

**SCHEME OF INSTRUCTION AND SYLLABUS  
Bachelor of Pharmacy**

**As per the PCI Regulation-2014**

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w.e.f. 2024-25



**Faculty of Pharmacy**

**United University**

Rawatpur-Jhalwa

(Prayagraj)Uttar Pradesh

## **University Vision**

“To establish a Value based Global University having dynamic learning environment encouraging creativity and innovation, research inspired experimental learning and focusing on topics that are pertinent to the development of the region, the Country and the World.”

## **University Mission**

- To provide a dynamic, inspiring, and varied learning environment with global exposure.
- To position the institution as a premier hub for research and experiential learning.
- To develop into an adaptable university meeting the demands of society and business.
- To incorporate Value thinking, integrity, wisdom and passion in professional for their career and life.

## **Department Vision**

“Striving to become the foremost hub for pharmaceutical education, training, and research, with a commitment to address the healthcare needs of the broader community”

## **Department Mission**

1. To provide top-notch education and foster ground breaking research across undergraduate and diploma levels at the forefront of pharmaceutical knowledge and the best possible learning experience.
2. To create an environment that fuels innovation and state-of-the-art facilities to support research and development activities, enabling our faculty and students to explore new frontiers in pharmaceutical science and technology.
3. To Bridge the gap between academia and industry for offering personalized academic guidance and career counseling to our students, helping them navigate their educational journey and prepare for successful careers in the pharmaceutical field.
4. To develop effective pedagogical and research potential among the faculty members for ensuring their inspiration and empowerment in the next generation of pharmaceutical professionals.
5. To nurture a pharmaceutical familiarity pool that symbolizes professional values and leadership qualities for the positive role towards the society.
6. To promote collaboration with academia, industries, and research organizations, both nationally and internationally in mutual manner and to address global challenges.

## **Program Educational Objectives (Undergraduate)**

1. PEO-1:  
To create pharmacy professional with respect to society & environment with excellence in acquiring knowledge in various field of pharmaceutical sciences.
2. PEO-2:  
To create professionals with skills of analyzing and applying the technical knowledge in pharmaceutical industry for research & development of quality medicines.

## 3. PEO-3:

To develop communication skills that enable students to understand, analyze the values and principles of pharmacy profession through proper ethical foundation.

## **Program Outcomes**

On successful completion of B. Pharm program the student will be able to:

PO1-Pharmacy Knowledge: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.

PO2-Planning Abilities: Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

PO3-Problem analysis: Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.

PO4-Modern tool usage: Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.

PO5-Leadership skills: Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being.

PO6-Professional Identity: Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).

PO7-Pharmaceutical Ethics: Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

PO8-Communication: Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.

PO9-The Pharmacist and society: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.

PO10-Environment and sustainability: Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

PO11-Life-long learning: Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

## **Program Specific Outcomes**

**PSO1:**

The graduates will gain fundamental knowledge for conventional and novel pharmaceutical dosage forms, their dispensing methods and new advancements adopted in the field of Pharmaceutical Sciences.

**PSO2:**

Pharmacy Graduates with entrepreneurial skills will uniquely positioned to innovate and succeed in the healthcare industry, leveraging their clinical expertise to develop and launch innovative pharmacy- related businesses, services and products that improve patient outcomes and advance healthcare delivery.

**FACULTY OF PHARMACY  
SCHEME OF INSTRUCTION FOR FOUR YEAR UG PROGRAMME**

# **SCHEME OF INSTRUCTION**

## **COURSE CATEGORY ABBREVIATIONS**

1. Program Core-PC
2. Soft Skills-SS
3. Skill Enhancement Course-SEC
4. Compulsory Course-MC
5. Program Elective-PE
6. Open Elective-OE
7. Internship/Project

**FACULTY OF PHARMACY**  
**SCHEME OF INSTRUCTION FOR FOUR YEAR UG PROGRAMME**

**Table-I: Course of study for Semester I**

S. No.	Course code	Course Category	Name of the course	No. of Hours (L/P)	Tutorial (T)	Credit Points (C)
1.	FPUCBP101T	MC	Human Anatomy and Physiology I– Theory	3	1	4
2.	FPUCBP102T	SS	Pharmaceutical Analysis I – Theory	3	1	4
3.	FPUCBP103T	PC	Pharmaceutics I – Theory	3	1	4
4.	FPUCBP104T	MC	Pharmaceutical Inorganic Chemistry – Theory	3	1	4
5.	FPUCBP105T	SEC	Communication skills – Theory *	2	-	2
6.	FPUCBP106T/ FPUCBP107T	MC	Remedial Biology/ Remedial Mathematics – Theory*	2	-	2
7.	FPUCBP101P	MC	Human Anatomy and Physiology – Practical	4	-	2
8.	FPUCBP102P	SEC	Pharmaceutical Analysis I – Practical	4	-	2
9.	FPUCBP103P	PC	Pharmaceutics I – Practical	4	-	2
10.	FPUCBP104P	MC	Pharmaceutical Inorganic Chemistry – Practical	4	-	2
11.	FPUCBP105P	SEC	Communication skills – Practical*	2	-	1
12.	FPUCBP106P	MC	Remedial Biology – Practical*	2	-	1
			<b>Total</b>	<b>32/34<sup>§</sup>/36<sup>#</sup></b>	<b>4</b>	<b>27/29<sup>§</sup>/30<sup>#</sup></b>

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

<sup>§</sup>Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM) course.

\* Non-University Examination (NUE)

**Table-II: Course of study for Semester II**

S. No.	Course Code	Course Category	Name of the course	No. of Hours (L/P)	Tutorial (T)	Credit Points (C)
1.	FPUCBP201T	MC	Human Anatomy and Physiology II – Theory	3	1	4
2.	FPUCBP202T	MC	Pharmaceutical Organic Chemistry I – Theory	3	1	4
3.	FPUCBP203T	MC	Biochemistry – Theory	3	1	4
4.	FPUCBP204T	MC	Pathophysiology – Theory	3	1	4
5.	FPUCBP205T	SS	Computer Applications in Pharmacy – Theory *	3	-	3
6.	FPUCBP206T	SEC	Environmental sciences – Theory *	3	-	3
7.	FPUCBP201P	MC	Human Anatomy and Physiology II – Practical	4	-	2
8.	FPUCBP202P	MC	Pharmaceutical Organic Chemistry I – Practical	4	-	2
9.	FPUCBP203P	MC	Biochemistry – Practical	4	-	2
10.	FPUCBP205P	SS	Computer Applications in Pharmacy – Practical*	2	-	1
			<b>Total</b>	<b>32</b>	<b>4</b>	<b>29</b>

\*Non University Examination (NUE)

