Rabeprazole, Pantoprazole</p> <p>Anti-neoplastic agents:</p> <p>Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa</p> <p>Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine</p> <p>Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin</p> <p>Plant products: Etoposide, Vinblastine sulphate, Vincristine sulphate</p> <p>Miscellaneous: Cisplatin, Mitotane.</p> | |
| Unit II | <p>Anti-anginal:</p> <p>Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritoltetranitrate, Isosorbidedinitrite*, Dipyridamole.</p> <p>Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.</p> <p>Diuretics:</p> <p>Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.</p> <p>Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,</p> <p>Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid.</p> <p>Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.</p> <p>Osmotic Diuretics: Mannitol</p> <p>Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride, * Clonidine hydrochloride, Guanethidinemonosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.</p> | 10 hours |
| Unit III | <p>Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcaïnide hydrochloride, Amiodarone, Sotalol.</p> <p>Anti-hyperlipidemic agents: Clofibrate, Lovastatin,</p> | 10 hours |

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| | <p>Cholestyramine and Colestipol</p> <p>Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel</p> <p>Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.</p> | |
| Unit IV | <p>Drugs acting on Endocrine system</p> <p>Nomenclature, Stereochemistry and metabolism of steroids</p> <p>Sex hormones: Testosterone, Nandralone, Progesterone, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.</p> <p>Drugs for erectile dysfunction: Sildenafil, Tadalafil.</p> <p>Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrel</p> <p>Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone</p> <p>Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.</p> | 8 hours |
| Unit V | <p>Antidiabetic agents:</p> <p>Insulin and its preparations</p> <p>Sulfonylureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride. Biguanides: Metformin.</p> <p>Thiazolidinediones:</p> <p>Pioglitazone, Rosiglitazone.</p> <p>Meglitinides: Repaglinide, Nateglinide. Glucosidase inhibitors: Acarbose, Voglibose.</p> <p>Local Anesthetics: SAR of Local anesthetics</p> <p>Benzoic Acid derivatives: Cocaine, Hexylcaine, Mepylcaine, Cyclomethycaine, Piperocaine.</p> <p>Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.</p> <p>Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.</p> <p>Miscellaneous: Phenacaine, Dipreron, Dibucaine.*</p> | 07 hours |

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to VI.

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

BP 502 T. Industrial PharmacyI (Theory)

| | | | |
|--------------------------|----|---------------------------|----|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

Objectives:

Upon completion of the course the student shall be able to

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

Course Content:

| | | |
|---------|---|----------|
| Unit I | <p>Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.</p> <p>a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism</p> <p>b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs & its significance.</p> <p>Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.</p> | 07 hours |
| Unit II | <p>Tablets:</p> <p>a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.</p> <p>b. Tablet coating: Types of coating, coating materials,</p> | 10 hours |

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| | <p>formulation of coating composition, methods of coating, equipment employed and defects in coating.</p> <p>c. Quality control tests: In process and finished product tests</p> <p>Liquid orals: Formulation and manufacturing consideration of syrups and elixirssuspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia</p> | |
| Unit III | <p>Capsules:</p> <p>a. Hard gelatin capsules: Introduction, Production of hard gelatin capsule shells. sizeof capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.</p> <p>b. Soft gelatin capsules: Nature of shell and capsule content, size ofcapsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packaging, storage and stability testing of soft gelatin capsules and their applications.</p> <p>Pellets: Introduction, formulation requirements, pelletization process, equipments formanufacture of pellets</p> | 08 hours |
| Unit IV | <p>Parenteral Products:</p> <p>a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity</p> <p>b. Production procedure, production facilities and controls, aseptic processing</p> <p>c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products.</p> <p>d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.</p> <p>Ophthalmic Preparations: Introduction, formulation considerations; formulation of eyedrops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations</p> | 10 hours |
| Unit V | <p>Cosmetics: Formulation and preparation of the following cosmetic preparations:lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.</p> <p>Pharmaceutical Aerosols: Definition, propellants, containers,</p> | 10 hours |

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| | <p>valves, types of aerosolsystems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.</p> <p>Packaging Materials Science: Materials used for packaging of pharmaceutical products,factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.</p> | |
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BP 506 P. Industrial PharmacyI (Practical)

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|--------------------------|----|
| Credit Points | 02 |
| Practical Hours per week | 04 |

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

Recommended Books: (Latest Editions)

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

BP503.T. PHARMACOLOGY-II (Theory)

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|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of this course the student should be able to

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

Course Content:

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|-----------------|--|-----------------|
| Unit I | 1. Pharmacology of drugs acting on cardio vascular system a. Introduction to hemodynamic and electrophysiology of heart. b. Drugs used in congestive heart failure c. Anti-hypertensive drugs. d. Anti-anginal drugs. e. Anti-arrhythmic drugs. f. Anti-hyperlipidemic drugs. | 10 hours |
| Unit II | Pharmacology of drugs acting on cardio vascular system a. Drug used in the therapy of shock. b. Hematinics, coagulants and anticoagulants. c. Fibrinolytics and anti-platelet drugs d. Plasma volume expanders Pharmacology of drugs acting on urinary system e. Diuretics f. Anti-diuretics. | 10 hours |
| Unit III | Autocoids and related drugs a. Introduction to autacoids and classification b. Histamine, 5-HT and their antagonists. | 10 hours |

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| | c. Prostaglandins, Thromboxanes and Leukotrienes. d. Angiotensin, Bradykinin and Substance P. e. Non-steroidal anti-inflammatory agents f. Anti-gout drugs g. Antirheumatic drugs | |
| Unit IV | Pharmacology of drugs acting on endocrine system a. Basic concepts in endocrine pharmacology. b. Anterior Pituitary hormones- analogues and their inhibitors. c. Thyroid hormones- analogues and their inhibitors. d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D. d. Insulin, Oral Hypoglycemic agents and glucagon. e. ACTH and corticosteroids. | 08 hours |
| Unit V | Pharmacology of drugs acting on endocrine system a. Androgens and Anabolic steroids. b. Estrogens, progesterone and oral contraceptives. c. Drugs acting on the uterus. Bioassay a. Principles and applications of bioassay b. Types of bioassay c. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT | 07 hours |

BP 507 P. PHARMACOLOGY-II (Practical)

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|--------------------------|----|
| Credit Points | 02 |
| Practical Hours per week | 04 |

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA_2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD_2 value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods
16. Bioassay of acetyl Choline using chick ileum.

