

Syllabus

B. Pharm Syllabus

I SEM

Course Code	Course Name	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO01	Human Anatomy and Physiology- I	3	1	4	8	6

Course Objectives: After studying this paper, the students will –

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

Curriculum:

UNIT - I

• **Introduction to the human body**

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**

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**

Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.

UNIT - II

• **Integumentary system**

Structure and functions of the skin

• **Skeletal system**

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**

Structural and functional classification, types of joints movements and its articulation

UNIT - III

• **Body fluids and blood**

Body fluids, composition and functions of blood, hemopoiesis, formation of haemoglobin, anaemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo-endothelial system.

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• **Lymphatic system**

Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system

UNIT - IV

Peripheral nervous system:

Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system.

Origin and functions of spinal and cranial nerves.

• **Special senses**

Structure and functions of eye, ear, nose and tongue and their disorders.

UNIT - V

• **Cardiovascular system**

Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heartbeat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

List of Practical's:

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 haemoglobin 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.

Course Outcome:

After completion of this course, the students will be able to:

CO01	Describe cell and tissue organization, types, and location in the body with homeostasis.
CO02	Explain the anatomy and physiology of the skin, joints, and skeleton system.
CO03	Understand the physiology and compositions of blood and lymph.
CO04	Compare the functions of nerves and the nervous system.
CO05	Interpret the functioning of the cardiovascular system.
CO06	Apply practical aspects of the composition of blood and studies of organ systems.



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Suggested Readings:

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. Textbook 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. Chatterje, Academic Publishers Kolkata.

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Course Code	Courses	Hours Per week			Total	
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PY3CO02	Pharmaceutical Analysis- I	3	1	4	4	6

Course Objectives: After studying this paper the students will –

1. Understand the principles of volumetric and electrochemical analysis
2. Know different types of errors that occurs in pharmaceutical analysis
3. Carryout various volumetric and electrochemical titrations
4. Develop analytical skills.
5. Perform assay of different compounds.
- 6.

Curriculum:

UNIT-I

(a) Pharmaceutical Analysis- Definition and scope

- i) Different techniques of analysis
- ii) Methods of expressing concentration
- iii) Primary and secondary standards.
- iv) Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate

(b)Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

(c)Pharmacopoeia, Sources of impurities in medicinal agents, limit tests.

UNIT-II

• **Acid-base titration:** 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

• **Non-aqueous titration:** Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl

UNIT-III

• **Precipitation titrations:** Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride.

• **Complexometric titration:** Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.

• **Gravimetry:** Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post-precipitation, Estimation of barium sulphate.

• Basic Principles, methods and application of diazotisation titration.

UNIT-IV

Redox titrations

(a) Concepts of oxidation and reduction

(b) Types of redox titrations (Principles and applications)

(c) Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate.

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UNIT-V

- **Electrochemical methods of analysis**
- **Conductometry**- Introduction, Conductivity cell, Conductometric titrations, applications.
- **Potentiometry** - Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
- **Polarography** - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications

List of Practical:

I Limit Test of the following

- (1) Chloride
- (2) Sulphate
- (3) Iron
- (4) Arsenic

II Preparation and standardization of

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

III Assay of the following compounds along with Standardization of Titrant

- (1) Ammonium chloride by acid base titration
- (2) Ferrous sulphate by Cerimetry
- (3) Copper sulphate by Iodometry
- (4) Calcium gluconate by complexometry
- (5) Hydrogen peroxide by Permanganometry
- (6) Sodium benzoate by non-aqueous titration
- (7) Sodium Chloride by precipitation titration

IV Determination of Normality by electro-analytical methods

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

Course Outcome:

After completion of this course, the students will be able to:

CO01	Describe different impurities, limit tests, sources of errors and standardization procedures.
CO02	Understand the principles and procedures of various titrimetric analyses.
CO03	Classify the electrochemical methods of analysis
CO04	Compare the inorganic compound using the limit test with standards.
CO05	Apply the different titration procedures for various chemical compounds



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Suggested Readings:

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.

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Course Code	Courses	Hours Per week			Total	
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PY3CO03	Pharmaceutics- I	3	1	4	8	6

Course Objectives: After studying this paper the students will know –

1. Know the history of the profession of pharmacy
2. Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
3. Understand the professional way of handling the prescription
4. Preparation of various conventional dosage forms.
5. Know about factors affecting dose for different patients.

Curriculum:

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. Paediatric dose calculations based on age, body weight and body surface area.

UNIT – II

- **Pharmaceutical calculations:** Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, allegation, proof spirit and isotonic solutions based on freezing point and molecular weight.
- **Powders:** Definition, classification, advantages and disadvantages, Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.
- **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

UNIT – III

- **Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.
- **Biphasic liquids:**
- **Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.
- **Emulsions:** Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

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UNIT – IV

- **Suppositories:** Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.
- **Pharmaceutical incompatibilities:** Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

UNIV – V

- **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 dosages forms

list of Practical:

1. Syrups

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

2. Elixirs

- a) Piperazine citrate elixir
- b) Paracetamol paediatric 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) Aluminium 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

9. Semisolids

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

10. Gargles and Mouthwashes

- a) Iodine gargle
- b) Chlorhexidine mouthwash



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Course Outcome:

After completion of this course, the students will be able to:

CO ₀₁	Describe the historical background and development of the pharmacy profession, prescription writing and posology.
CO ₀₂	Understand the calculations and classification of powders and liquid dosage forms.
CO ₀₃	Compare the properties of monophasic and biphasic liquid dosage forms
CO ₀₄	Summarize the formulation of suppositories and classification of pharmaceutical incompatibilities.
CO ₀₅	Understand the mechanism of dermal penetration from semisolid dosage forms.
CO ₀₆	Complete preparation of different types of pharmaceutical formulations.

Suggested Readings:

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.

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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO04	Pharmaceutical Inorganic Chemistry	3	1	4	8	6

Course Objectives: After studying this paper the students will –

1. Knows the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals.
2. Understand the medicinal and pharmaceutical importance of inorganic compounds.
3. Know the different inorganic compounds used for therapeutic purposes.
4. Know about radiopharmaceuticals and their applications.
5. Perform the limit test, purity test and identification test of different compounds.

Curriculum:

UNIT - I

• **Impurities in pharmaceutical substances:** History of Pharmacopoeia, Sources and types of impurities, the 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

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.

UNIT - III

• **Gastrointestinal agents**

Acidifiers: Ammonium chloride* and Dil. HCl

Antacid: Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate*, Aluminium hydroxide gel, Magnesium hydroxide mixture

Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations

UNIT - IV

• **Miscellaneous compounds**

Expectorants: Potassium iodide, Ammonium chloride*.

Emetics: Copper sulphate*, Sodium potassium tartrate

Haematinics: Ferrous sulphate*, Ferrous gluconate

Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium nitrite

Astringents: Zinc Sulphate, Potash Alum

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UNIT - V

• **Radiopharmaceuticals:** Radioactivity, Measurement of radioactivity, Properties of α , β , γ radiations, Half-life, radioisotopes and study of radioisotopes - Sodium iodide I_{131} , Storage conditions, precautions & pharmaceutical application of radioactive substances.

List of Practical's:

1. 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

2. Identification test

- Magnesium hydroxide
- Ferrous sulphate
- Sodium bicarbonate
- Calcium gluconate
- Copper sulphate

3. Test for purity

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

4. Preparation of inorganic pharmaceuticals

- Boric acid
- Potash alum
- Ferrous sulphate

Course Outcome:

After completion of this course, the students will be able to:

CO01	Identify the sources of impurities and their determination using limit tests.
CO02	Explain the concepts of acid, base, buffers, and electrolytes.
CO03	Understand the applications of inorganic compounds according to therapeutic category.
CO04	Interpret monograph of official pharmaceutical inorganic compounds.
CO05	Understand dental products and radiopharmaceuticals.
CO06	Apply the limit test for impurities, identify inorganic compounds, and prepare inorganic pharmaceuticals.

Suggested Reading:

- A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
- A.I. Vogel, Text Book of Quantitative Inorganic analysis
- P. Gundu Rao, Inorganic Pharmaceutical Chemistry



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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.



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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3HS01	Communication Skills	2	-	2	4	3

Course Objectives: After studying this paper the students will –

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

Curriculum:

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

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 Communication Style, Systematic Communication Style, Considerate Communication Style

UNIT – III

- **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations
- **Effective Written Communication:** Introduction, When and When Not to Use Written Communication - 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

UNIT – IV

- **Interview Skills:** Purpose of an interview, Do's and Don'ts of an interview
- **Giving Presentations:** Dealing with Fears, Planning Your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

UNIT – V

- **Group Discussion:** Introduction, Communication skills in group discussion, Do's and

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Don'ts of group discussion

List of Practical:

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

1. Basic communication covering the following topics

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

2. Pronunciations covering the following topics

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

3. Advanced Learning

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

Course Outcome:

After completion of this course, the students will be able to:

CO01	Understand the importance of communication skills and different barriers to communication.
CO02	Classify elements of communication and different styles of communication.
CO03	Understand different listing skills and effective ways of writing communication.
CO04	Understand various interview and presentation skills.
CO05	Use skills in group discussion and dos and don'ts.

Suggested Readings:

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, Oxford Press, 2011
3. Organizational Behaviour, Stephen .P. Robbins, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for Success, Gopala Swamy Ramesh, 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, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, Cengage Learning india pvt.ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, Mc Graw Hill Education, 2011

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Course Code	Courses	Hours Per week			Total	
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PY3RC01	Remedial Biology	2	-	2	4	3

Course Objective: After studying this paper the students will –

1. Know the classification and salient features of the five kingdoms of life
2. Understand the basic components of the anatomy & physiology of plant
3. Know and understand the basic components of anatomy & physiology of animals with special reference to humans.
4. Understand the process of photosynthesis and other plant processes.
5. Know the structure and function of cells and tissues.

Curriculum:

UNIT - I

Living world:

- 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

- Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.
- General Anatomy of Root, stem, leaf of monocotyledons & Dicotyledons.

UNIT - II

Body fluids and circulation

- 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

- Human alimentary canal and digestive glands
- Role of digestive enzymes
- Digestion, absorption and assimilation of digested food

Breathing and respiration

- Human respiratory system
- Mechanism of breathing and its regulation
- Exchange of gases, transport of gases and regulation of respiration
- Respiratory volumes

UNIT - III

Excretory products and their elimination

- Modes of excretion

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- Human excretory system- structure and function
- Urine formation
- Rennin angiotensin system

Neural control and coordination

- Definition and classification of nervous system
- Structure of a neuron
- Generation and conduction of nerve impulse
- Structure of brain and spinal cord
- Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical coordination and regulation

- Endocrine glands and their secretions
- Functions of hormones secreted by endocrine glands

Human reproduction

- Parts of the female reproductive system
- Parts of the male reproductive system
- Spermatogenesis and Oogenesis
- Menstrual cycle

UNIT - IV

Plants and mineral nutrition:

- Essential mineral, macro and micronutrients
- Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

Photosynthesis

- Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.