**Table-III: Course of study for Semester III**

S. No.	Course Code	Course Category	Name of the course	No. of Hours (L/P)	Tutorial (T)	Credit Points (C)
1.	FPUCBP301T	MC	Pharmaceutical Organic Chemistry II – Theory	3	1	4
2.	FPUCBP302T	PC	Physical Pharmaceutics I – Theory	3	1	4
3.	FPUCBP303T	MC	Pharmaceutical Microbiology – Theory	3	1	4
4.	FPUCBP304T	PC	Pharmaceutical Engineering – Theory	3	1	4
5.	FPUCBP301P	MC	Pharmaceutical Organic Chemistry II – Practical	4	-	2
6.	FPUCBP302P	PC	Physical Pharmaceutics I – Practical	4	-	2
7.	FPUCBP303P	MC	Pharmaceutical Microbiology – Practical	4	-	2
8.	FPUCBP304P	PC	Pharmaceutical Engineering – Practical	4	-	2
			<b>Total</b>	<b>28</b>	<b>4</b>	<b>24</b>

**Table-IV: Course of study for Semester IV**

S. No.	Course Code	Course Category	Name of the course	No. of Hours (L/P)	Tutorial (T)	Credit Points (C)
1.	FPUCBP401T	MC	Pharmaceutical Organic Chemistry III– Theory	3	1	4
2.	FPUCBP402T	PC	Medicinal Chemistry I – Theory	3	1	4
3.	FPUCBP403T	PC	Physical Pharmaceutics II – Theory	3	1	4
4.	FPUCBP404T	PC	Pharmacology I – Theory	3	1	4
5.	FPUCBP405T	PC	Pharmacognosy and Phytochemistry I– Theory	3	1	4
6.	FPUCBP402P	PC	Medicinal Chemistry I – Practical	4	-	2
7.	FPUCBP403P	PC	Physical Pharmaceutics II – Practical	4	-	2
8.	FPUCBP404P	PC	Pharmacology I – Practical	4	-	2
9.	FPUCBP405P	PC	Pharmacognosy and Phytochemistry I – Practical	4	-	2
			<b>Total</b>	<b>31</b>	<b>5</b>	<b>28</b>

**Table-V: Course of study for Semester V**

S. No.	Course Code	Course Category	Name of the course	No. of Hours (L/P)	Tutorial (T)	Credit Points (C)
1.	FPUCBP501T	PC	Medicinal Chemistry II – Theory	3	1	4
2.	FPUCBP502T	PC	Industrial Pharmacy I– Theory	3	1	4
3.	FPUCBP503T	PC	Pharmacology II – Theory	3	1	4
4.	FPUCBP504T	PC	Pharmacognosy and Phytochemistry II– Theory	3	1	4
5.	FPUCBP505T	SEC	Pharmaceutical Jurisprudence – Theory	3	1	4
6.	FPUCBP502P	PC	Industrial Pharmacy I – Practical	4	-	2
7.	FPUCBP503P	PC	Pharmacology II – Practical	4	-	2
8.	FPUCBP504P	PC	Pharmacognosy and Phytochemistry II – Practical	4	-	2
			<b>Total</b>	<b>27</b>	<b>5</b>	<b>26</b>



**Table-VI: Course of study for Semester VI**

S. No.	Course Code	Course Category	Name of the course	No. of Hours (L/P)	Tutorial (T)	Credit Points (C)
1.	FPUCBP601T	PC	Medicinal Chemistry III – Theory	3	1	4
2.	FPUCBP602T	PC	Pharmacology III – Theory	3	1	4
3.	FPUCBP603T	PC	Herbal Drug Technology – Theory	3	1	4
4.	FPUCBP604T	PC	Biopharmaceutics and Pharmacokinetics – Theory	3	1	4
5.	FPUCBP605T	SEC	Pharmaceutical Biotechnology – Theory	3	1	4
6.	FPUCBP606T	SS	Quality Assurance –Theory	3	1	4
7.	FPUCBP601P	PC	Medicinal Chemistry III – Practical	4	-	2
8.	FPUCBP602P	PC	Pharmacology III – Practical	4	-	2
9.	FPUCBP603P	PC	Herbal Drug Technology – Practical	4	-	2
			<b>Total</b>	<b>30</b>	<b>6</b>	<b>30</b>

**Table-VII: Course of study for Semester VII**

S. No.	Course Code	Course Category	Name of the course	No. of Hours (L/P)	Tutorial (T)	Credit Points (C)
1.	FPUCBP701T	SS	Instrumental Methods of Analysis – Theory	3	1	4
2.	FPUCBP702T	PC	Industrial Pharmacy II – Theory	3	1	4
3.	FPUCBP703T	SEC	Pharmacy Practice – Theory	3	1	4
4.	FPUCBP704T	PC	Novel Drug Delivery System – Theory	3	1	4
5.	FPUCBP701P	SS	Instrumental Methods of Analysis – Practical	4	-	2
6.	FPUCBP703P	Project	Practice School*	12	-	6
			<b>Total</b>	<b>28</b>	<b>5</b>	<b>24</b>

\* Non University Examination (NUE)

**Table-VIII: Course of study for Semester VIII**

S. No.	Course Code	Course Category	Name of the course	No. of Hours (L/P)	Tutorial (T)	Credit Points (C)
1.	FPUCBP801T	SS	Biostatistics and Research Methodology	3	1	4
2.	FPUCBP802T	PC	Social and Preventive Pharmacy	3	1	4
3.	FPUCBP803ET	OE	Pharma Marketing Management*	3 + 3 =6	1 + 1 = 2	4 + 4 =8
4.	FPUCBP804ET	OE	Pharmaceutical Regulatory Science*			
5.	FPUCBP805ET	OE	Pharmacovigilance*			
6.	FPUCBP806ET	OE	Quality Control and Standardization of Herbals*			
7.	FPUCBP807ET	OE	Computer Aided Drug Design*			
8.	FPUCBP808ET	OE	Cell and Molecular Biology*			
9.	FPUCBP809ET	OE	Cosmetic Science*			
10.	FPUCBP810ET	OE	Experimental Pharmacology*			
11.	FPUCBP811ET	OE	Advanced Instrumentation Techniques*			
12.	FPUCBP812ET	OE	Dietary Supplements and Nutraceuticals*			
13.	FPUCBP813PW	Project	Project Work (On Elective)	12	-	6
<b>Total</b>				<b>24</b>	<b>4</b>	<b>22</b>

[L - Lecture, T - Tutorial, P - Practical, C - Credits]

**Note:**

- 1 (ET- Elective subject) Every candidate has to opt for two of the elective subjects, and has to carry out project on any one of them.
- 2 (NUE- Non University Exam)- There will be no evaluation exam and the courses under this category are compulsory course (MC), skill enhancement course (SEC) and project course.