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

Recommended Books (Latest Editions)

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

BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

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|--------------------------|----|---------------------------|----|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

The main purpose of subject is to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate, identify and produce them industrially. The subject involves modern extraction techniques and the utilization of latest techniques like spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs. The study of producing the plants and phytochemicals through plant tissue culture and basic principles of traditional system of medicine.

Objectives:

Upon completion of the course, the student shall be able

- To know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
- To know the applications and utilization of spectroscopy, chromatography and electrophoresis techniques.

Course Content:

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|---------|--|----------|
| Unit I | Metabolic pathways in higher plants and their determination: a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway. b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies. c) <u>Biogenesis of Morphine, Hyoscyamine and Reserpine.</u> | 10 hours |
| Unit II | General introduction, composition, chemistry & chemical classes, general methods of extraction & analysis, biosources, therapeutic uses and commercial applications of following secondary metabolites: Alkaloids: Vinca, Rauwolfia, Belladonna, Opium, <u>cinchona and aswagandha</u> Phenylpropanoids and Flavonoids: Lignans, Tea, <u>Ginko</u> , Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis | 17 hours |

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| | Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander, Tannins: <u>Black catechu, Pale Catechu, Myrobalan, Amla,</u> Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony Glycosides: Senna, Aloes, Bitter Almond Iridoids, Other terpenoids&Naphthaquinones: Gentian, Artemisia, taxus, carotenoids | |
| Unit III | Isolation, Identification and Analysis of Phytoconstituents a) Terpenoids: Menthol, Citral, Artemisin b) Glycosides: Glycyrrhetic acid &Rutin c) Alkaloids: Atropine, Quinine, Reserpine, Caffeine d) Resins: Podophyllotoxin, Curcumin | 05 hours |
| Unit IV | Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Diosgenin, Digoxin, Atropine, Caffeine, Taxol. | 05hours |
| Unit V | Basics of Phytochemistry (a) Modern methods of extraction- <u>Sonication, ultrasound, microwave and SCFE methods.</u> (b) Application of latest techniques like Spectroscopy- <u>UV, IR, NMR and Mass</u> , chromatography- <u>Paper, thin layer, HPLC, HPTLC and GC.</u> Electrophoresis – <u>Agarose and SDS</u> in the isolation, purification and identification of crude drugs. | 08 hours |

BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

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| Credit Points | 02 |
| Practical Hours per week | 04 |

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles
 - a. Caffeine - from tea dust.
 - b. Diosgenin from Dioscorea
 - c. Atropine from Belladonna
 - d. Sennosides from Senna
3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstituents by TLC
6. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, NiraliPrakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), 1stEdn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, 1st edition, Birla publications, New Delhi, 2007
6. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
7. Text book of Pharmacognosy by Beren shah
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
9. Anatomy of Crude Drugs by M.A. Iyengar.
10. Indian Herbal Drug Microscopy ShailendraGurav Springer publications.

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

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|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

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

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

Course Content:

| | | |
|----------------|---|-----------------|
| Unit I | Drugs and Cosmetics Act, 1940 and its rules 1945: Objectives, Definitions, Legal definitions of schedules to the Act and Rules Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties. Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license. | 10 hours |
| Unit II | Drugs and Cosmetics Act, 1940 and its rules 1945. Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted | 10 hours |

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| | <p>colors. Offences and penalties.</p> <p>Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors</p> | |
| Unit III | <p>Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties</p> <p>Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.</p> <p>Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties</p> | 10 hours |
| Unit IV | <p>Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties</p> <p>Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties</p> <p>National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)</p> | 08 hours |
| Unit V | Pharmaceutical Legislations –A brief review, Introduction, | 07 |

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| | <p>Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee</p> <p>Code of Pharmaceutical ethics Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath</p> <p>Medical Termination of Pregnancy Act</p> <p>Right to Information Act</p> <p>Introduction to Intellectual Property Rights (IPR)</p> | hours |
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Recommended Books (Latest Editions)

- Forensic Pharmacy by B. Suresh
- Text book of Forensic Pharmacy by B.M. Mithal
- Hand book of drug law-by M.L. Mehra
- A text book of Forensic Pharmacy by N.K. Jain
- Drugs and Cosmetics Act/Rules by Govt. of India publications.
- Medicinal and Toilet preparations act 1955 by Govt. of India publications.
- Narcotic drugs and psychotropic substances act by Govt. of India publications
- Drugs and Magic Remedies act by Govt. of India publication
- Bare Acts of the said laws published by Government. Reference books (Theory)
- Pharmaceutical Jurisprudence: G.K. Jani & N. Gandhi
- Pharmaceutical Jurisprudence: Dr. B.S. Kuchekar

Semester VI

Course of study for semester VI

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

BP601T. MEDICINAL CHEMISTRY – III (Theory)

| | | | |
|--------------------------|----|---------------------------|----|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of the course student shall be able to

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

Course Content:

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

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|----------------|--|-----------------|
| Unit I | Antibiotics Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes. β-Lactam antibiotics: Penicillin, Cephalosporins, β-Lactamase inhibitors, Monobactams Aminoglycosides: Streptomycin, Neomycin, Kanamycin Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline | 10 hours |
| Unit II | Antibiotics Historical background, Nomenclature, Stereochemistry, | 10 hours |

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| | <p>Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mafenide acetate, Sulfasalazine.</p> <p>Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.</p> <p>Sulfones: Dapsone*.</p> | |
| Unit V | <p>Introduction to Drug Design</p> <p>Various approaches used in drug design.</p> <p>Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis.</p> <p>Pharmacophore modeling and docking techniques.</p> <p>Combinatorial Chemistry: Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.</p> | 07 hours |

BP607P. MEDICINAL CHEMISTRY- III (Practical)

| | |
|--------------------------|----|
| Credit Points | 02 |
| Practical Hours per week | 04 |

Preparation of drugs and intermediates (Any six)

- 1 Sulphanilamide
- 2 7-Hydroxy, 4-methyl coumarin
- 3 Chlorobutanol
- 4 Triphenyl imidazole
- 5 Tolbutamide
- 6 Hexamine
- 7 INH
- 8 Dicloramine T
- 9 4-Methyl Carbostyryl
- 10 Methyl pyrazolone
- 11 2 – Phenyl Indole

II Assay of drugs (Any six)

- 2 Isonicotinic acid hydrazide
- 3 Chloroquine
- 4 Metronidazole
- 5 Dapsone
- 6 Chlorpheniramine maleate
- 7 Benzyl penicillin/ Amoxicillin/ cefalexin
- 8 Quinine Sulfate
- 9 Chloramine T
- 10 Benzoic acid/Salicylic acid
- 11 Hexamine
- 12 Nicotinic Acid
- 13 Paracetamol
- 14 Thiamine HCl
- 15 Vit. C

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

1. Beginelli reaction
2. 3 Methyl 5 Pyrazolone

IV Drawing structures and reactions using chemdraw®

V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinski's R5)

Recommended Books (Latest Editions)

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

BP602 T. PHARMACOLOGY-III (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

This subject is intended to impart the fundamental knowledge on various aspects(classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition,emphasis on the principles of toxicology and chronopharmacology.