UNIT - V

Plant respiration: Respiration, glycolysis, fermentation (anaerobic).

Plant growth and development

- Phases and rate of plant growth, Condition of growth, Introduction to plant growth regulators

Cell - The unit of life

- Structure and functions of cell and cell organelles. Cell division

Tissues

- Definition, types of tissues, location and functions.

List of Practical:

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 cells and its inclusions
3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
4. Detailed study of frogs by using computer models
5. Microscopic study and identification of tissues pertinent to Stem, Root Leaf, seed, fruit and flower
6. Identification of bones



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7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Course Outcome:

After completion of this course, the students will be able to:

CO01	Identify the features of living organisms, kingdoms of life, and morphology of plants.
CO02	Explain the anatomy and physiology of major organ systems of the body.
CO03	Describe various nutritional requirements, respiration, and photosynthesis for plant growth.
CO04	Understand the structure and function of cells and tissues.
CO05	Compare parts of plants and organ systems using microscopy.

Suggested Readings:

Text Books:

- a. Text book of Biology by S. B. Gokhale
- b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books:

- a. A Textbook of Biology by B.V. Sreenivasa Naidu
- b. A Textbook of Biology by Naidu and Murthy
- c. Botany for Degree students By A.C.Dutta.
- d. Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.
- e. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate
- f. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
- g. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
- h. Biology practical manual according to National core curriculum. Biology forum of Karnataka. Prof .M.J.H.Shafi

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Course Code	Courses	Hours Per week			Total	
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PY3RC02	Remedial Mathematics	2	-	-	2	2

Course Objective: After studying this paper the students will-

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

Curriculum:

UNIT – I

• **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

• **Logarithms**

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristics and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

• **Function:**

Real-Valued function, Classification of real-valued functions,

• **Limits and continuity:**

Introduction, Limit of a function, Definition of limit of a function ($\epsilon - \delta$ definition), $\lim_{x \rightarrow a} x^n = a^n$, $\lim_{\theta \rightarrow 0} \sin \theta = \theta$, $\lim_{\theta \rightarrow 0} \frac{\sin \theta}{\theta} = 1$

UNIT –II

• **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

UNIT – III

• **Calculus**

Differentiation: Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function, Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions (Quotient formula) – **Without Proof**, Derivative of x^n w.r.t x , where n is any rational number, Derivative of e^x , Derivative of $\log_e x$, Derivative of a^x Derivative of trigonometric functions from first principles (**without Proof**), Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point. Application

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UNIT – IV

• **Analytical Geometry**

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

UNIT-V

• **Differential Equations:** Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations, Application in solving Pharmacokinetic equations

• **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

Course Outcome:

After completion of this course, the students will be able to:

CO01	Describe the function and application of partial fractions, and logarithms.
CO02	Understand the analytical geometry and integration and methods of the partial fraction.
CO03	Derive function, constant and quotient formulas and their applications.
CO04	Solve different types of matrix, properties and products of determinants
CO05	Solve differential equations and understand the properties of the Laplace transform and its application.

Suggested Readings:

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.

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II SEM

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO05	Human Anatomy and Physiology- II	3	1	4	8	6

Course Objectives: After studying this paper the students will know –

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of the human body.
4. Perform the haematological tests like blood cell counts, hemoglobin estimation,
5. Understand the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of the human body.

Curriculum:

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)

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 and disorders of GIT.

• **Energetics**

Formation and role of ATP, Creatinine Phosphate and BMR.

UNIT- III

• **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.

• **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.

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UNIT - IV

• **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.

UNIT - V

• **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

List of Practical:

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. 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.

Course Outcome:

After completion of this course, the students will be able to:

CO ₀₁	Describe the Anatomy and Physiology of CNS.
CO ₀₂	Summarize energetics and the digestive system process with special reference to enzymes.
CO ₀₃	Understand the anatomy and physiology of the respiratory system and the mechanism of artificial respiration and resuscitation.
CO ₀₄	Summarize the anatomy and functions of the urinary and endocrine systems.
CO ₀₅	Understand the anatomy and physiology of the reproductive system and the basics of genetics.
CO ₀₆	Relate the anatomy and physiology of organ systems with the help of specimens, models, and charts.

Suggested Readings:



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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 brothers medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers 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:

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. Chatterje, Academic Publishers Kolkata



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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO06	Pharmaceutical Organic Chemistry- I	3	1	4	8	6

Course Objectives: After studying this paper the students will –

1. able to draw the structure, name and type of isomerism of the organic compound
2. able to write the reaction, name the reaction and orientation of reactions
3. account for the reactivity/stability of compounds,
4. identify/confirm the identification of organic compound

Curriculum:

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

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

UNIT-I

• **Classification, nomenclature and isomerism**

Classification of Organic Compounds. Common and IUPAC systems of nomenclature of organic compounds (up to 10 Carbons open chain and carbocyclic compounds) Structural isomerism in organic compounds

UNIT-II

• **Alkanes*, Alkenes* and Conjugated dienes***

SP₃ hybridization in alkanes, Halogenation of alkanes, uses of paraffins.

Stabilities of alkenes, SP₂ hybridization in alkenes

E₁ and E₂ reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E₁ versus E₂ reactions, Factors affecting E₁ and E₂ reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement

UNIT-III

• **Alkyl halides***

SN₁ and SN₂ reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

SN₁ versus SN₂ reactions, Factors affecting SN₁ and SN₂ reactions

Structure and uses of ethyl chloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

• **Alcohols***- Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol

UNIT-IV

• **Carbonyl compounds* (Aldehydes and ketones)**

Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin

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condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde.

UNIT-V

• Carboxylic acids*

The acidity of carboxylic acids, the effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids, amide and ester

Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetylsalicylic acid

• Aliphatic amines* - Basicity, the effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine

List of Practical:

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

Course Outcome:

After completion of this course, the students will be able to:

CO ₀₁	Describe the classification & IUPAC nomenclature of organic compounds with basic concepts of isomerism.
CO ₀₂	Explain the mechanism of elimination reactions for alkane, alkene, and conjugation dienes.
CO ₀₃	Understand the concept of substitution reactions for alkyl halides and alcohols.
CO ₀₄	Classify nucleophilic additions and different condensation reactions like aldol condensation, Cannizzaro reaction, etc. for aldehyde and ketones.
CO ₀₅	Summarize the structure, uses and effect of substitution on various carboxylic acid and aliphatic amines.
CO ₀₆	Compare unknown organic compounds by qualitative tests.

Suggested Readings:

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar, Volume-I



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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 textbook 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.

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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO07	Biochemistry	3	1	4	8	6

Course Objectives: After studying this paper the students will know –

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

Curriculum:

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

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 significance

Hormonal regulation of blood glucose level and Diabetes mellitus

• **Biological oxidation**

Electron transport chain (ETC) and its mechanism.

Oxidative phosphorylation & its mechanism and substrate phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers level

UNIT - III

• **Lipid metabolism**

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.

• **Amino acid metabolism**

General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders

Catabolism of phenylalanine and tyrosine and their metabolic disorders

(Phenylketonuria, Albinism, alkaptonuria, tyrosinemia)

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Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline

Catabolism of heme; hyperbilirubinemia and jaundice

UNIT - IV

• **Nucleic acid metabolism and genetic information transfer**

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease

Organization of mammalian genome

Structure of DNA and RNA and their functions

DNA replication (semi-conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

UNIT - V

• **Enzymes**

Introduction, properties, nomenclature and IUB classification of enzymes

Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

Enzyme inhibitors with examples

Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation

Therapeutic and diagnostic applications of enzymes and isoenzymes

Coenzymes –Structure and biochemical functions

list of Practical:

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
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.

Course Outcome:

After completion of this course, the students will be able to:

CO01	Describe the classification, biological role of biomolecules and concept of bioenergetics.
CO02	Explain the metabolism and biological oxidation of carbohydrates.
CO03	Understand the metabolism of lipids and amino acids with their disorders.
CO04	Summarize nucleic acid metabolism and genetic information processes.
CO05	Classify enzymes and their regulation and application.
	Apply different methods for the qualitative and quantitative estimation of biological samples.



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Suggested Readings:

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.

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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO08	Pathophysiology	3	1	-	4	4

Course Objectives: After studying this paper the students will –

1. Describe the etiology and pathogenesis of the selected disease states.
2. Name the signs and symptoms of the diseases.
3. Mention the complications of the diseases.

Curriculum:

UNIT – I

Basic principles of Cell injury and Adaptation:

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:

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

UNIT - II

Cardiovascular System:

Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis)

Respiratory system: Asthma, Chronic obstructive airways diseases.

Renal system: Acute and chronic renal failure.

UNIT - III

Haematological Diseases:

Iron deficiency, megaloblastic anaemia (Vit B12 and folic acid), sickle cell anaemia, thalassemia, hereditary acquired anaemia, haemophilia

Endocrine system: Diabetes, thyroid diseases, disorders of sex hormones

Nervous system: Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.

UNIT- IV

Gastrointestinal system: Peptic Ulcer

Inflammatory bowel diseases, jaundice, hepatitis (A, B,C,D,E,F) alcoholic liver disease.

Disease of bones and joints: Rheumatoid arthritis, osteoporosis and gout

Principles of cancer: classification, etiology and pathogenesis of cancer

UNIT -V

Infectious diseases: Meningitis, Typhoid, Leprosy, Tuberculosis Urinary tract infections

Syllabus

Sexually transmitted diseases: AIDS, Syphilis, Gonorrhoea

Course Outcome:

After completion of this course, the students will be able to:

CO01	Describe elements responsible for cell injury, cell death, inflammation and repair
CO02	Understand the pathophysiology of cardiovascular, respiratory, and renal systems.
CO03	Summarize the pathophysiology for the generation of haematological diseases and factors responsible for disease generation in the endocrine and nervous systems.
CO04	Understand the causative factors for diseases of GIT, bones, and joints and the generation of cancer.
CO05	Interpret causative factors for infectious and sexually transmitted diseases.

Suggested Reading:

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier;
2. Harsh Mohan; Text book of Pathology; India; Jaypee Publications;
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; New York; McGraw-Hill;
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; united states;
5. William and Wilkins, Baltimore
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; London; ELBS/Churchill Livingstone;
7. Guyton A, John. E Hall; Textbook of Medical Physiology; WB Saunders Company.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; London; McGraw-Hill Medical;
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; Philadelphia; WB Saunders Company.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; London; Churchill Livingstone publication

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.