**Table-IX: Semester wise credits distribution**

Semester	Credit Points
I	27/29 <sup>s</sup> /30 <sup>#</sup>
II	29
III	26
IV	28
V	26
VI	26
VII	24
VIII	22
Extracurricular/ Co-curricular activities	01*
<b>Total credit points for the program</b>	<b>209/211<sup>s</sup>/212<sup>#</sup></b>

\*The credit points assigned for extracurricular and or co-curricular activities shall be given by the principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

§Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course.

#Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology course.

**Semester I**

**FPUCBP101T/ HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)****COURSE OUTCOME:**

Upon completion of this course the student should be able to

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

**Unit I:****Introduction to 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 tissue

**Unit II:****Integumentary system**

Structure and functions of 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 hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system.

**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.

### **FPUCBP101P / HUMAN ANATOMY AND PHYSIOLOGY (Practical)**

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

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

**Recommended Books (Latest Editions)**

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers' medical publishers, New Delhi, January 2019.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York, seventh edition.
3. Physiological basis of Medical Practice-Best and Tailor. Williams & WilkinsCo, Riverview, MI USA, thirteenth edition.
4. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH,U.S.A, third South Asia edition.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A, ninth edition.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi, 8<sup>th</sup> edition.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers,New Delhi, 8<sup>th</sup> edition.
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, thirteenth edition.
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH,U.S.A, third South Asia edition.
3. Human Physiology (Volume 1 and 2) by Dr. C.C. Chatterjee , Academic Publishers Kolkata, fourteenth edition.

## FPUCBP102T/PHARMACEUTICAL ANALYSIS (Theory)

### COURSE OUTCOMES:

Upon completion of the course student shall be able to

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

### UNIT-I

**Pharmaceutical analysis-** Definition and scope

Different techniques of analysis

Methods of expressing concentration

Primary and secondary standards.

Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulfuric acid, potassium permanganate and ceric ammonium sulphate

**Errors:** Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

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**



Concepts of oxidation and reduction

Types of redox titrations (Principles and applications)

Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

## **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

## **FPUCBP102P/ PHARMACEUTICAL ANALYSIS (Practical)**

### **I Limit Test of the following**

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

### **II Preparation and standardization of**

- (5) Sodium hydroxide
- (6) Sulfuric acid
- (7) Sodium thiosulfate
- (8) Potassium permanganate
- (9) Ceric ammonium sulphate

### **III Assay of the following compounds along with Standardization of Titrant**

- (10) Ammonium chloride by acid base titration
- (11) Ferrous sulphate by Cerimetry
- (12) Copper sulphate by Iodometry
- (13) Calcium gluconate by complexometry
- (14) Hydrogen peroxide by Permanganometry
- (15) Sodium benzoate by non-aqueous titration
- (16) Sodium Chloride by precipitation titration

### **IV Determination of Normality by electro-analytical methods**

- (17) Conductometric titration of strong acid against strong base
- (18) Conductometric titration of strong acid and weak acid against strong base
- (19) Potentiometric titration of strong acid against strong base

**Recommended Books: (Latest Editions)**

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, StahlonePress of University of London, fourth edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis, new edition.
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, updated version.
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry, eighth edition
5. John H. Kennedy, Analytical chemistry principles, India edition.
6. Indian Pharmacopoeia, 2022

## FPUCBP103T/PHARMACEUTICS- I (Theory)

### COURSE OUTCOME:

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

1. Know the history of 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

### UNIT – I

**Historical background and development of profession of pharmacy:** History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.

**Dosage forms:** Introduction to dosage forms, classification and definitions

**Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.

**Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

### UNIT – II

**Pharmaceutical calculations:** Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.

**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.

### 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.

#### **UNIT – 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

## **FPUCBP103P / PHARMACEUTICS I (Practical)**

### **1. Syrups**

#### **1. Elixirs**

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

#### **2. Linctus**

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

#### **3. Solutions**

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

#### **4. Suspensions**

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

#### **5. Emulsions**

- a) Turpentine Liniment
- b) Liquid paraffin emulsion
- c) Powders and Granules
- d) ORS powder (WHO)
- e) Effervescent granules
- f) Dusting powder
- g) Divided powders

#### **6. Suppositories**

- a) Glycerol gelatin suppository
- b) Cocoa butter suppository
- c) Zinc Oxide suppository

#### **7. Semisolids**

- a) SulFPUCr ointment
- b) Non staining-iodine ointment with methyl salicylate
- c) Carbopal gel

8. Gargles and Mouthwashes
9. Iodine gargle
10. Chlorhexidine mouthwash
11. Syrup IP'66

Compound syrup of Ferrous Phosphate BPC'68

**Recommended Books: (Latest Editions)**

1. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi, twelfth edition.
2. M.E. Aulton, *Pharmaceutics, The Science & Dosage Form Design*, Churchill Livingstone, Edinburgh, sixth edition.
3. Indian pharmacopoeia, 2022.
4. British pharmacopoeia, 2024.
5. Lachmann, *Theory and Practice of Industrial Pharmacy*, Lea & Febiger Publisher, The University of Michigan, fourth edition.
6. Alfonso R. Gennaro Remington. *The Science and Practice of Pharmacy*, Lippincott Williams, New Delhi, 20<sup>th</sup> edition, December 2000.
7. Carter S.J., Cooper and Gunn's. *Tutorial Pharmacy*, CBS Publications, New Delhi, twelfth edition.
8. E.A. Rawlins, Bentley's *Text Book of Pharmaceutics*, English Language Book Society, Elsevier Health Sciences, USA, January 2010.
9. Isaac Ghebre Sellassie: *Pharmaceutical Pelletization Technology*, Marcel Dekker, INC, New York, February 2022.
10. Dilip M. Parikh: *Handbook of Pharmaceutical Granulation Technology*, Marcel Dekker, INC, New York, 2<sup>nd</sup> edition, August 2005.
11. Francoise Nieloud and Gilberte Marti-Mestres: *Pharmaceutical Emulsions and Suspensions*, Marcel Dekker, INC, New York, 2<sup>nd</sup> edition, 2000.

## FPUCBP104T/ PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

### COURSE OUTCOMES:

Upon completion of course student shall be able to

1. Know 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

### UNIT I

**Impurities in pharmaceutical substances:** History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

**General methods of preparation,** assay for the compounds superscripted with **asterisk (\*)**, properties and medicinal uses of inorganic compounds belonging to the following classes

### 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\*, Aluminum 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 tartarate

**Haematinics:** Ferrous sulphate\*, Ferrous gluconate

**Poison and Antidote:** Sodium thiosulphate\*, Activated charcoal, Sodiumnitrite333

**Astringents:** Zinc Sulphate, Potash Alum

## UNIT V

**Radiopharmaceuticals:** Radio activity, Measurement of radioactivity, Properties of  $\alpha$ ,  $\beta$ ,  $\gamma$  radiations, Half-life, radio isotopes and study of radio isotopes - Sodium iodide  $I^{131}$ , Storage conditions, precautions & pharmaceutical application of radioactive substances.