Objectives:

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

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

Course Content:

| | | |
|----------------|---|-----------------|
| Unit I | Pharmacology of drugs acting on Respiratory system a. Anti -asthmatic drugs b. Drugs used in the management of COPD c. Expectorants and antitussives d. Nasal decongestants e. Respiratory stimulants Pharmacology of drugs acting on the Gastrointestinal Tract a. Antiulcer agents. b. Drugs for constipation and diarrhoea. c. Appetite stimulants and suppressants. d. Digestants and carminatives. e. Emetics and anti-emetics. | 10 hours |
| Unit II | Chemotherapy a. General principles of chemotherapy. b. Sulfonamides and cotrimoxazole. c. Antibiotics- Penicillins, cephalosporins, monobactams, carbapenum, chloramphenicol, macrolides, quinolones and fluoroquinolins, | 10 hours |

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|-----------------|---|-----------------|
| | tetracycline and aminoglycosides | |
| Unit III | Chemotherapy <ol style="list-style-type: none"> Antitubercular agents Antileprotic agents Antifungal agents Antiviral drugs Anthelmintics Antimalarial drugs Antiamoebic agents | 10 hours |
| Unit IV | Chemotherapy <ol style="list-style-type: none"> Urinary tract infections and sexually transmitted diseases. Chemotherapy of malignancy. Immunopharmacology <ol style="list-style-type: none"> Immunostimulants Immunosuppressant Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars | 08 hours |
| Unit V | Principles of toxicology <ol style="list-style-type: none"> Definition and basic knowledge of acute, subacute and chronic toxicity. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity General principles of treatment of poisoning Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning. Chronopharmacology <ol style="list-style-type: none"> Definition of rhythm and cycles. Biological clock and their significance leading to chronotherapy. | 07 hours |

BP 608 P. PHARMACOLOGY-III (Practical)

| | |
|--------------------------|----|
| Credit Points | 02 |
| Practical Hours per week | 04 |

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

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

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

BP 603 T. HERBAL DRUGTECHNOLOGY (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

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

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

Course Content:

| | | |
|----------------|---|-----------------|
| Unit I | Herbs as raw materials Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs Selection, identification and authentication of herbal materials Processing of herbal raw material Biodynamic Agriculture Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides. Indian Systems of Medicine a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma. | 11 hours |
| Unit II | Nutraceuticals Definition and classification, General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases. | 07 hours |

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| | <p>Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina</p> <p>Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Forskolin, Liquorice, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.</p> | |
| Unit III | <p>Herbal Cosmetics Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.</p> <p>Herbal excipients: Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.</p> <p>Herbal formulations : Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes</p> | 10 hours |
| Unit IV | <p>Evaluation of Drugs WHO & ICH guidelines for the quality control of herbal drugs Stability testing of herbal drugs.</p> <p>Patenting and Regulatory requirements of natural products: a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.</p> <p>Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.</p> | 10 hours |
| Unit V | <p>General Introduction to Herbal Industry Herbal drugs industry: Present scope and future prospects. A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.</p> <p>Schedule T-Good Manufacturing Practice of Indian systems of medicine Components of GMP (Schedule – T) and its objectives Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.</p> | 07 hours |

BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)

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|--------------------------|----|
| Credit Points | 02 |
| Practical Hours per week | 04 |

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

Recommended Books: (Latest Editions)

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

BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

| | | | |
|--------------------------|----|---------------------------|----|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of the course student shall be able to:

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

Course Content:

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| Unit I | Introduction to Biopharmaceutics: Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes, Distribution Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs | 15 hours |
| Unit II | Elimination: Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, <i>in-vitro</i> drug dissolution models, <i>in-vitro-in-vivo</i> correlations, bioequivalence | 15 hours |

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| | studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs. | |
| Unit III | Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - K_E , $t_{1/2}$, V_d , AUC , K_a , Cl_t and CL_R - definitions methods of eliminations, understanding of their significance and application | 08 hours |
| Unit IV | Multicompartment models: Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their significance in clinical setting. | 04 hours |
| Unit V | Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Explanation with example of drugs. | 03 hours |

Recommended Books: (Latest Editions)

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

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

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|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

- ☐ Biotechnology has a long promise to revolutionize the biological sciences and technology.
- ☐ Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting.
- ☐ Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs.
- ☐ Biotechnology has already produced transgenic crops and animals and the future promises lot more.
- ☐ It is basically a research-based subject.

Objectives:

Upon completion of the subject student shall be able to;

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. Appreciate the use of microorganisms in fermentation technology

Course Content:

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|----------------|---|-----------------|
| Unit I | a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences. b) Enzyme Biotechnology- Methods of enzyme immobilization and applications. c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries. d) Brief introduction to Protein Engineering. e) Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase. f) Basic principles of genetic engineering. | 10 hours |
| Unit II | a) Study of cloning vectors, restriction endonucleases and DNA ligase. b) Recombinant DNA technology. Application of genetic engineering in medicine. c) Application of r DNA technology and genetic engineering in the production of: | 10 hours |

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|-----------------|---|-----------------|
| | i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin. d) Brief introduction to PCR | |
| Unit III | Types of immunity- humoral immunity, cellular immunity a) Structure of Immunoglobulins b) Structure and Function of MHC c) Hypersensitivity reactions, Immune stimulation and Immune suppressions. d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity. e) Storage conditions and stability of official vaccines f) Hybridoma technology- Production, Purification and Applications g) Blood products and Plasma Substitutes. | 10 hours |
| Unit IV | a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting. b) Genetic organization of Eukaryotes and Prokaryotes c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons. d) Introduction to Microbial biotransformation and applications. Mutation: Types of mutation/mutants. | 08 hours |
| Unit V | a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring. b) Large scale production fermenter design and its various controls. c) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin, d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes. | 07 hours |

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
2. RA Goldsby et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal

Society of Chemistry.