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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO33	Computer Applications in Pharmacy	3	-	2	3	4

Course Objectives: After studying this paper the students will –

1. knows the various types of applications of computers in pharmacy
2. knows the various types of databases
3. knows the various applications of databases in pharmacy

Curriculum:

UNIT – I

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One’s complement, Two’s complement method, binary multiplication, binary division

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

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

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

UNIT – IV

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

UNIT-V

Computers as data analysis in Preclinical development:

Chromatographic data analysis (CDS), Laboratory Information management System (LIMS) and Text Information Management System (TIMS)

List of Practical:

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create an HTML web page to show personal information.
- 3 Retrieve the information about a drug and its adverse effects using online tools
- 4 Creating mailing labels Using Label Wizard, generating labels in MS WORD
- 5 Create a database in MS Access to store the patient information with the required

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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

Course Outcome:

After completion of this course, the students will be able to:

CO01	Describe the number system and concepts of information software.
CO02	Explain the various types of databases in pharmacy, programming languages, web servers and pharmacy drug databases.
CO03	Understand applications of computers in hospital pharmacy and lab diagnostic systems.
CO04	Apply the concept of bioinformatics in drug and vaccine discovery.
CO05	Use the different information management systems and data analysis in preclinical development.
CO06	Relate the different computer languages and programs with their pharmaceutical applications.

Suggested Readings:

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

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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3HS02	Environmental Sciences	3	-	-	3	3

Course Objective: After studying this paper the students will –

1. Create awareness about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the environment.
4. Motivate learners to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.

Curriculum:

UNIT - I

The Multidisciplinary nature of environmental studies

Natural Resources, Renewable and non-renewable resources

- a) Forest resources b) Water resources c) Mineral resources d) Food Resources e) Energy resources f) Land resources:

Role of an individual in the Conservation of natural resources

Unit-II Natural Resources and associated problems

- a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources:

UNIT-III

Ecosystems, Concept of an ecosystem, Structure and function of an ecosystem, food chain and food web, Ecological succession, factors of succession, stages and types of succession, Ecological pyramids

Introduction, types, characteristic features, structure and function of the ecosystems of the following Forest ecosystem;

UNIT-IV.

Introduction, types, characteristic features, structure and function of the ecosystems of the following

Grassland ecosystems, Desert ecosystems; Aquatic ecosystems (Ponds, Streams, Lakes, Rivers, Oceans, Estuaries)

UNIT- V

Environmental Pollution: Air pollution; Water pollution; Soil pollution

Course Outcomes (COs):

After completion of this course, the students will be able to:

CO01	Define renewable and non-renewable resources.
CO02	Describe the problem associated with natural resources.
CO03	Understand the concept of ecosystem, ecological succession and ecological pyramids.
CO04	Summarize types and functions of grassland, desert and aquatic ecosystems.
CO05	Classify different environmental pollutions.



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Suggested Readings:

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, Clarendon 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.

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III SEM

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO09	Pharmaceutical Organic Chemistry-II	3	1	4	8	6

Course Objectives: After studying this paper the students will –

1. write the structure, name and type of isomerism of the organic compound
2. write the reaction, name the reaction and the orientation of the reactions
3. for the reactivity/stability of compounds,
4. prepare organic compounds

Curriculum:

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, Friedel crafts alkylation-reactivity, limitations, Friedel crafts 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

UNIT - II

Phenols* - Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthol

Aromatic Amines* - Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts

Aromatic Acids* –Acidity, effect of substituents on acidity and important reactions of benzoic acid.

UNIT- III

Fats and Oils

- a. Fatty acids – reactions.
- b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.
- c. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

UNIT – IV

Polynuclear hydrocarbons: a. Synthesis, reactions b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

Syllabus

UNIT - V

Cyclo alkanes* Stabilities – Baeyer’s strain theory, limitation of Baeyer’s strain theory, Coulson and Moffitt’s modification, Sachse Mohr’s theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only

List of Practical:

1. Experiments involving laboratory techniques □ Recrystallization □ Steam distillation
2. Determination of the following oil values (including standardization of reagents)
 - a. Acid value
 - b. Saponification value
 - c. Iodine value
3. Preparation of compounds
 - a. Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
 - b. 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
 - c. Acetanilide by halogenation (Bromination) reaction.
 - d. 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
 - e. Benzoic acid from Benzyl chloride by oxidation reaction. □ Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
 - f. 1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.
 - g. Benzil from Benzoin by oxidation reaction.
 - h. Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction
 - i. Cinnamic acid from Benzaldehyde by Perkin reaction
 - j. P-Iodo benzoic acid from P-amino benzoic acid

Course Outcome:

After completion of this course, the students will be able to:

CO01	Describe the preparations, reactions, and applications of different aromatic organic compounds.
CO02	Summarize reactions and analytical constants of fats and oils.
CO03	Understand the synthesis and reactions of polynuclear hydrocarbons.
CO04	Understand the stability theories and reactions of cycloalkanes
CO05	Apply knowledge of reaction and recrystallization to synthesize various organic compounds in the laboratory.

Suggested Readings:

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.

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO10	Physical Pharmaceutics-I	3	1	4	8	6

Course Objectives: After studying this paper the students will –

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

Curriculum:

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

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

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.

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.

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.

Syllabus

List of Practical:

1. Determination of the solubility of the drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
3. Determination of Partition co- efficiency 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 a 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's constants using activated charcoal
9. Determination of critical micellar concentration of surfactants
10. Determination of stability constant and donor-acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor-acceptor ratio of Cupric-Glycine complex by pH titration method

Course Outcome:

After completion of this course, the students will be able to:

CO ₀₁	Describe principles, properties and applications of solubility of drugs.
CO ₀₂	Define the various physicochemical properties of drug molecules like refractive index, optical activity, and dipole moment.
CO ₀₃	Understand the mechanism of surface and interfacial phenomenon.
CO ₀₄	Summarize applications of complexation, and protein binding.
CO ₀₅	Understand the concept of pH, buffers and isotonic solutions in pharmaceutical and biological systems.
CO ₀₆	Relate the various physicochemical properties of different pharmaceutical compounds.

Suggested Readings:

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, Marcel Dekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1 to 3 Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C and Manavalan R.
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.

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO11	Pharmaceutical Microbiology	3	1	4	8	6

Course Objectives: After studying this paper the students will know –

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

Curriculum:

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.

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.

Equipment's employed in large scale sterilization.

Sterility indicators.

UNIT - III

Study of morphology, classification, reproduction/replication 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

Evaluation of bactericidal & Bacteriostatic.

Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

UNIT - IV

Designing of aseptic area, laminar flow equipment; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification. Principles and methods of

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different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic.

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.80

list of Practical:

1. Introduction and study of different equipment and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, and microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Subculturing 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 techniques 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.

Course Outcome:

After completion of this course, the students will be able to:

CO01	Identify nutrition requirements for growth and preservation of various micro-organisms,
CO02	Understand different staining techniques and principles of sterilization and disinfectants.
CO03	Summarize the different aspects of fungi and viruses and the principles of sterility testing.
CO04	Interpret the importance of an aseptic area and a clean area.
CO05	Classify different types of spoilage and preservation techniques of pharmaceutical products.
CO06	Apply the concept of microbiology for the identification, preservation and serialization of microbes.

Suggested Readings:

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.



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6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Pepler: 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, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO12	Pharmaceutical Engineering	3	1	4	8	6

Course Objectives: After studying this paper, the students will –

1. Know various unit operations used in pharmaceutical industries.
2. Understand the material handling techniques.
3. Perform various processes involved in the pharmaceutical manufacturing process.
4. Carry out various tests to prevent environmental pollution.
5. Comprehend the significance of plant layout design for optimum use of resources.

Curriculum:

UNIT – I

Flow of fluids: Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturi meter, Pitot tube and Rotometer.

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.

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.

UNIT - II

Heat Transfer: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.

Evaporation: Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator & Economy of multiple effect evaporator.

Distillation: Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

UNIT - III

Drying: Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.

Mixing: Objectives, applications & factors affecting mixing, Difference between solid and 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,

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UNIT- IV

Filtration: Objectives, applications, Theories & Factors influencing filtration, filter aids, filter media. 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.

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.

UNIT -V

Materials of pharmaceutical plant construction, Corrosion and its prevention, Factors affecting materials selected for pharmaceutical plant construction, Theories of corrosion, types of corrosion and their prevention. Ferrous and nonferrous metals, inorganic and organic non-metals, and basic of material handling systems.

Course Outcome:

After completion of this course, the students will be able to:

CO01	Explain the concepts of the flow of fluids, size reduction and size separation.
CO02	Understand the mechanism involved in heat transfer, evaporation, and distillation.
CO03	Understand the mechanism and applications of drying and mixing.
CO04	Summarize the concept of filtration and centrifugation with the help of various equipment.
CO05	Understand the materials of pharmaceutical plant construction, the concept of corrosion, and their prevention.
CO06	Apply engineering concepts to the determination of a variety of compounds' physical properties.

list of Practical:

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.



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Suggested Reading:

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 pharmaceutics- C.V.S Subrahmanyam et al., Latest edition. 8. Cooper and Gunn's Tutorial Pharmacy, S.J. Carter, Latest edition.



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B. Pharm Syllabus

IV SEM

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO13	Pharmaceutical Organic Chemistry-III	3	1	0	4	4

Course Objectives: After studying this paper the students will –

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

Curriculum:

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

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.

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

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



Syllabus

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

Course Outcome:

After completion of this course, the students will be able to:

CO ₀₁	Understand the mechanism, uses and application of stereoisomerism, optical isomerism, chiral molecules and racemic mixtures.
CO ₀₂	Summarize the mechanism, uses and application of geometric and conformational isomerism and their stereo-specific and stereoselective reactions.
CO ₀₃	Interpret the classification, synthesis, properties, medicinal uses and other applications of five-membered heterocyclic organic compounds.
CO ₀₄	Interpret the classification, synthesis, properties, medicinal uses and other applications of six-membered heterocyclic organic compounds.
CO ₀₅	Relate the importance of different name reactions in the synthesis of drugs.

Suggested Readings:

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.

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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO14	Medicinal Chemistry-I	3	1	4	8	6

Course Objectives: After studying this paper the students will –

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

Curriculum:

UNIT-I

A)- 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.

B)- Drug metabolism

- Drug metabolism principles- Phase I and Phase II.
- Factors affecting drug metabolism including stereochemical aspects.

UNIT-II

- **Drugs acting on Autonomic Nervous System**

Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic agents

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine, Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitoltero Naphazoline, Oxymetazoline and Xylometazoline.

Indirect-acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.

Agents with mixed mechanism: Ephedrine, Metaraminol.

Adrenergic Antagonists:

Alpha-adrenergic blockers: Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

Beta-adrenergic blockers: SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

UNIT-III

- **Cholinergic neurotransmitters:**

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

Syllabus

Direct acting agents: Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible): Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isoflurophate, Echothiophate iodide, Parathione, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking Agents: SAR of cholinolytic agents

Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*.