## FPUCBP104P/ PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

### I Limit tests for following ions

Limit test for Chlorides and Sulphates

Modified limit test for Chlorides and Sulphates

Limit test for Iron

Limit test for Heavy metals

Limit test for Lead

Limit test for Arsenic

### II Identification test

Magnesium hydroxide

Ferrous sulphate

Sodium bicarbonate

Calcium gluconate

Copper sulphate

### III Test for purity

Swelling power of Bentonite

Neutralizing capacity of aluminum hydroxide gel

Determination of potassium iodate and iodine in potassium Iodide

### IV Preparation of inorganic pharmaceuticals

Boric acid

Potash alum

Ferrous sulphate

### Recommended Books (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4<sup>th</sup> edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis, new edition.
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3<sup>rd</sup> Edition
4. M.L Schroff, Inorganic Pharmaceutical Chemistry, 1969.
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry, eighth edition.



6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian Pharmacopoeia, 2022.

## FPUCBP105T/ COMMUNICATION SKILLS (Theory)

### COURSE OUTCOMES:

Upon completion of the course the student shall be able to

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

### 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 Dont's 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 andDont's of group discussion

### **FPUCBP105P/ COMMUNICATION SKILLS (Practical)**

The following learning modules are to be conducted using words worth<sup>®</sup> English language lab software

#### **Basic communication covering the following topics**

Meeting People Asking Questions Making Friends What did you do? Do's and Don'ts

#### **Pronunciations covering the following topics**

Pronunciation (Consonant Sounds) Pronunciation and Nouns

Pronunciation (Vowel Sounds)

#### **Advanced Learning**

Listening Comprehension / Direct and Indirect Speech Figures of Speech

Effective Communication Writing Skills

Effective Writing Interview Handling Skills E-Mail etiquette Presentation Skills

#### **Recommended Books: (Latest Edition)**

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2<sup>nd</sup> Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1<sup>st</sup> Edition, Oxford Press, 2011
3. Organizational Behaviour, Stephen .P. Robbins, 1<sup>st</sup> Edition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1<sup>st</sup> Edition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5<sup>th</sup> Edition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Greenhall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2<sup>nd</sup> Edition, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1<sup>st</sup> Edition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning India pvt. ltd, 2011

10. Soft skills and professional communication, Francis Peters SJ, 1<sup>st</sup>Edition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4<sup>th</sup>Edition, Pan Mac Millan,2009
12. Bringing out the best in people, Aubrey Daniels, 2<sup>nd</sup> Edition, Mc Graw Hill, 1999

## FPUCBP106T/ REMEDIAL BIOLOGY (Theory)

### **COURSE OUTCOME:**

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

1. Know the classification and salient features of five kingdoms of life
2. Understand the basic components of anatomy & physiology of plant
3. Know understand the basic components of anatomy & physiology animal with special reference to human

### **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 & Dicotyledones.

### **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

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 female reproductive system

Parts of 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 growthregulators

#### **Cell - The unit of life**

Structure and functions of cell and cell organelles. Cell division

#### **Tissues**

Definition, types of tissues, location and functions.

**Text Books**

- a. Text book of Biology by S. B. Gokhale, Nirali Prakashan.
- b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram, 2<sup>nd</sup> edition.

**Reference Books**

- a. A Text book of Biology by B.V. Sreenivasa Naidu
- b. A Text book of Biology by Naidu and Murthy
- c. Botany for Degree students By A. C. Dutta, revised edition.
- d. Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Anantha krishnan.
- e. A manual for Pharmaceutical Biology practical by S.B. Gokhale and C. K. Kokate, Nirali Prakashan.

## **FPUCBP106P/ REMEDIAL BIOLOGY (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 cell and its inclusions
3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues pertinent to  
Stem, Root, Leaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

### **Reference Books**

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



## FPUCBP107T/ REMEDIAL MATHEMATICS (Theory)

### COURSE OUTCOME:

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

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

### 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, Characteristic 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 ( $\epsilon - \delta$

$$\text{definition), } \lim_{x \rightarrow a} \frac{x^n - a^n}{x - a} = na^{n-1}, \quad \lim_{\theta \rightarrow 0} \frac{\sin \theta}{\theta} = 1,$$

$$x \rightarrow a \quad x - a \qquad \theta \rightarrow 0 \quad \theta$$

### 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

**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**

**Recommended Books (Latest Edition)**

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

**Semester II**

## **FPUCBP201T/ HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)**

### **COURSE OUTCOME:**

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

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 human body.
4. Perform the hematological tests like blood cell counts, hemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.
5. Appreciate coordinated working pattern of different organs of each system
6. Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

### **Unit I**

#### **Nervous system**

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fiber, 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.

### **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

**FPUCBP201P/ HUMAN ANATOMY AND PHYSIOLOGY (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.

**Recommended Books (Latest Editions)**

1. Sembuling, K. and Sembuling, P. (2012) Essential of Medical Physiology. 6th Edition, New Jaypee Brothers Medical Publishers, Delhi, India.
2. Waugh, A., Grant, A.W. and Ross, J.S. (2001) Ross and Wilson Anatomy and Physiology in Health and Illness. 9th Edition, Churchill Livingstone, New York.
3. Williams & Wilkins . (1991) 12th edition, Physiological basis of Medical Practice-Best and Tailor. Co, Riverview, MI USA.
4. Hall, J. E. (2015). *Guyton and hall textbook of medical physiology* (13th ed.). W B Saunders.
5. Inderbir Singh (2023). *Textbook of human histology* (11th ed.). Jaypee Brothers Medical Publishers Pvt. Ltd.
6. Ghai, C. L. (2024). *Textbook of practical physiology* (10th). Jaypee Brothers Medical Publishers Pvt. Ltd.
7. Srinageswari, K., & Sharma, R. (2017). *Practical workbook of human physiology* (2nd ed.). Jaypee Brothers Medical Publishers Pvt. Ltd.
8. Tortora, Gerard J., and Bryan Derrickson.( 2014), Principles of Anatomy & Physiology. 14th edition. Danvers, MA, Wiley.

**Reference Books:**

1. C. H., & Taylor, N. B. (2012). *Physiological basis of medical practice*. (13<sup>th</sup> ed.). Williams & Wilkins Co. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
2. Chatterjee, C.C. (2022). *Human Physiology* (Vol. 1 & 2, 14th ed.). Kolkata: Academic Publishers.