5. Zaborsky: Immobilized Enzymes, CRC Press, Degrand, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitaker A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

BP606 T PHARMACEUTICAL QUALITY ASSURANCE (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of the course student shall be able to:

- ☑ understand the cGMP aspects in a pharmaceutical industry
- ☑ appreciate the importance of documentation
- ☑ understand the scope of quality certifications applicable to pharmaceutical industries
- ☑ understand the responsibilities of QA & QC departments

Course Content:

| | | |
|-----------------|---|-----------------|
| Unit I | Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP Total Quality Management (TQM): Definition, elements, philosophy ICH Guidelines: Purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines Quality by design (QbD): Definition, overview, elements of QbD program, tools ISO 9000 & ISO14000: Overview, benefits, elements, steps for registration NABL accreditation : Principles and procedures | 10 hours |
| Unit II | Organization and personnel: Personnel responsibilities, training, hygiene and personal records. Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials. | 10 hours |
| Unit III | Quality Control: Quality control test for containers, rubber | 10 hours |

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| | <p>closures and secondary packaging materials.</p> <p>Good Laboratory Practices: General provisions, Organization and Personnel, Facilities and equipment, testing facilities operation, test and control articles, Protocol for conduct of a Nonclinical Laboratory Study, Records and reports, Disqualification of testing facilities</p> | |
| Unit IV | <p>Complaints: Complaints and evaluation of complaints, Handling of return good, product recalling and pharmaceutical waste disposal.</p> <p>Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.</p> | 08 hours |
| Unit V | <p>Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.</p> <p>Warehousing: Good warehousing practice, materials management</p> | 07 hours |

Recommended Books (Latest Editions)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines
10. British Pharmaceutical Codex
11. Pharmaceutical Process Development by Nash
12. Pharmaceutical Quality Assurance by Mr. Manohar A. Potdar
13. FDA Regulatory Affairs by David Mantus and Douglas Pisano
14. Concise textbook of Drug Regulatory Affairs by N. Udupa and Krishnamurthy Bhat

Semester VII

Course of study for semester VII

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

* Non University Examination (NUE)

BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of the course the student shall be able to

- Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
- Understand the chromatographic separation and analysis of drugs.
- Perform quantitative & qualitative analysis of drugs using various analytical instruments.

Course Content:

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|----------------|--|-----------------|
| Unit I | UV Visible spectroscopy Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations. Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors-Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode. Applications - Spectrophotometric titrations, Single component and multi component analysis Fluorimetry Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications | 10 hours |
| Unit II | IR spectroscopy Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, | 10 hours |

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| | <p>Pyroelectric detector and applications</p> <p>Flame Photometry-Principle, interferences, instrumentation and applications</p> <p>Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications</p> <p>Nepheloturbidometry- Principle, instrumentation and applications</p> | |
| Unit III | <p>Introduction to chromatography</p> <p>Adsorption and partition column chromatography Methodology, advantages, disadvantages and applications.</p> <p>Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.</p> <p>Paper chromatography-Introduction, methodology, development techniques, advantages, disadvantages and applications</p> <p>Electrophoresis-Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications</p> | 10 hours |
| Unit IV | <p>Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications</p> <p>High performance liquid chromatography (HPLC)- Introduction, theory, instrumentation, advantages and applications.</p> | 08 hours |
| Unit V | <p>Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications</p> <p>Gel chromatography- Introduction, theory, instrumentation and applications</p> <p>Affinity chromatography- Introduction, theory, instrumentation and applications</p> | 07 hours |

BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)

| | |
|--------------------------|----|
| Credit Points | 02 |
| Practical Hours per week | 04 |

- 1 Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
- 2 Estimation of dextrose by colorimetry
- 3 Estimation of sulfanilamide by colorimetry
- 4 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
- 5 Assay of paracetamol by UV- Spectrophotometry
- 6 Estimation of quinine sulfate by fluorimetry
- 7 Study of quenching of fluorescence
- 8 Determination of sodium by flame photometry
- 9 Determination of potassium by flame photometry
- 10 Determination of chlorides and sulphates by nephelo turbidometry
- 11 Separation of amino acids by paper chromatography
- 12 Separation of sugars by thin layer chromatography
- 13 Separation of plant pigments by column chromatography
- 14 Demonstration experiment on HPLC
- 15 Demonstration experiment on Gas Chromatography

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

BP 702 T. INDUSTRIAL PHARMACY II (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

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

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

Course Content:

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|-----------------|---|-----------------|
| Unit I | Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology | 10 hours |
| Unit II | Technology development and transfer: WHO guidelines for Technology Transfer(TT):Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTT, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues | 10 hours |
| Unit III | Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals | 10 hours |

| | | |
|----------------|--|-----------------|
| | Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies. | |
| Unit IV | Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP | 08 hours |
| Unit V | Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs. | 07 hours |

Recommended Books: (Latest Editions)

1. A Text Book of Industrial Pharmacy (Selected Topics) Dr. Thimma Setty.
2. Drug Regulatory Affairs. Dr CVS Subramanyam, Dr J Thimma Setty
3. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http://en.wikipedia.org/wiki/Regulatory_Affairs.
4. International Regulatory Affairs Updates, 2005. available at <http://www.iraup.com/about.php>
5. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
6. Regulatory Affairs brought by learning plus, inc. available at <http://www.cgmp.com/ra.htm>.

BP 703T. PHARMACY PRACTICE (Theory)

| | | | |
|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

Objectives:

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

- know various drug distribution methods in a hospital
- appreciate the pharmacy stores management and inventory control
- monitor drug therapy of patient through medication chart review and clinical review
- obtain medication history interview and counsel the patients
- identify drug related problems
- detect and assess adverse drug reactions
- interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
- know pharmaceutical care services
- do patient counseling in community pharmacy;
- appreciate the concept of Rational drug therapy.