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

UNIT-IV

• **Drugs acting on Central Nervous System**

A)- **Sedatives and Hypnotics:**

- Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem
- Barbiturates: SAR of barbiturates, Barbitol*, Phenobarbital, Mephobarbital, Amobarbital, Butobarbital, Pentobarbital, Secobarbital
- Miscellaneous:
- Amides & imides: Glutethimide.
- Alcohol & their carbamate derivatives: Meproboamate, Ethchlorvynol.
- Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B)- **Antipsychotics:**

- Phenothiazines: SAR of Phenothiazines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.
- Ring Analogues of Phenothiazines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.
- Fluro buterophenones: Haloperidol, Droperidol, Risperidone.
- Beta amino ketones: Molindone hydrochloride.
- Benzamides: Sulpieride.

C)- **Anticonvulsants:** SAR of Anticonvulsants, mechanism of anticonvulsant action

- Barbiturates: Phenobarbitone, Methabarbitol. Hydantoins:
- Phenytoin*, Mephentyoin, Ethotoin Oxazolidine diones:
- Trimethadione, Paramethadione Succinimides:
- Phensuximide, Methsuximide, Ethosuximide* Urea and
- monoacylureas: Phenacemide, Carbamazepine*
- Benzodiazepines: Clonazepam
- Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate

Syllabus

UNIT-V

• **Drugs acting on Central Nervous System**

A)- General anaesthetics:

- Inhalation anaesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.
- Ultra-short acting barbiturates: Methohexital sodium*, Thiopental sodium.
- Dissociative anaesthetics: Ketamine hydrochloride.*

B)- Narcotic and non-narcotic analgesics

- Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anilerdine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartrate.
- Narcotic antagonists: Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.

- C)- Anti-inflammatory agents:** Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepirac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

List of Practical:

I Preparation of drugs/ intermediates

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

II Assay of drugs

- 1 Chlorpromazine
- 2 Phenobarbitone
- 3 Atropine
- 4 Ibuprofen
- 5 Aspirin
- 6 Furosemide

III Determination of Partition coefficient for any two drugs



Syllabus

Course Outcome:

After completion of this course, the students will be able to:

CO01	Describe the history & development of medicinal compounds, physiochemical properties, drug metabolism and their relationship with biological action.
CO02	Understand the pathway of adrenergic neurotransmitters, their receptors, classification, Mechanism of action, Structure-activity relationships, synthesis and uses of sympathomimetic and sympatholytic agents.
CO03	Summarize the pathway of adrenergic neurotransmitters, their receptors, classification, Mechanism of action, Structure-activity relationships, synthesis and uses of parasympathomimetic and parasympatholytic agents.
CO04	Understand the CNS receptors, classification, Mechanism of action, Structure-activity relationships, synthesis and uses of Sedative and hypnotics, antipsychotics, and anticonvulsants.
CO05	Summarize the CNS receptors, classification, Mechanism of action, Structure-activity relationships, synthesis and uses of general anaesthetics, analgesics and anti-inflammatory agents.
CO06	Apply the concept of chemistry for the preparation and assay of medicinal agents.

Suggested Readings:

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 pharmacopeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Textbook of practical organic chemistry- A.I. Vogel.

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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO15	Physical Pharmaceutics-II	3	1	4	8	6

Course Objectives: After studying this paper the students will –

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

Curriculum:

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.

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

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.

UNIT - IV

Micromeritics: Particle size and distribution, mean particle size, number and weight distribution, particle number, methods for determining particle size by different methods, counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.

UNIT - V

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of

Syllabus

medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

list of Practical:

1. Determination of particle size, and particle size distribution using the 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 the influence of lubricant on the angle of repose
5. Determination of viscosity of liquid using Ostwald's viscometer
6. Determination of sedimentation volume with the effect of different suspending agent
7. Determination of sedimentation volume with the effect of different concentrations 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

Course Outcome:

After completion of this course, the students will be able to:

CO01	Describe the classification and properties of colloidal dispersion.
CO02	Understand the concept of rheology and deformation of solids.
CO03	Compare the properties and stability of suspensions and emulsions.
CO04	Summarize the methods of determining particle size and surface area and derived properties of powders.
CO05	Apply the principles of reaction kinetics and determine the reaction rates to predict the drug stability of formulations.
CO06	Apply the knowledge about various physicochemical properties of drugs and excipients in dosage form designing.

Suggested Readings:

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 to 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO16	Pharmacology-I	3	1	4	8	6

Course Objectives: After studying this paper the students will –

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

Curriculum:

UNIT – I

8 Hours

1. 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

UNIT - II

12 hours

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 receptors, transmembrane enzyme-linked receptors, transmembrane JAK-STAT binding receptors and receptors that regulate transcription factors, dose-response relationship, therapeutic index, combined effects of drugs and factors modifying drug action. b. Adverse drug reactions. c. Drug interactions (pharmacokinetic and pharmacodynamic) d. 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

10 Hours

Pharmacology of drugs acting on the 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).

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- e. Local anesthetic agents.
- f. Drugs used in myasthenia gravis and glaucoma

UNIT- IV

8 Hours

Pharmacology of drugs acting on central nervous system

- a. Neurohumoral transmission in the C.N.S. special emphasis on the importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, and dopamine.
- b. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
- c. Sedatives, hypnotics and centrally acting muscle relaxants.
- d. Anti-epileptics

UNIT -V

7 Hours

Pharmacology of drugs acting on the central nervous system

- a. Drugs used in Parkinson's disease and Alzheimer's disease.
- b. Alcohols and disulfiram
- c. CNS stimulants and nootropics.
- d. Opioid analgesics and antagonists
- e. Drug addiction, drug abuse, tolerance and dependence.
- f. General anesthetics and pre-anesthetics

List of Practical:

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, anaesthetics and euthanasia are used for animal studies.
6. Study of different routes of drug administration in mice/rats.
7. Study of the effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog esophagus
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

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

Syllabus

Course Outcome:

After completion of this course, the students will be able to:

CO01	Explain the basic concepts of drugs, their receptors and pharmacokinetics.
CO02	Interpret the concepts of drug pharmacokinetics and pharmacodynamics in preclinical and clinical studies of the drug development process.
CO03	Understand the concept and pharmacology of the drug acting on the peripheral nervous system.
CO04	Summarize the concept of neurotransmitters and the pharmacology of the psychopharmacological agents.
CO05	Understand the concept and pharmacology of anti-Parkinson's, CNS stimulants, Opioid analgesics and general anesthetics.
CO06	Relate the effects of drugs on the peripheral nervous system and central nervous system using experimental pharmacology software and instruments.

Suggested Reading:

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. Vallabh Prakashan,

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO17	Pharmacognosy and Phytochemistry-I	3	1	4	8	6

Course Objectives: After studying this paper the students will –

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

Curriculum:

UNIT – I

Introduction to Pharmacognosy: (a) Definition, history, scope and development of Pharmacognosy (b) Sources of Drugs – Plants, Animals, Marine & Tissue culture (c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs: Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs

Quality control of Drugs of Natural Origin: Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties.

Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT - II

Cultivation, Collection, Processing and Storage of drugs of natural origin: Cultivation and Collection of Drugs of natural origin Factors influencing cultivation of medicinal plants. Plant hormones and their applications. Polyploidy, mutation and hybridization with reference to medicinal plants

Conservation of medicinal plants

UNIT - III

Plant tissue culture: Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance. Applications of plant tissue culture in pharmacognosy. Edible vaccines

UNIT- IV

Pharmacognosy in various systems of medicine: Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine.

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Introduction to secondary metabolites: Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

UNIT -V

Study of biological source, chemical nature and uses of drugs of natural origin containing the following drugs Plant Products: Fibers - Cotton, Jute, Hemp Hallucinogens, Teratogens, Natural allergens

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 from marine sources

List of Practical:

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

Course Outcome:

After completion of this course, the students will be able to:

CO01	Describe the history and scope of pharmacognosy, Classification, and quality control tests for crude drugs.
CO02	Understand the concept of cultivation and collection of medicinal plants with their conservation.
CO03	Understand plant tissue culture for the production of secondary metabolites.
CO04	Classify various systems of medicine with a brief introduction, properties and tests for secondary metabolites.
CO05	Summarize the biological source, chemical nature, and uses of drugs of natural origin such as Cotton, Jute, etc and a detailed study of primary metabolites.
CO06	Apply the different pharmacognostic parameters on crude drugs.



Syllabus

Suggested Reading:

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), Ist Edn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhale
9. Anatomy of Crude Drugs by M.A. Iyenga

Syllabus

B. Pharm Syllabus

V SEM

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO18	Medicinal Chemistry-II	3	1	0	4	4

Course Objectives: After studying this paper the students will –

1. Understand the chemistry of drugs for their pharmacological activity
2. Understand the drug metabolic pathways, adverse effects and therapeutic value of drugs
3. Know the Structural Activity Relationship of different classes of drugs
4. Study the chemical synthesis of selected drugs

Curriculum:

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 the selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT – I

10 Hours

A. Anti-anginal:

- **Vasodilators:** Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole.
- **Calcium channel blockers:** Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.
- **Diuretics:**
Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.
Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,
Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid.
Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.
Osmotic Diuretics: Mannitol

- B. Anti-hypertensive Agents:** Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

UNIT- II

10 Hours

- A. Anti-arrhythmic Drugs:** Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcaïnide hydrochloride, Amiodarone, Sotalol.
- B. Anti-hyperlipidaemic agents:** Clofibrate, Lovastatin, Cholesteramine and Cholestipol
- C. Coagulant & Anticoagulants:** Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel
- D. Drugs used in Congestive Heart Failure:** Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

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UNIT – III

10 Hours

- A. Antihistaminic agents:** Histamine, receptors and their distribution in the human body H1-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium
- **H2-antagonists:** Cimetidine*, Famotidine, Ranitidine
- B. Anti-neoplastic agents:**
Alkylating agents: Meclourethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepe
Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine
Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin
Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate
Miscellaneous: Cisplatin, Mitotane.

UNIT – IV

8 Hours

Drugs acting on the Endocrine system

Nomenclature, Stereochemistry and Metabolism of Steroids

- Sex hormones: Testosterone, Nandralone, Progesterones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol. Drugs for erectile dysfunction: Sildenafil, Tadalafil. Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone
- Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

UNIT – V

7 Hours

A. Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

B. Antidiabetic agents:

Insulin and its preparations

Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acarbose, Voglibose.

C. Local Anaesthetics: SAR of Local anaesthetics

Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine.

Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Dipiperodon, Dibucaine.*



Syllabus

Course Outcome:

After completion of this course, the students will be able to:

CO01	Compare classification, Mechanism of action, Structure-activity relationships, and uses of cardiovascular agents.
CO02	Understand the pathway of histamine neurotransmitters, their receptors, classification, Mechanism of action, Structure-activity relationships, and uses of antihistamines.
CO03	Relate the cell cycle with classification, Mechanism of action, Structure-activity relationships, and uses of antineoplastic agents.
CO04	Correlate the drugs acting on the endocrine system and diabetes.
CO05	Illustrate classification, Mechanism of action, Structure-activity relationships, and uses of Local anaesthetics and proton pump inhibitors.

Suggested Readings:

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.
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.



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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO19	Industrial Pharmacy-I	3	1	4	8	6

Course Objectives: After studying this paper the students will –

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

Curriculum:

UNIT-I

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization

BCS classification of drugs & its significant

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT-II

Tablets:

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems.

Equipments and tablet tooling.

b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.

c. Quality control tests: In process and finished product tests

Liquid orals: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia

UNIT-III

Capsules:

a. Hard gelatin capsules: Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

b. Soft gelatin capsules: Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

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UNIT-IV

Parenteral Products:

- Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
- Production procedure, production facilities and controls, aseptic processing
- Formulation of injections, sterile powders, large volume parenteral and lyophilized products.
- Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labelling, containers; evaluation of ophthalmic preparations

UNIT-V

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

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.

List of Practical:

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

Course Outcome:

After completion of this course, the students will be able to:

CO01	Describe applications of physical and chemical properties in the development of pharmaceutical dosage forms.
CO02	Define formulations and evaluation of tablets and liquid orals.
CO03	Understand the production and evaluation of capsules and pellets
CO04	Summarize formulation parameters and quality control tests for parenteral and ophthalmic preparations.



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CO05	Understand the preparation, packaging and evaluation of cosmetics and pharmaceutical aerosols.
CO06	Apply the knowledge of industrial pharmacy in the preparation and evaluation of different pharmaceutical preparations

Suggested Readings:

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, 5th edition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO20	Pharmacology-II	3	1	4	8	6

Course Objectives: After studying this paper the students will know –

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

Curriculum:

UNIT - I

10 Hours

1. Pharmacology of drugs acting on the cardiovascular system

- a. Introduction to hemodynamic and electrophysiology of the heart.
- b. Drugs used in congestive heart failure
- c. Anti-hypertensive drugs.
- d. Anti-anginal drugs.

2. Pharmacology of drugs acting on the urinary system

- a. Diuretics
- b. Anti-diuretics.

UNIT- II

1. Pharmacology of drugs acting on cardiovascular system

- a. Anti-arrhythmic drugs.
- b. Anti-hyperlipidaemic drugs.
- b. Hematinics, coagulants and anticoagulants.
- c. Fibrinolytics and anti-platelet drugs
- d. Plasma volume expanders
- e. Drug used in the therapy of shock.

UNIT – III

10 Hours

1. Autocoids and related drugs

- a. Introduction to autocoids and classification
- b. Histamine, 5-HT and their antagonists.
- 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

8 Hours

1. 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.

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- d. Androgens and Anabolic steroids.
- e. Estrogens, progesterone and oral contraceptives.
- f. Drugs acting on the uterus.
- g. ACTH and corticosteroids.

UNIT – V

7 Hours

1. Pharmacology of drugs acting on endocrine system

- A. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
- B. Insulin, Oral Hypoglycaemic agents and glucagon.

2. 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

list of Practical:

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 the 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 PA₂ value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD₂ value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

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

Course Outcome:

After completion of this course, the students will be able to:

CO ₀₁	Understand the pharmacology of the drug acting on CVS and the urinary system
CO ₀₂	Summarize the mechanism of action of autocooids and pharmacology of NSAID and antigout drugs.
CO ₀₃	Understand the concept and pharmacology of the drug acting on the endocrine system
CO ₀₄	Relate the principle and application of bioassay.
CO ₀₅	Illustrate computer simulation experiments by using suitable software for the effect of various drugs on CVS and isolated tissue (DRCs).



Syllabus

Suggested Readings:

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. Vallabh Prakashan.

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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO21	Pharmacognosy and Phytochemistry-II	3	1	4	8	6

Course Objectives: After studying this paper the students will –

1. Know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
2. Understand the preparation and development of herbal formulation.
3. Understand the herbal drug interactions.
4. Carry out isolation and identification of phytoconstituents

Curriculum:

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.

UNIT - II

General introduction, composition, chemistry & chemical classes, bio sources, therapeutic uses and commercial applications of the following secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,

Tannins: Catechu, Pterocarpus

Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

Glycosides: Senna, Aloes, Bitter Almond

Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT - III

Basics of Phytochemistry: Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification, and identification of crude drugs.

UNIT- IV

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

UNIT -V

Industrial production, estimation and utilization of the following phytoconstituents:

Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

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list of Practical:

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna
2. Morphology, histology and powder characteristics & extraction & detection of: Clove and Ephedra
3. Morphology, histology and powder characteristics & extraction & detection of: Fennel and Coriander
4. Isolation & detection of active principles of:
 - a. Caffeine - from tea dust.
 - b. Diosgenin from Dioscorea
5. Isolation & detection of active principles of:
 - a. Atropine from Belladonna
 - b. Sennosides from Senna
6. Separation of sugars by Paper chromatography
7. TLC of herbal extract from marketed preparations
8. TLC of herbal extract from prepared herbal formulation
9. Distillation of volatile oils and detection of phytoconstituents by TLC
10. Analysis of crude drugs by chemical tests:
 - (i) Benzoin
 - (ii) Aloes
11. Analysis of crude drugs by chemical tests:
 - (i) Colophony
 - (ii) Myrrh

Course Outcome:

After completion of this course, the students will be able to:

CO01	Explain the metabolic pathways of plants for the formation of metabolites.
CO02	Define chemical composition, therapeutic uses, and various classes of secondary metabolites in a commercial application.
CO03	Understand the methods for extraction and application of the latest techniques.
CO04	Summarize the isolations, identification, and analysis of phytoconstituents
CO05	Apply the knowledge of different techniques for industrial production and estimation of phytoconstituents.
	Analyse the latest techniques for the isolation and purification of phytoconstituents

Suggested Reading:

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, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, 1st edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.



मेडी-केप्स विश्वविद्यालय, इंदौर

Medi-Caps University, Indore

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7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO22	Pharmaceutical Jurisprudence	3	1	0	4	4

Course Objectives: After studying this paper the students will –

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

Curriculum:

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 the 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.

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 Labelling & Packing of drugs- General labelling requirements and specimen labels for drugs and cosmetics, List of permitted colours. Offences and penalties. 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

UNIT - III

- 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
- 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.
- Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic &

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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

UNIT- IV

- 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
- 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.
- 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)

UNIT -V

- Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- Code of Pharmaceutical ethics definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- Medical Termination of Pregnancy Act
- Right to Information Act
- Introduction to Intellectual Property Rights (IPR)

Course Outcome:

After completion of this course, the students will be able to:

CO01	Define the rules, regulations, and schedules of the Drugs and Cosmetics Act, of 1940 related to the manufacturing and marketing of Pharmaceuticals
CO02	Explain the different requirements for packaging and labelling of drugs and the administrative committee of the Drugs and Cosmetics Act.
CO03	Describe different acts like the Pharmacy Act, Medicinal and Toilet Preparation Act, and Narcotics Drugs and Psychotropic Substances Act for the benefit of the community.
CO04	Understand the different regulations related to CPCSEA, National Pharmaceutical Pricing Authority, and Drugs and Magic Remedies.
CO05	Summarize the Pharmaceutical legislation, code of Pharmaceutical Ethics, and IPR.

Suggested Reading:

1. Forensic Pharmacy by B. Suresh
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books.

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B. Pharm Syllabus

VI SEM

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO23	Medicinal Chemistry-III	3	1	4	8	6

Course Objectives: After studying this paper the students will –

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

Curriculum:

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

10 Hours

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

UNIT – II

10 Hours

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

- **Macrolide:** Erythromycin Clarithromycin, Azithromycin.
- **Miscellaneous:** Chloramphenicol*, Clindamycin.
- **Antimalarials:** Etiology of malaria.
Quinolines: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine.
Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.
Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovoquone.

UNIT- III

10 Hours

• **Anti-tubercular Agents**

Synthetic anti-tubercular agents: Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid. *

Anti-tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulfate.

- **Urinary tract anti-infective agents**

Syllabus

Quinolones: SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

- **Antiviral agents:**

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT – IV

8 Hours

- **Antifungal agents:**

Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole, Tioconazole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.

- **Anti-protozoal Agents:** Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

- **Anthelmintics:** Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

- **Sulphonamides and Sulfones**

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V

7 Hours

- **Introduction to Drug Design**

Various approaches used in drug design.

- Physicochemical parameters used in quantitative structure-activity relationships (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis.
- **Prodrugs:** Basic concepts and application of prodrugs design.
- Pharmacophore modeling and docking techniques.
- Combinatorial Chemistry: Concept and applications chemistry: solid phase and solution phase synthesis of combinatorial

List of Practical's

I Preparation of drugs and intermediates

- 1 Sulphanilamide
- 2 7-Hydroxy, 4-methyl coumarin
- 3 Chlorobutanol
- 4 Triphenyl imidazole
- 5 Tolbutamide
- 6 Hexamine

II Assay of drugs

- 1 Isonicotinic acid hydrazide
- 2 Chloroquine
- 3 Metronidazole

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4 Dapsone

5 Chlorpheniramine maleate

6 Benzyl penicillin

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

IV Drawing structures and reactions using chem draw®

V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for the class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Course Outcome:

After completion of this course, the students will be able to:

CO01	Compare classification, Mechanism of action, Structure-activity relationships, and uses of antibacterial agents.
CO02	Understand classification, Mechanism of action, Structure-activity relationships, and uses of antimalarial agents.
CO03	Understand classification, Mechanism of action, Structure-activity relationships, and uses of antitubercular, UTI, and antiviral agents.
CO04	Summarize classification, Mechanism of action, Structure-activity relationships, and uses of sulphonamides, antiprotozoal, antifungal and anthelmintics.
CO05	Relate various drug designing approaches like Prodrug, Combinatorial Chemistry, QSAR, docking and pharmacophore modeling.
CO06	Apply reaction mechanisms and modern drug-designing approaches for the synthesis of medicinal agents.

Suggested Readings:

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.
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.