**FPUCBP202T/ PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)****COURSE OUTCOME:**

Upon completion of the course the student shall be able to

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

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****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 isomerisms in organic compounds

**UNIT-II****Alkanes\*, Alkenes\* and Conjugated dienes\***

SP<sup>3</sup> hybridization in alkanes, Halogenation of alkanes, uses of paraffins.

Stabilities of alkenes, SP<sup>2</sup> hybridization in alkenes

E<sub>1</sub> and E<sub>2</sub> reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeff's orientation and evidences. E<sub>1</sub> versus E<sub>2</sub> reactions, Factors affecting E<sub>1</sub> and E<sub>2</sub> 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\***

SN<sub>1</sub> and SN<sub>2</sub> reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

SN<sub>1</sub> versus SN<sub>2</sub> reactions, Factors affecting SN<sub>1</sub> and SN<sub>2</sub> reactions

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

#### **UNIT-V**

##### **Carboxylic acids\***

Acidity of carboxylic acids, 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 Acetyl salicylic acid

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

**FPUCBP202P/ PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)**

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

**Recommended Books (Latest Editions)**

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

## **FPUCBP203T/ BIOCHEMISTRY (Theory)**

### **Course Outcomes:**

Upon completion of course student shall be able to

1. Understand the catalytic role of enzymes, importance of enzyme inhibitors in 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 mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

### **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

### **UNIT III**

#### **Lipid metabolism**

$\beta$ -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, alcaptonuria, tyrosinemia)

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

**FPUCBP203P / BIOCHEMISTRY (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.

**Recommended Books (Latest Editions)**

1. Nelson, David L., and Michael M. Cox. (2017). *Lehninger Principles of Biochemistry*. 7th ed. New York
2. Kennelly, Peter J., Kathleen M. Botham, Owen P. McGuinness, Victor W. Rodwell, and P. Anthony Weil, eds. 2023. *Harper's Illustrated Biochemistry*. 32nd ed. New York: McGraw Hill.
3. U. Sathyanarayan and U. Chakrapani, (2007) "Biochemistry," Books and Allied (P) Ltd., 3rd Edition, Kolkata.
4. Stryer, L., Berg, J. M., Tymoczko, J. L., & Gatto, G. J. Jr. (2019). **Biochemistry**. 9th ed., W.H. Freeman and Company.
5. Rama Rao, K. (2019.), **Textbook of Biochemistry**. 4th ed., New Age International Publishers.
6. Deb, A. (2020), **Textbook of Biochemistry**. 1st ed., Academic Publishers.
7. Conn, E. E., & Stumpf, P. K. (1987), **Outlines of Biochemistry**. 5th ed., John Wiley & Sons.

8. Gupta, R. C., & Bhargavan, S. (2017). *Practical Biochemistry* (3rd ed.). Jaypee Brothers Medical Publishers
9. Plummer, D. T. (2001). *Introduction to Practical Biochemistry* (3rd ed.). McGraw-Hill Education.
10. Rajagopal, K., & Ramakrishna, K. (2019). *Practical Biochemistry for Medical Students*. 2<sup>nd</sup> ed., Jaypee Brothers Medical Publishers.
11. Varley, H. (2017). *Practical Biochemistry* (8th ed.). CBS Publishers & Distributors.

## FPUCBP204T/ PATHOPHYSIOLOGY (THEORY)

### COURSE OUTCOMES:

Upon completion of the subject student shall be able to –

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

### 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 II

#### Haematological Diseases:

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

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

**Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders:

depression, schizophrenia and Alzheimer's disease.

**Gastrointestinal system:** Peptic Ulcer

#### Unit IV

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

**Diseases of bones and joints:** Rheumatoid Arthritis, Osteoporosis, Gout

**Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

#### Unit V

**Infectious diseases:** Meningitis, Typhoid, Leprosy, Tuberculosis

Urinary tract infections

**Sexually transmitted diseases:** AIDS, Syphilis, Gonorrhoea

#### Recommended Books (Latest Editions)

1. Kumar, V., Abbas, A. K., & Aster, J. C. (2014). *Robbins & Cotran pathologic basis of disease* (9<sup>th</sup> ed.) Elsevier.
2. Harsh Mohan; Text book of Pathology; 6<sup>th</sup> edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12<sup>th</sup> edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12<sup>th</sup> ed; united states;
5. Smith, J. (1991). *The Fundamentals of Biology* (2nd ed.). Baltimore: William and Wilkins.
6. Colledge, N. R., Walker, B. R., & Ralston, S. H. (2010). *Davidson's principles and practice of medicine* (21st ed.). London: ELBS/Churchill Livingstone.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12<sup>th</sup> edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9<sup>th</sup> edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6<sup>th</sup> edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3<sup>rd</sup> edition; London; Churchill Livingstone publication; 2003.

#### Recommended Journals

1. The Journal of Pathology. ISSN: 1096-9896 (Online)
2. The American Journal of Pathology. ISSN: 0002-9440
3. Pathology. 1465-3931 (Online)

4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171(Online)
5. Indian Journal of Pathology and Microbiology. ISSN-0377-4929.



**FPUCBP205T/ COMPUTER APPLICATIONS IN PHARMACY (Theory)****COURSE OUTCOMES:**

Upon completion of the course the student shall be able to

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

**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/o, 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 ServerProducts

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)

**FPUCBP205P/ COMPUTER APPLICATIONS IN PHARMACY (Practical)**

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

**Recommended books (Latest edition):**

1. Computer Application in Pharmacy – William E. Fassett – Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development – Sean Ekins – Wiley-Interscience, A John Wiley 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

## **FPUCBP206T/ ENVIRONMENTAL SCIENCES (Theory)**

### **Course Outcome:**

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

1. Create the 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 learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

### **Unit-I**

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

### **Unit-II**

Ecosystems

Concept of an ecosystem.

Structure and function of an ecosystem.

Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

### **Unit- III**

Environmental Pollution: Air pollution; Water pollution; Soil pollution

**Recommended Books (Latest edition):**

1. Singh, Y. K. (2006) *Environmental Science*. 1st ed., New Age International Pvt. Publishers.
2. Agarwal, K. C. (2001). *Environmental biology*. 1st ed., Nidi Publ. Ltd.
3. Bharucha, E. (2000). *The biodiversity of India*. Mapin 1<sup>st</sup> edition, Publishing Pvt. Ltd.
4. Brunner, R. C. (1989). *Hazardous waste incineration*. 1st ed., McGraw-Hill.
5. Clark, R. S. (1986). *Marine pollution*. 1st ed., Clarendon Press.
6. Cunningham, W. P., Cooper, T. H., Gorhani, E., & Hepworth, M. T. (2001). *Environmental encyclopedia*. 1st ed., Jaico Publishing House.
7. De, A. K. (1992). *Environmental chemistry*. 1st ed., Wiley Eastern Ltd.