Course Content:

| | | |
|---------------|---|-----------------|
| Unit I | a) Hospital and its organization Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non-clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions. b) Hospital pharmacy and its organization Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and | 10 hours |
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| | <p>Responsibilities and functions of hospital pharmacists.</p> <p>c) Adverse drug reaction Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, pharmacokinetic and Pharmacodynamic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.</p> <p>d) Community Pharmacy Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.</p> | |
| Unit II | <p>a) Drug distribution system in a hospital Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.</p> <p>b) Hospital formulary Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.</p> <p>c) Therapeutic drug monitoring Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.</p> <p>d) Medication adherence Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.</p> <p>e) Patient medication history interview Need for the patient medication history interview, medication interview forms.</p> <p>f) Community pharmacy management Financial, materials, staff, and infrastructure requirements.</p> | 10 hours |
| Unit III | <p>a) Pharmacy and therapeutic committee Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.</p> | 10 hours |

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| | <p>b) Drug information services: Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.</p> <p>c) Patient counseling</p> <p>Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist</p> <p>d) Education and training program in the hospital</p> <p>Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.</p> <p>e) Prescribed medication order and communication skills</p> <p>Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.</p> | |
| Unit IV | <p>a) Budget preparation and implementation</p> <p>Budget preparation and implementation</p> <p>b) Clinical Pharmacy</p> <p>Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.</p> <p>Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.</p> <p>c) Over the counter (OTC) sales</p> <p>Introduction and sale of over the counter, and Rational use of common over the counter medications.</p> | 08 hours |
| Unit V | <p>a) Drug store management and inventory control</p> <p>Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure</p> <p>b) Investigational use of drugs Description, principles involved, classification, control, identification, role of hospital</p> | 07 hours |

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| | <p>pharmacist, advisory committee.</p> <p>c) Interpretation of Clinical Laboratory Tests</p> <p>Blood chemistry, hematology, and urinalysis</p> | |
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Recommended Books (Latest Edition):

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

Journals:

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

BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

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| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

This subject is designed to impart basic knowledge on the area of Novel Drug Delivery Systems.

Objectives:

Upon completion of the course student shall be able

- To understand various approaches for development of Novel Drug Delivery Systems.
- To understand the criteria for selection of drugs and polymers for the development of Novel Drug Delivery Systems, their formulation and evaluation.

Course Content:

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| Unit I | Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems. | 10 hours |
| Unit II | Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications Mucosal Drug Delivery system: Introduction, Principles of bioadhesion /mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump | 10 hours |
| Unit III | Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches Gastroretentive drug delivery systems: Introduction, | 10 hours |

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| | advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers | |
| Unit IV | Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications | 08 hours |
| Unit V | Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome – Preliminary study, ocular formulations and ocuserts Intrauterine and Intravaginal Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications. | 07 hours |

Recommended Books: (Latest Editions)

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
6. Pharmaceutical Dosage Forms and Drug Delivery Systems. [Howard C. Ansel](#), [Nicholas G. Popovich](#), [Lloyd V. Allen](#)

Journals

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

Semester VIII

Course of study for semester VIII

| Course code | Name of the course | No. of hours | Tutorial | Credit points |
|--------------|--|--------------|-----------|---------------|
| BP801T | Biostatistics and Research Methodology-Theory | 3 | 1 | 4 |
| BP802T | Social and Preventive Pharmacy | 3 | 1 | 4 |
| BP803ET | Pharmaceutical Marketing Management | 3 + 3 = 6 | 1 + 1 = 2 | 4 + 4 = 8 |
| BP804ET | Pharmaceutical Regulatory Science | | | |
| BP805ET | Pharmacovigilance | | | |
| BP806ET | Quality Control and Standardization of Herbals | | | |
| BP807ET | Computer Aided Drug Design | | | |
| BP808ET | Cell and Molecular Biology | | | |
| BP809ET | Cosmetic Science | | | |
| BP810ET | Pharmacological Screening methods | | | |
| BP811ET | Advanced Instrumentation Techniques | | | |
| BP812ET | Dietary Supplements and Nutraceuticals | | | |
| BP813ET | Pharmaceutical Product Development | | | |
| BP814PW | Project Work | 12 | - | 6 |
| Total | | 24 | 4 | 22 |

Course of study for semester VIII

(Compulsory)

| Course code | Name of the course | No. of hours | Tutorial | Credit points |
|-------------|---|--------------|----------|---------------|
| BP801T | Biostatistics and Research Methodology-Theory | 3 | 1 | 4 |
| BP802T | Social and Preventive Pharmacy | 3 | 1 | 4 |

BP801T. BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)

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|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of the course the student shall be able to

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

Course Content:

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|----------------|---|-----------------|
| Unit I | Introduction: Statistics, Biostatistics, Frequency distribution Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples | 10 hours |
| Unit II | Regression: Curve fitting by the method of least squares, fitting the lines $y = a + bx$ and $x = a + by$, Multiple regression, standard error of regression- Pharmaceutical Examples Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties – problems Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples Parametric test: t-test (Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference. | 10 hours |

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| Unit III | <p>Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test</p> <p>Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, and plagiarism.</p> <p>Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Contour Plot graph</p> <p>Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.</p> | 10 hours |
| Unit IV | <p>Blocking and confounding system for Two-level factorials</p> <p>Regression modeling: Hypothesis testing in Simple and Multiple regression models</p> <p>Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach</p> | 08 hours |
| Unit V | <p>Design and Analysis of experiments.</p> <p>Factorial Design: Definition, 2^2, 2^3 design. Advantage of factorial design</p> <p>Response Surface methodology: Central composite design, Historical design, Optimization Techniques</p> | 07 hours |

Recommended Books (Latest editions):

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. New York.
2. Fundamental of Statistics – Himalaya Publishing House-S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannarselvam,
4. Design and Analysis of Experiments –Wiley Students Edition, Douglas and C.Montgomery.
5. Research Methodology- C.R.Kothari, Gaurav Garg.
6. Research Methodology- Avadhesh Jha.
7. Research: How to Plan, Speak and Write About it.- Clifford Hawkins, Marco Sorgi.
8. Statistical Methods for Research Workers: Fisher R.A 13th Edition Hafner Publishing.
9. The Design of Experiments: Fisher R.A 7th Edition (Revised) Hafner Publishing.
10. The Grammar of Science: Karl Pearson-Meridian Books.
11. The Principles of Scientific Research: Freedman P, 2nd Edition Pregamon Press.
12. Hand Book of Research Methodology: Shantibhushan Mishra, Shashi Alok.
13. Pharmaceutical Statistics: T.E.Gopala Krishna Murthy, P Srinivasa Babu, P.Seshagiri Rao

BP 802T SOCIAL AND PREVENTIVE PHARMACY (Theory)

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| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

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

- Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related to health and pharmaceutical issues.