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO24	Pharmacology- III	3	1	4	8	6

Course Objectives: After studying this paper the students will –

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

Curriculum:

UNIT-I **10 Hours**

1. Chemotherapy
 - a. General principles of chemotherapy.
 - b. Sulfonamides and cotrimoxazole.
 - c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolones, tetracycline and aminoglycosides

UNIT-II **10 Hours**

1. Chemotherapy
 - a. Antitubercular agents
 - b. Antileprotic agents
 - c. Antifungal agents
 - d. Antiviral drugs
 - e. Anthelmintics
 - f. Antimalarial drugs
 - g. Antiamoebic agents

UNIT-III **8 Hours**

1. Chemotherapy
 - a. Urinary tract infections and sexually transmitted diseases.
 - b. Chemotherapy of malignancy.
2. Immunopharmacology
 - a. Immunostimulants
 - b. Immunosuppressant Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-IV **10 Hours**

1. 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
2. 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.

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e. Emetics and anti-emetics.

UNIT-V

7 Hours

1. Principles of toxicology

- a. Definition and basic knowledge of acute, subacute and chronic toxicity.
- b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
- c. General principles of treatment of poisoning
- d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning.

2. Chronopharmacology

- a. Definition of rhythm and cycles.
- b. Biological clock and their significance leading to chronotherapy.

List of Practical:

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 the effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyzer
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycaemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation/corrosion of a test substance
12. Determination of acute eye irritation/corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology (student's t-test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi-square test, Wilcoxon Signed Rank test)

***Experiments are demonstrated by simulated experiments/videos**

Course Outcome:

After completion of this course, the students will be able to:

CO01	Understand the concept and pharmacology of the chemotherapy for antibiotics and sulphonamides.
CO02	Summarize the mechanism and pharmacology of chemotherapy for various antimicrobial and antimalarial agents.
CO03	Interpret Immunopharmacology with chemotherapy for UTI, STD, and malignancy.
CO04	Understand the pharmacology of drugs acting on respiratory and GIT systems.
CO05	Relate the chronopharmacology and toxicology of drugs with the biological system.
CO06	Analyse computer simulation experiments and bioassay methods for the organ systems.



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Suggested Readings:

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.

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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO25	Herbal Drug Technology	3	1	4	8	6

Course Objectives: After studying this paper the students will know –

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

Curriculum:

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 the 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.

UNIT- II

Nutraceuticals

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 Gastrointestinal diseases. Study of the following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

Herbal-Drug and Herb-Food Interactions

General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

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UNIT - III

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.

Herbal excipients

Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrates, flavours & perfumes.

Herbal formulations

Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

UNIT - IV

Evaluation of Drugs

WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.

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.

Regulatory Issues

Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT - V

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.

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.

list of Practical:

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



Syllabus

Course Outcome:

After completion of this course the students will be able to:

CO01	Define the herbs and their processing through GAP cultivations, pest control and authentication with the Indian Medicine System.
CO02	Understand the different aspects, and role of nutraceuticals for health benefits, including the herbal-drug and herbs-food interactions.
CO03	Summarize the sources and description of herbal cosmetics, excipients and formulations.
CO04	Understand the guidelines, regulatory requirements and patenting procedures for assessment of herbal drugs.
CO05	Apply the knowledge of the herbal drug industry and GMP in manufacturing.
CO06	Evaluate phytoconstituents of crude drugs.

Suggested Readings:

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.

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Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO26	Biopharmaceutics and Pharmacokinetics	3	1	0	4	4

Course Objectives: After studying this paper the students will –

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

Curriculum:

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

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, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence 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 - KE , $t_{1/2}$, V_d , AUC , K_a , Cl_t and CLR - definitions methods of eliminations, understanding of their significance and application

Syllabus

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 settings.

UNIT -V

Nonlinear Pharmacokinetics:

- a. Introduction,
- b. Factors causing non-linearity.
- c. Michaelis-menton method of estimating parameters, Explanation with an example of drugs.

Course Outcome:

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

CO01	Understand basic concepts, mechanisms, and factors affecting the pharmacokinetics of drugs in the human body.
CO02	Compare the concept of bioavailability and bioequivalence and <i>in-vitro in-vivo</i> correlations.
CO03	Relate the significance and applications of different pharmacokinetic models in drug therapy.
CO04	Correlate single/multiple dosing and non-linear kinetics in the efficacy of drugs.

Suggested Reading:

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. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Gibaldi Donald, R. Marcel 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 Thomas, N. Tozen, Lea and Febiger, 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

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO27	Pharmaceutical Biotechnology	3	1	0	4	4

Course Objectives: After studying this paper the students will –

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

Curriculum:

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.

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:
 - 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

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.

Syllabus

e) Mutation: Types of mutation/mutants.

UNIT -V

- Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
- Large scale production fermenter design and its various controls.
- Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,
- Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.

Course Outcome:

After completion of this course, the students will be able to:

CO01	Summarize the basic concepts of biotechnology, biosensors, protein and genetic engineering.
CO02	Relate the application of enzyme immobilization in the pharmaceutical industry.
CO03	Understand Recombinant DNA technology, PCR and its applications.
CO04	Apply knowledge of immunology, hypersensitivity reactions and hybridoma techniques for the development of vaccines.
CO05	Relate the principles of immunoblotting techniques and microbial genetics with microbial transformation and mutations of eukaryotic and prokaryotic cells.
CO06	Categorize Fermentation technology for the production of antibiotics and vitamins.

Suggested Reading:

- B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
- RA Goldshy et. al., : Kuby Immunology.
- J.W. Goding: Monoclonal Antibodies.
- J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
- Zaborsky: Immobilized Enzymes, CRC Press, Degrand, Ohio.
- S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
- Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO28	Pharmaceutical Quality Assurance	3	1	0	4	4

Course Objectives: After studying this paper the students will –

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

Curriculum:

UNIT – I

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

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

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.

Equipment and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT - III

Quality Control: Quality control test for containers, rubber closures and secondary packing materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

UNIT- IV

Complaints: Complaints and evaluation of complaints, handling of return good, recalling and waste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

Syllabus

UNIT -V

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.

Warehousing: Good warehousing practice, materials management

Course Outcome:

After completion of this course, the students will be able to:

CO01	Interpret various quality assurance and quality management concepts with current regulatory guidelines (ICH, ISO, NABL and TQM).
CO02	Understand various aspects of the organization and persons involved in the manufacturing unit along with the process of selection for equipment and raw materials.
CO03	Relate Good Laboratory Practices and quality control parameters for primary and secondary packaging material.
CO04	Correlate document maintenance and handling of complaints in the pharmaceutical industry.
CO05	Categorize the knowledge of calibration, validation, and warehousing for the maintenance of different equipment and instruments.

Suggested Reading:

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



Syllabus

B. Pharm Syllabus

VII SEM

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO29	Instrumental Methods of Analysis	3	1	4	8	6

Course Objectives: After studying this paper the students will –

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

Curriculum:

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

UNIT - II

IR spectroscopy

Introduction, fundamental modes of vibrations in polyatomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications



Syllabus

UNIT- III

Introduction to Chromatography

Adsorption and partition column chromatography-Methodology, advantages, disadvantages and applications.

Thin layer Chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

Paper Chromatography-Introduction, methodology, development techniques, advantages, disadvantages and applications

Electrophoresis- Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

UNIT - IV

Gas Chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

High-performance liquid chromatography (HPLC)-Introduction, theory, instrumentation, advantages and applications.

UNIT - V

Ion exchange Chromatography- Introduction, classification, ion exchange resins, properties, mechanism of the ion exchange process, factors affecting ion exchange, methodology and applications

Gel Chromatography- Introduction, theory, instrumentation and Applications

Affinity Chromatography- Introduction, theory, instrumentation and Applications

List of Practical:

- 1 Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
- 2 Estimation of dextrose by colorimetry
- 3 Estimation of sulphanilamide by colorimetry
- 4 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
- 5 Assay of paracetamol by UV- Spectrophotometry
- 6 Estimation of quinine sulphate 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 Nepheloturbidometry
- 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



Syllabus

Course Outcome:

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

CO01	Interpret the concept of EMR, principles, and applications of UV Spectroscopy and Fluorimetry.
CO02	Understand the principles, instrumentation, and applications of different spectroscopic techniques.
CO03	Summarize the principles, instrumentation, and applications of chromatographic techniques and electrophoresis.
CO04	Apply various spectroscopic techniques for the identification and characterization of elements and drugs.
CO05	Apply various chromatographic techniques for the identification and characterization of drugs.

Suggested Readings:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Textbook of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Textbook 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



Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO30	Industrial Pharmacy-II	3	1	0	4	4

Course Objectives: After studying this paper the students will –

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

Curriculum:

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

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 - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

UNIT-III

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

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



Syllabus

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.

Course Outcome:

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

CO01	Understand the significance of pilot plant scale-up techniques for different formulations with emphasis on SUPAC guidelines.
CO02	Compare various technological developments and guidelines as per WHO and various technology transfer protocols.
CO03	Relate the roles and responsibilities of regulatory authorities along with different regulatory requirements for drug approval.
CO04	Use various Quality management systems and concepts of QbD, OOS and ISO
CO05	Correlate the requirements of the Central Drug Standard Control Organization (CDSCO) and State Licensing Authority for approval of new drugs.

Suggested Readings:

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

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO31	Pharmacy Practice	3	1	0	4	4

Course Objectives: After studying this paper the students will know –

1. Know various drug distribution methods in a hospital
2. Monitor the drug therapy of the patient through medication chart review and clinical review
3. Identify drug-related problems and detect and assess adverse drug reactions
4. Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
5. Know pharmaceutical care services and do patient counselling in a community pharmacy

Curriculum:

UNIT - I

a) Hospital and its organization

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on the clinical and non-clinical basis, Organization Structure of a Hospital, and Medical staff 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 Responsibilities and functions of hospital pharmacists.

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, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

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.

UNIT- II

a) Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labeling, dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs

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.



Syllabus

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.

d) Medication adherence

Causes of medication non-adherence, pharmacist's role in medication adherence, and monitoring of patient medication adherence.

e) Patient medication history interview

Need for the patient medication history interview, and medication interview forms.

f) Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

UNIT - III

a) Pharmacy and therapeutic committee

Organization, functions, and Policies of the pharmacy and therapeutics committee in including drugs in formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

b) Drug information services

Drug and Poison information center, Sources of drug information, Computerised services, and storage and retrieval of information.

c) Patient counselling

Definition of patient counselling; steps involved in patient counseling, and Special cases that require the pharmacist

d) Education and training program in the hospital

Role of the 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.

e) Prescribed medication order and communication skills

Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.

UNIT - IV

a) Budget preparation and implementation

Budget preparation and implementation

b) Clinical Pharmacy

Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of a clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease patterns.

c) Over-the-counter (OTC) sales

Introduction and sale of over-the-counter, and Rational use of common over-the-counter medications.