**SEMESTER III**

**FPUCBP301T / PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)****COURSE OUTCOME:**

Upon completion of the course the student shall be able to

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

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**

Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule

Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.

Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction

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, naphthols

**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**

Fatty acids – reactions.

Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.

Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

#### **UNIT IV**

##### **Polynuclear hydrocarbons:**

Synthesis, reactions Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

#### **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

**FPUCBP301P / PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)****I Experiments involving laboratory techniques**

Recrystallization

Steam distillation

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

Acid value

Saponification value

Iodine value

**III Preparation of compounds**

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

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

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

Benzoic acid from Benzyl chloride by oxidation reaction.

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

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

Benzi from Benzoin by oxidation reaction.

Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction

Cinnamic acid from Benzaldehyde by Perkin reaction

P-Iodo benzoic acid from P-amino benzoic acid

**Recommended Books (Latest Editions)**

1. Organic Chemistry by Morrison and Boyd, 7<sup>th</sup> Edition published by Pearson Education in 2010
2. Organic Chemistry, Volume 1 by I.L. Finar, 6<sup>th</sup> edition, published by Pearson Education in 2012
3. Textbook of Organic Chemistry by B.S. Bahl and Arun Bahl, 22<sup>nd</sup> edition, published by S. Chand Publishing in 2019.
4. Organic Chemistry by P.L. Soni, 31<sup>st</sup> edition, published by S. Chand Publishing in 2019.
5. Practical Organic Chemistry by F.G. Mann and B.C. Saunders, 4<sup>th</sup> edition, published by Pearson Education in 2009.
6. Vogel's Textbook of Practical Organic Chemistry, 5<sup>th</sup> edition, published by Pearson Education in 1989
7. Advanced Practical Organic Chemistry by N.K. Vishnoi 4<sup>th</sup> edition, published by Vikas Publishing House in 2011
8. Introduction to Organic Laboratory Techniques by Donald L. Pavia, Gary M. Lampman, and George S. Kriz, 5<sup>th</sup> edition, published by Cengage Learning in 2014.



**FPUCBP302T / PHYSICAL PHARMACEUTICS-I (Theory)****COURSE OUTCOME:**

Upon the completion of the course student shall be able to

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

**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.

**FPUCBP302P / PHYSICAL PHARMACEUTICS – I (Practical)**

1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalchequation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in CCl<sub>4</sub> and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of surface tension of given liquids by drop count and drop weight method
7. Determination of HLB number of a surfactant by saponification method
8. Determination of Freundlich and Langmuir constants using activated 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-Glycinecomplex by pH titration method

**Recommended Books: (Latest Editions)**

1. Physical Pharmacy" by Alfred Martin is the 4th edition, published by Lippincott Williams & Wilkins in 1993
2. Experimental Pharmaceutics by Eugene Parrott , 2nd edition, published by Lea & Febiger in 1988.
3. Tutorial Pharmacy by Cooper and Gunn, 7th edition, published by CBS Publishers & Distributors in 2010.
4. Pharmaceutical Calculation by Joseph A. Stocklosam, 3rd edition, published by Lea & Febiger, Philadelphia, in 1997
5. Pharmaceutical Dosage Forms: Tablets" (Volumes 1 to 3) by Liberman H.A. and Lachman C. 2nd edition, published by Marcel Dekker Inc. in 1989
6. Physical Pharmaceutics by Ramasamy C. and Manavalan R., 1st edition, published by Vallabh Prakashan in 2011
7. Laboratory Manual of Physical Pharmaceutics by C.V.S. Subramanyam and J. Thimma Setty, 1st edition, published by Vallabh Prakashan in 2014
8. Physical Pharmaceutics by C.V.S. Subramanyam, 2nd edition, published by Vallabh Prakashan in 2014
9. Textbook of Physical Pharmacy by Gaurav Jain and Roop K. Khar, 1st edition, published by CBS Publishers & Distributors in 2016.

## **FPUCBP303T / PHARMACEUTICAL MICROBIOLOGY (Theory)**

### **COURSE OUTCOME:**

Upon completion of the subject student shall be able to;

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 the cell culture technology and its applications in pharmaceutical industries.

### **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. Equipments 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 equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.

Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.

Assessment of a new antibiotic.

#### **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.

**FPUCBP303P / PHARMACEUTICAL MICROBIOLOGY (Practical)**

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

**Recommended Books (Latest edition)**

1. Pharmaceutical Microbiology by W.B. Hugo and A.D. Russell, 6th edition, published by Blackwell Scientific Publications in 1998
2. Prescott and Dunn., Industrial Microbiology, 4<sup>th</sup> edition, CBS Publishers & Distributors, Delhi.
3. Microbiology by J.P. Pelczar, E.C.S. Chan, and N.R. Krieg, 7th edition, published by Tata McGraw Hill in 2006.
4. Pharmaceutical Microbiology" by Malcolm Harris, 2nd edition, published by Bailliere Tindall in 1997.
5. Industrial Microbiology by Rose, 3rd edition, published by Chapman & Hall in 1996
6. Fundamentals of Microbiology by Probisher, Hinsdill, et al., 9th edition, published by Wiley in 2013
7. Tutorial Pharmacy by Cooper and Gunn, 7th edition, published by CBS Publishers & Distributors in 2010
8. Microbial Technology by Pepler, 1st edition, published by 1990.
9. I.P., B.P., U.S.P.- latest editions.
10. Textbook of Microbiology by Ananthanarayan, 10th edition, published by Orient Longman in 2018
11. Fundamentals of Microbiology" by Edward, 10th edition, published by Jones & Bartlett Learning in 2013
12. Pharmaceutical Microbiology" by N.K. Jain, 1st edition, published by Vallabh Prakashan in 2011
13. Bergey's Manual of Systematic Bacteriolog, 2nd edition, published by Williams & Wilkins (A Waverly Company) in 2001

**FPUCBP304T / PHARMACEUTICAL ENGINEERING (Theory)****COURSE OUTCOME:**

Upon completion of the course student shall be able:

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

**UNIT-I**

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

**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, Airseparator, 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,

#### UNIT-IV

**Filtration:** Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.

**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 during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. Ferrous and nonferrous metals, inorganic and organic non metals, basic of material handling systems.