Course Content:

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| Unit I | <p>Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.</p> <p>Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.</p> <p>Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health</p> <p>Hygiene and health: personal hygiene and health care; avoidable habits</p> | 10 hours |
| Unit II | <p>Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse</p> | 10 hours |
| Unit III | <p>National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program,</p> | 10 hours |

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| | National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme. | |
| Unit IV | National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program | 08 hours |
| Unit V | Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school. | 07 hours |

Recommended Books (Latest edition):

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

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

Course of study for semester VIII

(Elective)

| Course code | Name of the course | No. of hours | Tutorial | Credit points |
|-------------|--|--------------|-----------|---------------|
| BP803ET | Pharmaceutical Marketing Management | 3 + 3 = 6 | 1 + 1 = 2 | 4 + 4 = 8 |
| BP804ET | Pharmaceutical Regulatory Science | | | |
| BP805ET | Pharmacovigilance | | | |
| BP806ET | Quality Control and Standardization of Herbals | | | |
| BP807ET | Computer Aided Drug Design | | | |
| BP808ET | Cell and Molecular Biology | | | |
| BP809ET | Cosmetic Science | | | |
| BP810ET | Pharmacological Screening methods | | | |
| BP811ET | Advanced Instrumentation Techniques | | | |
| BP812ET | Dietary Supplements and Nutraceuticals | | | |
| BP813ET | Pharmaceutical Product Development | | | |

BP803ET. PHARMACEUTICAL MARKETING MANAGEMENT (Theory)

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| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Productmanagement.

Objective:

The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Course content:

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| Unit I | Marketing: Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior. Pharmaceutical Market: Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and sociopsychological characteristics of the consumer; market segmentation & targeting.Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist.Analyzing the Market;Role of marketresearch. | 10 hours |
| Unit II | Product decision: Classification, product line and product mix decisions, product life cycle,product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry. | 10 hours |
| Unit III | Promotion: Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, | 10 hours |

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| | online promotional techniques for OTC Products. | |
| Unit IV | <p>Pharmaceutical marketing channels: Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.</p> <p>Professional sales representative (PSR): Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.</p> | 08 hours |
| Unit V | <p>Pricing: Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).</p> <p>Emerging concepts in marketing: Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.</p> | 07 hours |

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC Graw Hill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Management: Global Perspective, Indian Context, Macmillan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.
9. Principles of Pharmaceutical Management: Smith.

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

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|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of the subject student shall be able to;

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

Course content:

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| Unit I | New Drug Discovery and development Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development. | 10 hours |
| Unit II | Regulatory Approval Process Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA. Regulatory authorities and agencies Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications) | 10 hours |
| Unit III | Registration of Indian drug product in overseas market Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD) research. | 10 hours |

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| Unit IV | Clinical trials: Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials | 08 hours |
| Unit V | Regulatory Concepts: Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book | 07 hours |

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol. 185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol. 190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons, Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics / edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol. 143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

BP 805T: PHARMACOVIGILANCE (Theory)

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|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- Why drug safety monitoring is important?
- History and development of pharmacovigilance
- National and international scenario of pharmacovigilance
- Dictionaries, coding and terminologies used in pharmacovigilance
- Detection of new adverse drug reactions and their assessment
- International standards for classification of diseases and drugs
- Adverse drug reaction reporting systems and communication in pharmacovigilance
- Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
- Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
- Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
- ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
- CIOMS requirements for ADR reporting
- Writing case narratives of adverse events and their quality.

Course Content

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| Unit I | Introduction to Pharmacovigilance <ul style="list-style-type: none">• History and development of Pharmacovigilance• Importance of safety monitoring of Medicine• WHO international drug monitoring programme• Pharmacovigilance Program of India (PvPI) Introduction to Adverse Drug Reactions <ul style="list-style-type: none">• Definitions and classification of ADRs• Detection and reporting• Methods in Causality assessment• Severity and seriousness assessment | 10 hours |
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| | <ul style="list-style-type: none"> • Predictability and preventability assessment • Management of adverse drug reactions <p>Basic terminologies used in pharmacovigilance:</p> <ul style="list-style-type: none"> • Terminologies of adverse medication related events • Regulatory terminologies | |
| Unit II | <p>Drug and disease classification</p> <ul style="list-style-type: none"> • Anatomical, therapeutic and chemical classification of drugs • International classification of diseases • Daily defined doses • International Non proprietary Names for drugs <p>Drug dictionaries and coding in pharmacovigilance</p> <ul style="list-style-type: none"> • WHO adverse reaction terminologies • MedDRA and Standardised MedDRA queries • WHO drug dictionary • Eudragilance medicinal product dictionary <p>Information resources in pharmacovigilance</p> <ul style="list-style-type: none"> • Basic drug information resources • Specialised resources for ADRs <p>Establishing pharmacovigilance programme</p> <ul style="list-style-type: none"> • Establishing in a Hospital • Establishment & operation of Drug Safety Department in industry • Contract Research Organisations (CROs) • Establishing a national programme | 10 hours |
| Unit III | <p>Vaccine safety surveillance</p> <ul style="list-style-type: none"> • Vaccine Pharmacovigilance • Vaccination failure • Adverse events following immunization <p>Pharmacovigilance methods</p> <ul style="list-style-type: none"> • Passive surveillance – Spontaneous reports and case series • Stimulated reporting • Active surveillance – Sentinel sites, drug event monitoring and registries • Comparative observational studies – Cross sectional study, case control study and cohort study • Targeted clinical investigations <p>Communication in pharmacovigilance</p> <ul style="list-style-type: none"> • Effective communication in Pharmacovigilance • Communication in Drug Safety Crisis management • Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media | 10 hours |
| Unit IV | <p>Safety data generation</p> <ul style="list-style-type: none"> • Pre clinical phase • Clinical phase • Post approval phase (PMS) <p>ICH Guidelines for Pharmacovigilance</p> <ul style="list-style-type: none"> • Organization and objectives of ICH • Expedited reporting | 08 hours |

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| | <ul style="list-style-type: none"> • Individual case safety reports • Periodic safety update reports • Post approval expedited reporting • Pharmacovigilance planning • Good clinical practice in pharmacovigilance studies | |
| Unit V | <p>Pharmacogenomics of adverse drug reactions</p> <ul style="list-style-type: none"> • Genetics related ADR with example focusing PK parameters. <p>Drug safety evaluation in special population</p> <ul style="list-style-type: none"> • Paediatrics • Pregnancy and lactation • Geriatrics <p>CIOMS</p> <ul style="list-style-type: none"> • CIOMS Working Groups • CIOMS Form <p>CDSCO (India) and Pharmacovigilance</p> <ul style="list-style-type: none"> • D&C Act and Schedule Y • Differences in Indian and global pharmacovigilance requirements | 07 hours |