Syllabus

UNIT - V

a) Drug store management and inventory control

Organization 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

b) Investigational use of drugs

Description, principles involved, classification, control, identification, the role of a hospital pharmacist, and advisory committee.

c) Interpretation of Clinical Laboratory Tests

Blood chemistry, haematology, and urinalysis

Course Outcome:

After completion of this course, the students will be able to:

CO1	Define hospital, hospital and community pharmacy, and classification of adverse drug reaction.
CO2	Understand the knowledge of the drug distribution process, therapeutic drug monitoring, medication and hospital formulary.
CO3	Summarize the organization and function of PTC, drug information services and the importance of medication order in patient counseling.
CO4	Interpret the concept of clinical pharmacy, OTC sales, and budget preparations.
CO5	Relate clinical laboratory tests of specific disease states to provide better patient-centered service.
CO6	Apply the principles of drug store management and inventory control methods during practice.

Suggested Readings:

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, 1st ed. Chennai: Orient Longman 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.

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO32	Novel Drug Delivery Systems	3	1	0	4	4

Course Objectives: After studying this paper the students will –

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

Curriculum:

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.

UNIT - II

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications

Mucosal Drug Delivery system: Introduction, Principles of bio adhesion / muco-adhesion, 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

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, 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

Syllabus

UNIT- IV

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

UNIT -V

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome – Preliminary study, ocular formulations and ocuserts

Intrauterine Drug Delivery Systems: Introduction, advantages and Disadvantages, development of intrauterine devices (IUDs) and Applications

Course Outcome:

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

CO01	Compare different types of controlled drug delivery systems and polymers used for formulations.
CO02	Understand principles and applications of microencapsulation, mucosal and implantable drug delivery systems.
CO03	Relate the formulation and evaluation of transdermal, gastroprotective and Nasopulmonary drug delivery systems.
CO04	Apply the concept and approaches of targeted drug delivery.
CO05	Correlate principles of ocular and intrauterine drug delivery systems for the development of various devices

Suggested Reading:

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 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.

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).

Syllabus

B. Pharm Syllabus

VIII SEM

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO34	Biostatistics and Research Methodology	3	1	0	4	4

Course Objectives: After studying this paper the students will –

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

Curriculum:

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

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

UNIT- III

Non-Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test

Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph

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.



Syllabus

UNIT - IV

Blocking and confounding system for Two-level factorials

Regression modelling: Hypothesis testing in Simple and Multiple regression models

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

UNIT - V

Design and Analysis of experiments:

Factorial Design: Definition, 2^2 , 2^3 design. Advantage of factorial design Response

Surface methodology: Central composite design, Historical design, Optimization Techniques

Course Outcome:

After completion of this course, the students will be able to:

CO01	Understand various statistical methods to solve statistical problems.
CO02	Apply probability correlation and regression methods for data analysis.
CO03	Correlate non-parametric tests for demonstration of data and designing the methodology of research.
CO04	Illustrate the regression modeling and various statistical software like SPSS, R and MINITAB®, DoE (Design of Experiment).
CO05	Plan research by factorial design and surface methodology

Suggested Readings:

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3CO35	Social and Preventive Pharmacy	3	1	0	4	4

Course Objectives: After studying this paper the students will –

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

Curriculum:

UNIT-I

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.

Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health

Hygiene and health: personal hygiene and health care; avoidable habits

UNIT-II

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

UNIT-III

National health programs, its objectives, functioning and outcome of the following:

HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

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



Syllabus

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.

Course Outcome:

After completion of this course, the students will be able to:

CO01	Understand the basic concepts of health, personal hygiene, and the role of nutrition in diet to prevent diseases.
CO02	Interpret general principles of prevention and control of various diseases
CO03	Relate national health programs run by the government to prevent diseases.
CO04	Illustrate national health intervention programs and the role of WHO for social health.
CO05	Analyse the rural and urban community-related effects on health conditions as a pharmacist.

Suggested Readings:

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



Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3EL01	Pharmaceutical Marketing Management	3	1	0	4	4

Course Objectives: After studying this paper the students will know –

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

Curriculum:

UNIT - I

Marketing: Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analysing consumer buying behaviour; industrial buying behaviour.

Pharmaceutical market: Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation & targeting. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market; Role of market research.

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 labelling decisions, Product management in pharmaceutical industry.

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, online promotional techniques for OTC Products.

UNIT - IV

Pharmaceutical marketing channels: Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

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.



Syllabus

UNIT - V

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).

Emerging concepts in marketing: Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

Course Outcome:

- a. The students will know various concept of marketing and selling, analysing various consumers behaviours. They will aware about quantitative as well as other aspect of pharmaceutical marketing including the role of research
- b. The students will know various concept of product decision, branding, packaging and product management in pharmaceutical Industry.
- c. The students will know various concept of product promotion, selling, selling and other methods of promotions.
- d. The students will know various concept of various pharmaceutical marking channels, their advantages and their importance. Also, duties, purpose, selection and norms for PSR
- e. The students will know various concept, meaning, objective of pricing and various methods of pricing. Also, will have over view of emerging concept of marketing's.

Suggested Readings:

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 GrawHill, 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 Managemnt:Global Perspective, IndianContext,Macmilan 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.



Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3EL02	Pharmaceutical Regulatory Science	3	1	0	4	4

Course Objectives: After studying this paper the students will –

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

Curriculum:

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.

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)

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.

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

Syllabus

UNIT -V

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Course Outcome:

After completion of this course, the students will be able to:

CO01	Understand the concept of innovator, generics, and process of drug development.
CO02	Relate the timelines involved in IND, NDA and ANDA submission.
CO03	Categorize different regulatory authorities and registration of Indian drug products in overseas markets.
CO04	Illustrate the knowledge of regulatory guidelines in developing clinical trial protocols.
CO05	Analyze the different regulations and regulatory guidelines like orange book, purple book and federal registers.

Suggested Reading:

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

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3EL03	Pharmacovigilance	3	1	0	4	4

Course Objectives: After studying this paper the students will –

1. History and development of pharmacovigilance
2. National and international scenario of pharmacovigilance
3. Dictionaries, coding and terminologies used in pharmacovigilance
4. Detection of new adverse drug reactions and their assessment
5. International standards for classification of diseases and drugs
6. Adverse drug reaction reporting systems and communication in pharmacovigilance

Curriculum:

UNIT – I

Introduction to Pharmacovigilance

- 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

- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

UNIT - II

Drug and disease classification

- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- International Non-proprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- WHO drugs dictionary
- Eudravigilance medicinal product dictionary

Syllabus

Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishing a national programme

UNIT - III

Vaccine safety surveillance

- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

Pharmacovigilance methods

- 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

Communication in pharmacovigilance

- Effective communication in Pharmacovigilance
- Communication in Drug Safety Crisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

UNIT- IV

Safety data generation

- Pre-clinical phase
- Clinical phase
- Post approval phase (PMS)

ICH Guidelines for Pharmacovigilance

- Organization and objectives of ICH
- Expedited reporting
- Individual case safety reports
- Periodic safety update reports
- Post approval expedited reporting
- Pharmacovigilance planning
- Good clinical practice in pharmacovigilance studies

UNIT -V

Syllabus

Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements.

Course Outcomes (COs):

After completion of this course the students will be able to

CO01	Understand the basics of adverse drug reactions and pharmacovigilance including its history, importance and definitions.
CO02	Summarize the knowledge of coding, drug information resources, drug and disease classification, drug dictionaries, and establishment of a pharmacovigilance program.
CO03	Apply various pharmacovigilance methods, vaccine safety surveillance and communicate with stakeholders in pharmacovigilance.
CO04	Use ICH guidelines for pharmacovigilance and safety data generation.
CO05	Analyse drug safety evaluation in special populations, Pharmacogenomics of adverse drug reactions and safety guidelines in CIOMS and CDSCO.

Suggested Reading:

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



Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3EL04	Quality Control and Standardization of Herbals	3	1	0	4	4

Course Objectives: After studying this paper the students will –

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

Curriculum:

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

UNIT - II

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines
WHO Guidelines on GACP for Medicinal Plants.

UNIT - III

EU and ICH guidelines for quality control of herbal drugs. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

UNIT- IV

Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products. Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.

UNIT -V

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems
Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products.

Course Outcome:

- A. Students will know various WHO guidelines, evaluation methods and basic test used for medicinal plant materials

Syllabus

- B. Students will know various quality assurance systems used in herbal drug industry, like CGMP, GLP ETC..
- C. Students will know about various ICH and EU guidelines for quality controls of herbal drugs
- D. Student will know about stability testing, documentation procedures for new drug application
- E. Students will know various regulatory requirements, safety requirements as per WHO guidelines along with standardization of Herbal products

Suggested Reading:

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I, Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3EL05	Computer-Aided Drug Design	3	1	0	4	4

Course Objectives: After studying this paper the students will –

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

Curriculum:

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

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.

UNIT - III

Molecular Modelling 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. De novo drug design.



Syllabus

UNIT- IV

Informatics & Methods in drug design

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT -V

Molecular Modelling:

Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Course Outcome:

- Students will know aspects and stages of drug discovery, lead discovery based on traditional medicine
- Students will know about the history, types of parameters and various parameters for SAR and QSAR
- Students will know about the various molecular modelling and virtual screening techniques & molecular docking
- Students will know about bio-informatics, chemo informatics and ADME databases.
- Students will know about molecular modelling, molecular mechanics and quantum mechanics.

Suggested Reading:

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



Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3EL07	Cosmetic Science	3	1	0	4	4

Course Objectives: After studying this paper the students will –

1. Cosmetic dosage form classification, formulation and evaluation as per Indian and EU regulation.
2. Excipient used in skin care products and their formulations.
3. Formulation, Excipient used, analytical method of testing of Sun Protecting cream, Shampoo, and toothpaste.
4. Principles of Cosmetic Product Evaluation and instrumentation.
5. Skin diseases and importance of cosmetics to treat skin problems.

Curriculum:

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.

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.

Chemistry and formulation of Para-phenylene diamine-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.

UNIT- IV

Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Colour, Hair tensile strength, Hair combing properties Soaps, and syndet bars. Evolution and skin benefits.



Syllabus

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 odour. Antiperspirants and Deodorants- Actives and mechanism of action

Course Outcome:

After completion of this course, the students will be able to:

CO01	Classify different cosmetic excipients and cosmeceutical products.
CO02	Compare the formulation of skin care products, antiperspirants, and hair dye.
CO03	Relate the sunscreen and different herbs used in hair and oral care.
CO04	Apply the principles of cosmetic evaluation for skin and hair preparations.
CO05	Analyse the cosmetic problems associated with hair and skin.

Suggested Reading:

- 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 cosmecology by Sanju Nanda & Roop K. Khar, Tata Publishers.

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3EL08	Experimental Pharmacology	3	1	0	4	4

Course Objectives: After studying this paper the students will –

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

Curriculum:

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.