**FPUCBP304P/ PHARMACEUTICAL ENGINEERING (Practical)**

- I. Determination of radiation constant of brass, iron, unpainted and painted glass.
- II. Steam distillation – To calculate the efficiency of steam distillation.
- III. To determine the overall heat transfer coefficient by heat exchanger.
- IV. Construction of drying curves (for calcium carbonate and starch).
- V. Determination of moisture content and loss on drying.
- VI. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
- VII. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
- VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of varioussize frequency curves including arithmetic and logarithmic probability plots.
- IX. 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.
- X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such othermajor equipment.
- XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
- XII. To study the effect of time on the Rate of Crystallization.
- XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.

**Recommended Books: (Latest Editions)**

1. Introduction to Chemical Engineering by Walter L. Badger and Julius Banchemo, 8th edition, published by McGraw-Hill Education in 2014.
2. Solid Phase Extraction: Principles, Techniques, and Applications by Nigel J.K. Simpson, 2nd edition, published by Elsevier in 2019
3. Unit Operations of Chemical Engineering" by Warren McCabe and Julian Smith is the 7th edition, published by McGraw-Hill Education in 2014
4. Pharmaceutical Engineering: Principles and Practices" by C.V.S. Subrahmanyam et al., 1st edition, published by Vallabh Prakashan in 2015
5. Remington: The Science and Practice of Pharmacy" edited by David B. Troy and Paul J. Trickett (often referred to as "Remington's Practice of Pharmacy"),22nd edition, published by Lippincott Williams & Wilkins in 2013.
6. Theory and Practice of Industrial Pharmacy" by Liberman, Lachman, and Schwartz is the 3rd edition, published by Varghese Publishing House in 2019
7. Physical Pharmaceutics" by C.V.S. Subrahmanyam et al. is the 2nd edition, published by Vallabh

Prakashan in 2014

8. Cooper and Gunn's Tutorial Pharmacy" edited by S.J. Carter,7th edition, published by CBS Publishers & Distributors in 2010

**SEMESTER IV**

**FPUCBP401T / PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)****COURSE OUTCOME:**

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

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

**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

**UNIT-V****Reactions of synthetic importance**

Metal hydride reduction ( $\text{NaBH}_4$  and  $\text{LiAlH}_4$ ), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement. Claisen-Schmidt condensation

**Recommended Books (Latest Editions)**

1. Organic chemistry by I.L. Finar, Fourth edition, Volume-I & II, Published by Pearson education limited.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl, 22<sup>nd</sup> edition, Published by S.Chand and company.
3. Heterocyclic Chemistry by Raj K. Bansal, 3<sup>rd</sup> edition, published by Pearson education limited.
4. Organic Chemistry by Robert Neilson Boyd and Robert T. Morrison, 7<sup>th</sup> edition, published by Pearson education limited.
5. Heterocyclic Chemistry by T.L. Gilchrist, 3<sup>rd</sup> edition, published by Pearson education limited.

**FPUCBP402T / MEDICINAL CHEMISTRY – I (Theory)****COURSE OUTCOME:**

Upon completion of the course the student shall be able to

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 class of drugs
4. write the chemical synthesis of some drugs

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

**UNIT- I****Introduction to Medicinal Chemistry****History and development of medicinal chemistry Physicochemical properties in relation to biological action**

Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Proteinbinding, Chelation, Bioisosterism, Optical and Geometrical isomerism.

**Drug metabolism**

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical 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\*, Bitolterol, 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**

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

**Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible):** Physostigmine, Neostigmine\*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, 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**

Sedatives and Hypnotics:

**Benzodiazepines:** SAR of Benzodiazepines, Chlordiazepoxide, Diazepam\*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem

**Barbiturtes:** SAR of barbiturates, Barbitol\*, Phenobarbital, Mephobarbital, Amobarbital, Butobarbital, Pentobarbital, Secobarbital

**Miscellaneous:**

Amides & imides: Glutethimide.

Alcohol & their carbamate derivatives: Meprobamate, Ethchlorvynol. Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

**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.

**Anticonvulsants:** SAR of Anticonvulsants, mechanism of anticonvulsant action

**Barbiturates:** Phenobarbitone, Methabarbitol. **Hydantoins:**

Phenytoin\*, Mephentyoin, Ethotoin **Oxazolindione diones:**

Trimethadione, Paramethadione **Succinimides:**

Phensuximide, Methsuximide, Ethosuximide\* **Urea and**

**monoacylureas:** Phenacemide, Carbamazepine\* **Benzodiazepines:**

Clonazepam

**Miscellaneous:** Primidone, Valproic acid, Gabapentin, Felbamate

## UNIT – V

### Drugs acting on Central Nervous System

#### General anesthetics:

**Inhalation anesthetics:** Halothane\*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

**Ultra short acting barbiturates:** Methohexital sodium\*, Thiopental sodium, Thiopental sodium.

**Dissociative anesthetics:** Ketamine hydrochloride.\*

#### Narcotic and non-narcotic analgesics

**Morphine and related drugs:** SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anileridine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate\*, Methadone hydrochloride\*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate.

**Narcotic antagonists:** Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.

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



**FPUCBP402P / MEDICINAL CHEMISTRY – I  
(Practical)**

**I Preparation of drugs/ intermediates**

1,3-pyrazole

1,3-oxazole

Benzimidazole

Benztriazole

2,3- diphenyl quinoxaline

Benzocaine

Phenytoin

Phenothiazine

Barbiturate

**II Assay of drugs**

Chlorpromazine

Phenobarbitone

Atropine

Ibuprofen

Aspirin

Furosemide

**III Determination of Partition coefficient for any two drugs**

**Recommended Books (Latest Editions)**

1. Organic medicinal and Pharmaceutical Chemistry by Wilson and Giswold, , published by Wolters Kluwer India Pvt. Ltd, 12<sup>th</sup> edition
2. Foye's Principles of Medicinal Chemistry by Victoria, F. Roche, S. William, PhD Zito, Thomas Lemke, David A. Williams Published by Lippincott Williams & Wilkins; 8<sup>th</sup> edition.
3. Burger's Medicinal Chemistry, by Alfred Burger, Published by Wiley-Blackwell; 6<sup>th</sup> Edition, Vol I to IV.
4. Introduction to principles of drug design- by H. John Smith , Hywel Williams Published by CRC press 4<sup>th</sup> edition.
5. Remington's Pharmaceutical Sciences, by Adeboye Adejare published by elsevier exclusive, 23<sup>rd</sup> edition.

6. The Organic Chemistry of Drug Synthesis by Daniel Lednicer, Published by Wiley interscience 1<sup>st</sup> edition Vol. 1-5.
7. Text book of practical organic chemistry- A.I.Vogel, Published by longman 4<sup>th</sup> edition.