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By 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 edited by 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
12. <http://www.who.int/dynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297>
13. <http://www.ich.org/>
14. <http://www.cioms.ch/>
15. <http://cdsco.nic.in/>
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS

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| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of the subject student shall be able to;

- know WHO guidelines for quality control of herbal drugs
- know Quality assurance in herbal drug industry
- know the regulatory approval process and their registration in Indian and international markets
- appreciate EU and ICH guidelines for quality control of herbal drugs

Course Content:

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| Unit I | Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use | 10 hours |
| Unit II | <u>Quality assurance in herbal drug industry of cGMP, GAP and GLP in traditional system of medicine.</u> GMP requirements and Drugs & Cosmetics Act pro WHO Guidelines on GACP for Medicinal Plants. <u>GMP requirements and Drugs & Cosmetics Act provisions.</u> WHO Guidelines on GACP for Medicinal Plants. | 10 hours |
| Unit III | <u>EU guidelines for quality control of herbal drugs.</u> <u>Preparation of documents for new drug application and export registration</u> | 10 hours |
| Unit IV | <u>Application of various chromatographic techniques in standardization of herbal products.</u> | 08 hours |

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| | <ul style="list-style-type: none"> • <u>Importance of standardization of raw materials, extracts, and formulations with suitable examples.</u> • <u>WHO guidelines for the assessment of extracts</u> • <u>Applications of HPLC and HPTLC for the evaluation of drugs and extracts</u> • <u>Role of chemical and biological markers in standardization of herbal products</u> • <u>Standardization of the following drugs: Gokhru, Ashwagandha, Kalmegh, Brahmi, Vasaka, Curcuma and Glycyrrhiza</u> | |
| Unit V | <u>Regulatory requirements for herbal medicines:</u> <u>WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems</u> <u>Comparison of various Herbal Pharmacopoeias.</u> | 07 hours |

Recommended Books: (Latest Editions)

1. Trease G. E. and Evans, W. C., Pharmacognosy, 16th Ed, BailliereTindall, Eastbourne, U.K., 2010.
2. Kokate C. K., Purohit A. P. and Gokhale S. B., Pharmacognosy 41st Ed., NiraliPrakashan, 2008.
3. Tyler V. E., Brady R., Textbook of Pharmacognosy, 8th Ed, Lea and Febiger, Philadelphia, 1981.
4. Iyengar, M. A., and Nayak, S. G. K., Anatomy of Crude Drugs, 8th Ed., Manipal Power Press, Manipal., 2001.
5. Kokate, C. K., Practical Pharmacognosy, 3rd Ed., VallabhPrakashan, Delhi., 1991.
6. Medicinal plants of India, Indian Council of Medical Research, New Delhi.
7. Wallis, T. E., Textbook of Pharmacognosy, 5th Ed., J. A., Churchill Limited, London, 1985.
8. WHO guidelines for standardization of herbal drugs, WHO.
9. Harborne, J. B., Phytochemical methods, Chapman and Hall, International Ed., London.
10. Pulok, K. Mukharjee, Quality control of Herbal Drugs, Buisness horizons, New Delhi.

BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

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| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

Objectives:

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

- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

Course Content:

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| Unit I | Introduction to Drug Discovery and Development Stages of drug discovery and development Lead discovery and Analog Based Drug Design Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation. Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies | 10 hours |
| Unit II | Quantitative Structure Activity Relationship (QSAR) SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammett's substituent constant and Taft's steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA. | 10 hours |
| Unit III | Molecular Modeling and virtual screening techniques Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening, Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. <i>De novo</i> drug design. | 10 hours |

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| Unit IV | Informatics & Methods in drug design Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases. | 08 hours |
| Unit V | Molecular Modeling: Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination. | 07 hours |

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Park Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvold's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry" Lea & Febiger.
5. Korolkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)

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| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

- Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cellfunction.
- This is done both on a microscopic and molecularlevel.
- Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organismssuch as humans, plants, andsponges.

Objectives:

Upon completion of the subject student shall be able to;

- Summarize cell and molecular biologyhistory.
- Summarize cellular functioning andcomposition.
- Describe the chemical foundations of cellbiology.
- Summarize the DNA properties of cellbiology.
- Describe protein structure andfunction.
- Describe cellular membrane structure andfunction.
- Describe basic molecular geneticmechanisms.
- Summarize the CellCycle

Course content:

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| Unit I | a. Cell and Molecular Biology: Definitions theory and basics andApplications. b. Cell and Molecular Biology: History andSummation. c. Properties of cells and cellmembrane. d. Prokaryotic versusEukaryotic e. CellularReproduction f. Chemical Foundations – an Introduction and Reactions(Types) | 10 hours |
| Unit II | a. DNA and the Flow of MolecularInformation b. DNAFunctioning c. DNA andRNA d. Types ofRNA e. Transcription andTranslation | 10 hours |
| Unit III | a. Proteins and AminoAcids b. ProteinStructure | 10 hours |

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| | c. Regularities in Protein Pathways d. Cellular Processes e. Positive Control and significance of Protein Synthesis | |
| Unit IV | a. Science of Genetics b. Transgenics and Genomic Analysis c. Cell Cycle analysis d. Mitosis and Meiosis e. Cellular Activities and Checkpoints | 08 hours |
| Unit V | a. Cell Signals: Introduction b. Receptors for Cell Signals c. Signaling Pathways: Overview d. Misregulation of Signaling Pathways e. Protein-Kinases: Functioning | 07 hours |

Recommended Books (latest edition):

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

BP809ET. COSMETICSCIENCE (Theory)

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| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

Cosmetic industry is an ever growing field on par with Pharmaceutical Industry. The student will learn different aspects related to cosmetic science including formulation factors, Physiological factors.

Objective:

To enlighten the student about,

- Regulatory matters related to cosmetics.
- Thorough knowledge about various excipient used in cosmetics.
- Know about various physiological factors to be considered in formulation of cosmetics.
- Formulation and evaluation of wide varieties of cosmetics.