UNIT - II

Regulatory Approval Process

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, anti-asthmatics, Preclinical screening models: for CNS activity- analgesic, anti-pyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, anti-parkinsonism, Alzheimer's disease

UNIT - III

Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics

UNIT- IV

Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti-aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.



Syllabus

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

Course Outcome:

- a. students will know CPCSEA guideline regarding the animal handling and maintenance of laboratories animals.
- b. Students will know about proper dose selection, calculation and conversion of drugs and proper selection of animal model for diuretics, anti- asthmatic, etc.
- c. Students will know about Preclinical screening models for ANS activity, sympatholytic, parasympathomimetic, etc.
- d. Students will know about preclinical screening models for CVS, anti-diabetic and anti-ulcer etc. activity
- e. Students will know about research methodology and biostatistics and its application in research/

Suggested Reading:

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

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3EL09	Advanced Instrumentation Techniques	3	1	0	4	4

Course Objectives: After studying this paper the students will –

1. understand the advanced instruments used and its applications in drug analysis
2. understand the chromatographic separation and analysis of drugs.
3. understand the calibration of various analytical instruments
4. know analysis of drugs using various analytical instruments.

Curriculum:

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, Analysers-Time of flight and Quadrupole, instrumentation, applications.

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.

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

UNIT- IV

Radio immune 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

UNIT -V

Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS.



Syllabus

Course Outcome:

After completion of this course, the students will be able to:

CO ₀₁	Understand the principle, application and instrumentation of NMR, MASS spectroscopy, thermal methods of analysis like TGA, DTA and DSC, etc.
CO ₀₂	Summarize the validation, and calibration of analytical instruments as per ICH and USFDA guidelines.
CO ₀₃	Relate the principle of Radioimmunoassay and liquid-liquid extraction for analysis of pharmaceuticals.
CO ₀₄	Correlate analytical techniques of LC-MS, GC-MS AND HPTLC with the pharmaceutical industry.

Suggested Reading:

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

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3EL10	Dietary Supplements and Nutraceuticals	3	1	0	4	4

Course Objectives: After studying this paper the students will –

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

Curriculum:

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, Ginkgo, Flaxseeds

UNIT - II

Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following

- 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, Lacto bacillum
- f) Phyto estrogens : Isoflavones, daidzein, Geobustin, lignans
- g) Tocopherols
- h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

UNIT - III

- a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
- b) Dietary fibres and complex carbohydrates as functional food ingredients.

Syllabus

UNIT- IV

- a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
- b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α - Lipoic acid, melatonin Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.
- c) Functional foods for chronic disease prevention

UNIT -V

- a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.
- b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
- c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

Course Outcome:

- a. Students will about definition, classification of nutraceuticals and dietary supplements and its effect on public health.
- b. Students will know about occurrence and chemical nature of Phytochemicals as nutraceuticals
- c. Students will know the free radicals and its damaging effect on lipid, protein etc.
- d. Students will the damaging role of free radicals in diabetes, cancer, kidney functioning, and in ageing. Also the uses various anti-oxidants in controlling the damages
- e. Students will know the various factors affecting the quality of nutraceuticals and various regulatory aspect of FSSAI. FDA ETC.

Suggested Reading:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPublication.
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 2nd Edn., 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 (Modern Nutrition)

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3EL11	Good Manufacturing Practices	3	1	0	4	4

Course Objectives: After studying this paper the students will –

1. Concept of Good Manufacturing Practices, Good Clinical Practices, Good Laboratory Practices and SOP.
2. Documentation in Pharma Industry.
3. Code of federal Regulation and USFDA Product approval Process.
4. Product recall and its process
5. Sampling, Sampling plan, Documentation of sampling, and WHO guideline.

Curriculum:

UNIT – I

Introduction to good manufacturing practices (GMP), good clinical practices (GCP) and good laboratory practices (GLP). Schedule M. Standard operating procedure (SOP): Introduction, preparation, validation and revision.

UNIT - II

Documentation: Protocols, forms and maintenance of records in pharmaceutical industry, preparation of document for investigational new drug (IND), new drug application (NDA), abbreviated new drug application (ANDA) and export registration.

UNIT - III

Introduction to 21-Code of federal regulations. Current good manufacturing practices (c-GMP) guidelines according to United States Food and Drug Administration (USFDA), difference between GMP and c-GMP.

UNIT- IV

Pharmaceutical product recall: Recall classification, strategy for effective recall, FDA requested recall, firm-initiated recall, recall status reports, termination of recall. Introduction to finished product reprocessing and salvaging.

UNIT -V

Sampling: Introduction, WHO guidelines, sampling plans and techniques, operating characteristics curves, maintenance of sampling records of finished product and packaging material.

Syllabus

Course Outcomes (COs):

After completion of this course the students will be able to;

CO01	Compare the basic principles, concepts and requirements of GMP, GLP, GCP and SOP & their importance and implementation in Pharma.
CO02	Relate the Role of Documentation and flow of different documents in inter and intra-department.
CO03	Connect with the guidelines of CFR and other regulations of the USFDA for Pharmaceutical product approval.
CO04	Illustrate the concept, flow and applications of Pharmaceutical Product Recall and documentation in the pharmaceutical industry.
CO05	Analyse the sampling plan, sampling records and study of WHO guidelines for sampling in the Pharmaceutical Industry.

GOOD MANUFACTURING PRACTICES PROJECT (Any Two)

1. Study the steps to generate SOP.
2. Generation and validation of SOP for Autoclave.
3. Generation and validation of SOP for Dissolution apparatus.
4. Generation and validation of SOP for Centrifuge.
5. Generation and validation of SOP for Balance (electronic and dispensing).
6. Generation and validation of SOP for Cleaning.
7. Generation and validation of SOP for Hot air oven.
8. Generation and validation of SOP for Disintegration apparatus.
9. Generation and validation of SOP for Friability apparatus.
10. Generation and validation of SOP for Incubator.
11. Generation of Master formula record.
12. Generation of Batch formula record.

Suggested Reading:

1. Willing, Tuckerman and Hitchings, Good Manufacturing Practices for Pharmaceuticals, Marcel Dekker, New York.
2. Garfield, Quality Assurance Principles for Analytical Laboratories, Published by Oxford University Press, USA.
3. Potdar M. A., Current Good Manufacturing Practices for Pharmaceuticals. PharmaMed Press, Hyderabad.
4. Loftus and Nash, Pharmaceutical Process Validation, Taylor & Francis, New York.
5. Florey, Analytical Profile of Drugs (All volumes), Academic Press, United States.
6. Indian Pharmacopoeia. 7. United States Pharmacopoeia. 8. British Pharmacopoeia.

Syllabus

Course Code	Courses	Hours Per week			Total	
		L	T	P	Hrs	Credit
PY3EL12	Clinical Pharmacy	3	1	0	4	4

Course Objectives: After studying this paper the students will –

1. Clinical Pharmacy concept and uses of drug in different medical condition.
2. Data Analysis and compiling, patient counselling, Medical Writing, and Pharmacovigilance.
3. Role of Clinical Pharmacist and Quality Assurance of Clinical Pharmacy.
4. Research Design, Clinical Trials, Bioavailability and Bioequivalence Study.
5. biostatistical analysis, Type I error and type II errors and bio-statistical software.

Curriculum:

UNIT – I

Introduction to clinical pharmacy: Definition, development and scope of clinical pharmacy. Variability in human response to drugs and influence of disease processes: Drug handling and prescribing in the elderly, infants and children. Drug usage in pregnancy and in breast-feeding women. Prescribing for patients with renal or hepatic disease. Pharmacogenetics: implications for altered or unusual drug handling. Pharmacoepidemiology.

UNIT - II

Data analysis and compiling: The patient's case history, communication skills including patient medication history interview, patient counseling. Pharmacoeconomics. Medical writing: Regulatory and educational medical writing. Literature review and meta-analysis: Process, methods and application, research, report and paper / thesis writing. Pharmacovigilance programme of India (PvPI) and Geneva (UPSALA).

UNIT - III

Daily activities of clinical pharmacists: Drug therapy monitoring (medication chart view, clinical review), therapeutic drug monitoring, ward round participation, drug utilization evaluation/ review (DUE)/ (DUR). Quality assurance of clinical pharmacy services

UNIT- IV

Research design and conduct of clinical trials: Research support including planning and execution of clinical trials. Schedule Y, GLP, GCP and ICH Guidelines, trial master file and ethical requirements. Various phases of clinical trials. Categories of Phase IV studies. Bioavailability (BA) and bioequivalence (BE) studies and the estimation with the help of plasmaconcentration profile curve. Statistical analysis plan (SAP) and its importance in clinical research.

UNIT -V

Data collection and biostatistical analysis: Statistical principles underlying clinical trials, data handling and role of biostatistician. Sample size calculation, types of variables, Type I error and type II errors, application of parametric and non-parametric tests, confidence intervals, outliers. Data analysis with the help of bio-statistical software.



Syllabus

Course Outcome:

- a. Student will understand the concept and importance of Clinical Pharmacy and Uses of drugs in different medical condition.
- b. Student will know data analysis, Medical Writing and concept of Pharmacovigilance.
- c. Student will know the duties of Clinical Pharmacist and Quality Assurance of Clinical Services.
- d. Student will know clinical trials, research design, Concept of Bioavailability and Bioequivalence.
- e. Student will know biostatistical analysis and tools, Sampling, Types of Error and tests.

Suggested Reading:

1. Scott L.T., Basic skills in interpreting laboratory data, American Society of Health System Pharmacists Inc., USA.
2. Rowland and Tozer, Clinical Pharmacokinetics, Williams and Wilkins Publication, Philadelphia, USA.
3. Shargel L., Biopharmaceutics and Applied Pharmacokinetics, Prentice Hall publication, New Delhi.
4. Parthasarathi G., Nyfort-Hansen K. and Nahata M.C., A Text book of Clinical Pharmacy Practice-Essential Concepts and Skills, Orient Longman, Chennai.
5. Colledge N.R., Walker B. R. and Stuart H., Ralston Davisson's Principles and Practice of Medicine, ELBS/Churchill Livingstone, Edinburgh, U.K.
6. Herfindal E.T. and Hirashman J.L., Clinical Pharmacy and Therapeutics Williams and Wilkins, Philadelphia, USA.
7. Wagner J.G., Pharmacokinetics for the Pharmaceutical Scientist, Technomic Publishing A G Basel, Switzerland.
8. Katzung B., Masters S. and Trevor A., Basic and Clinical Pharmacology, McGraw Hill Professional, U.K.
9. Spilker B. and Schoenfelder J., Data Collection Forms in Clinical Trials, Raven Press, New York.
10. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London.
11. Stockley I.H., Drug interactions, Pharmaceutical Press, London.
12. Ravishankar K., Kiranmayi G.V.N., Clinical Pharmacy and Pharmacotherapeutics, PharmaMed Press, Hyderabad.