Course Content:

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| Unit I | Classification of cosmetic and cosmeceutical products Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application Skin: Basic structure and function of skin. Hair: Basic structure of hair. Hair growth cycle. Oral Cavity: Common problem associated with teeth and gums. | 10 hours |
| Unit II | Principles of formulation and building blocks of skin care products: Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmeceuticals. Antiperspirants & deodorants- Actives & mechanism of action. Principles of formulation and building blocks of Hair care products: Conditioning shampoo, Hair conditioner, anti-dandruff shampoo. Hair oils. | 10 hours |

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| | Chemistry and formulation of Para-phenylenediamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash. | |
| Unit III | Sun protection, Classification of Sunscreens and SPF. Role of herbs in cosmetics: Skin Care: Aloe and turmeric Hair care: Henna and amla. Oral care: Neem and clove Analytical cosmetics: BIS specification and analytical methods for shampoo, skin- cream and toothpaste. | 10 hours |
| Unit IV | Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties Soaps, and syndet bars. Evolution and skin benefits. | 08 hours |
| Unit V | Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis. Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor. | 07 hours |

Recommended Books (latest edition):

1. Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2. Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
3. Text book of cosmeticology by Sanju Nanda & Roop K. Khar, Tata Publishers.
4. Hand Book of Cosmetics. B.M. Mithal and Saha.
5. Cosmetic Formulation. Vimala Devi.

BP810 ET. PHARMACOLOGICAL SCREENING METHODS

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| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives

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

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

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| Unit I | Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia. | 08 Hours |
| Unit II | Preclinical screening models a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. b. Study of screening animal models for Diuretics, nootropics, anti-Parkinson's, antiasthmatics, Preclinical screening models: for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease | 10 Hours |

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| Unit III | Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anesthetics | 10 Hours |
| Unit IV | Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics. | 10 Hours |
| Unit -V | Research methodology and Bio-statistics Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data | 07 Hours |

Recommended Books (latest edition):

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

BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

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| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objectives:

Upon completion of the course the student shall be able to

- Understand the advanced instruments used and its applications in drug analysis
- Understand the chromatographic separation and analysis of drugs.
- Understand the calibration of various analytical instruments
- Know analysis of drugs using various analytical instruments.

Course Content:

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| Unit I | Nuclear Magnetic Resonance spectroscopy Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications Mass Spectrometry- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications | 10 hours |
| Unit II | Thermal Methods of Analysis: Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications. | 10 hours |
| Unit III | Calibration and validation- as per ICH and USFDA guidelines Calibration of following Instruments Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC | 10 hours |

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| Unit IV | Radio immuno assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay Extraction techniques: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction | 08 hours |
| Unit V | Hyphenated techniques -LC-MS/MS, GC-MS/MS, HPTLC-MS. | 07 hours |

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.KSharma
2. Organic spectroscopy by Y.RSharma
3. Text book of Pharmaceutical Analysis by Kenneth A.Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I.Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B.Stenlake
6. Organic Chemistry by I. L.Finar
7. Organic spectroscopy by WilliamKemp
8. Quantitative Analysis of Drugs by D. C.Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D.Sethi
10. Spectrophotometric identification of Organic Compounds bySilverstein

BP 812 ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS

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| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

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

Objective:

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to :

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

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| Unit I | a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc. b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community. c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds | 07 hours |
| Unit II | Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following <ul style="list-style-type: none"> a. Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin b. Sulfides: Diallyl sulfides, Allyl trisulfide. c. Polyphenolics: Resveratrol d. Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones e. Prebiotics / Probiotics.: Fructo oligosaccharides, | 15 hours |

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| | <p>Lactobacillum</p> <p>f. Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans</p> <p>g. Tocopherols</p> <p>h. Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and thelike.</p> | |
| Unit III | <p>Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids. Dietary fibres and complex carbohydrates as functional food ingredients.</p> | 07 hours |
| Unit IV | <p>a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.</p> <p>b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin</p> <p>c. Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.</p> <p>d. Functional foods for chronic disease prevention</p> | 10 hours |
| Unit V | <p>a. Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.</p> <p>b. Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.</p> <p>c. Pharmacopoeial Specifications for dietary supplements and nutraceuticals.</p> | 06 hours |

Recommended Books (Latest Editions)

1. Dietetics by SriLakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2ndEdn., Avery Publishing Group, NY (1997).
6. G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.

8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (ModernNutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea andFebiger

BP813ET Pharmaceutical Product Development

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|---------------------------------|-----------|----------------------------------|-----------|
| Credit Points | 04 | Total Teaching Hours | 45 |
| No. of lectures per week | 03 | No. of tutorials per week | 01 |

Scope:

This subject mainly deals with different stages of development of a pharmaceutical product and a wide variety of excipients.

Objective:

Upon completion of the course, the student understand,

- The importance of preformulation, formulation and stability parameters involved in the development of a pharmaceutical product.
- Various optimization techniques like factorial design, quality by design
- The importance of packaging material, quality control testing of packaging material.

Course Content

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| Unit I | Introduction to pharmaceutical product development, objectives, and regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms | 10 hours |
| Unit II | Study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories <ol style="list-style-type: none"> Solvents and solubilizers Cyclodextrins and their applications Non - ionic surfactants and their applications Polyethylene glycols and sorbitols Suspending and emulsifying agents Semi solid excipients | 10 hours |
| Unit III | Study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories <ol style="list-style-type: none"> Tablet and capsule excipients Directly compressible Excipients Coating materials Excipients in parenteral and aerosols preparation Excipients for formulation of NDDS Selection and application of excipients in pharmaceutical formulations with specific industrial applications | 10 hours |
| Unit IV | Optimization techniques in pharmaceutical product development. A study of various optimization techniques for | 08 hours |

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| | pharmaceutical product development with specific examples. Optimization by factorial designs and their applications. A study of QbD and its application in pharmaceutical product development. | |
| Unit V | Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations. | 07 hours |

Recommended Books (Latest editions)

1. Pharmaceutical Statistics Practical and Clinical Applications byStanford Bolton, CharlesBon; Marcel DekkerInc.
2. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick,Third Edition,Informa Healthcarepublishers.
3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A.Lieberman andLeonLachman; Marcel Dekker,Inc.
4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by RoopkKhar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd.2013.
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, editedby Patrick J. Sinko, BI Publications Pvt.Ltd.
6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyasand
7. R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
8. Pharmaceutical Dosage Forms and Drug Delivery Systems, LoydV. Allen Jr., Nicholas B.Popovich, Howard C. Ansel, 9th Ed.40
9. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, MichaelE. Aulton,3rdEd.
10. Remington – The Science and Practice of Pharmacy, 20thEd.
11. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon LachmanandJosephB. Schwartz
12. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
13. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis andH.A.Libermann.
14. Advanced Review Articles related to thetopics.