### FPUCBP403T / PHYSICAL PHARMACEUTICS-II (Theory)

#### COURSE OUTCOME:

Upon the completion of the course student shall be able to

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

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

**FPUCBP403P / PHYSICAL PHARMACEUTICS- II (Practical)**

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

**Recommended Books: (Latest Editions)**

1. Physical Pharmacy by Alfred Martin, Publisher. Ippincott Williams & Wilkins, 6<sup>th</sup> edition
2. Experimental pharmaceutics by Eugene, Parott published by Publisher. Burgess Pub. Co
3. Tutorial pharmacy by Cooper and Gunn Published by CBS publishers and distributors PVT LTD, 12<sup>th</sup> edition.
4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphi, Published by Lippincott Williams and Wilkins, 8<sup>th</sup> edition
5. Pharmaceutical Dosage forms, Tablets, by Herbert Lieberman, Leon Lachman, Joseph B. Schwartz, published by CRC press 2<sup>nd</sup> edition Volume-1 to 3
6. Pharmaceutical dosage forms Disperse systems, by Herbert Lieberman published by CRC press 2<sup>nd</sup> edition Volume-1 to 3.

**FPUCBP404T / PHARMACOLOGY-I (Theory)****COURSE OUTCOME:**

Upon completion of this course the student should be able to

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 the basic pharmacological knowledge in the prevention and treatment of various diseases.
4. Observe the effect of drugs on animals by simulated experiments
5. Appreciate correlation of pharmacology with other bio medical sciences

**UNIT-I****General Pharmacology**

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.

Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

**UNIT-II****General Pharmacology**

Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor,transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.

Adverse drug reactions.

Drug interactions (pharmacokinetic and pharmacodynamic)

Drug discovery and clinical evaluation of new drugs -Drug discovery phase,preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

**UNIT-III****Pharmacology of drugs acting on peripheral nervous system**

Organization and function of ANS.

Neurohumoral transmission,co-transmission and classification of neurotransmitters.

Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.

Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).

Local anesthetic agents.

Drugs used in myasthenia gravis and glaucoma

#### **UNIT-IV**

##### **Pharmacology of drugs acting on central nervous system**

Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.

General anesthetics and pre-anesthetics.

Sedatives, hypnotics and centrally acting muscle relaxants.

Anti-epileptics

Alcohols and disulfiram

#### **UNIT-V**

##### **Pharmacology of drugs acting on central nervous system**

Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.

Drugs used in Parkinsons disease and Alzheimer's disease.

CNS stimulants and nootropics.

Opioid analgesics and antagonists

Drug addiction, drug abuse, tolerance and dependence.

**FPUCBP404P / PHARMACOLOGY-I (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, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods

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

**Recommended Books (Latest Editions)**

1. Rang and Dale's Pharmacology, by H. P. Rang, J. M. Ritter, R. J. Flower, and G. Henderson, published by Churchill Livingstone Elsevier, 8<sup>th</sup> edition.
2. Basic and clinical pharmacology, by Bertram G. Katzung, Anthony J. Trevor, published by Tata McGraw-Hill, 16<sup>th</sup> edition.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics by Brunton, Laurence L., Knollmann, Bjorn C., M.D published by Tata McGraw-Hill, 14<sup>th</sup> edition.
4. Applied Therapeutics, The Clinical use of Drugs, by Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., published by LippincottWilliams & Wilkins, 9<sup>th</sup> edition.

5. Essentials of Medical Pharmacology, by K.D. Tripathi, published by JAYPEE Brothers Medical Publishers (P) Ltd, 9<sup>th</sup> edition.
6. Principles of Pharmacology, by H.L. Sharma, K.K. Sharma, published by Paras medical publisher, 4<sup>th</sup> edition.
7. Handbook of experimental pharmacology by S.K. Kulkarni Published by Vallabh Prakashan,



**FPUCBP405T / PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)****COURSE OUTCOME:**

Upon completion of the course, the student shall be able

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

**UNIT-I****Introduction to Pharmacognosy:**

Definition, history, scope and development of Pharmacognosy

Sources of Drugs – Plants, Animals, Marine & Tissue culture

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 serotaxonomical 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.

**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 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

**FPUCBP405P / PHARMACOGNOSY AND PHYTOCHEMISTRY I (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

**Recommended Books: (Latest Editions)**

1. W.C.Evans, Trease and Evans Pharmacognosy, 16<sup>th</sup> edition, published by W.B. Saunders & Co.,London,
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9<sup>th</sup> edition,published by Lea and Febiger,
3. Text Book of Pharmacognosy by T.E. Wallis, 5<sup>th</sup> edition, published by CBS publisher and distributors.
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae, 37<sup>th</sup> Edition,Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary, 1<sup>st</sup> Edition, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr.SH.Ansari, 2<sup>nd</sup> edition, Birla publications, New Delhi,
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae, Published by Nirali Publication.

**SEMESTER V**

**UCBP501T / MEDICINAL CHEMISTRY – II (Theory)****COURSE OUTCOME:**

1. Upon completion of the course the student shall be able to
2. Understand the chemistry of drugs with respect to their pharmacological activity
3. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
4. Know the Structural Activity Relationship of different class of drugs
5. Study the chemical synthesis of selected drugs

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**

**Antihistaminic agents:** Histamine, receptors and their distribution in the human body

**H<sub>1</sub>-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

**H<sub>2</sub>-antagonists:** Cimetidine\*, Famotidine, Ranitidin.

**Gastric Proton pump inhibitors:** Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

**Anti-neoplastic agents:**

**Alkylating agents:** Meclorothamine\*, 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 – II**

**Anti-anginal: Vasodilators:** Amyl nitrite, Nitroglycerin\*, Pentaerythritol tetranitrate, Isosorbide dinitrite\*, Dipyridamole.

**Calcium channel blockers:** Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Niacardipine, 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

**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- III**

**Anti-arrhythmic Drugs:** Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate\*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcinide hydrochloride, Amiodarone, Sotalol.

**Anti-hyperlipidemic agents:** Clofibrate, Lovastatin, Cholesteramine and Cholestipol

**Coagulant & Anticoagulants:** Menadione, Acetomenadione, Warfarin\*, Anisindione, clopidogrel  
Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

**UNIT- IV****Drugs acting on 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, Norgestrel, Levonorgestrol

**Corticosteroids:** Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

**Thyroid and antithyroid drugs:** L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

**UNIT – V****Antidiabetic agents:**

**Insulin and its preparations Sulfonyl ureas:** Tolbutamide\*, Chlorpropamide, Glipizide, Glimepiride.

**Biguanides:** Metformin. **Thiazolidinediones:** Pioglitazone, Rosiglitazone. **Meglitinides:** Repaglinide, Nateglinide. **Glucosidase inhibitors:** Acarbose, Voglibose.

**Local Anesthetics:** SAR of Local anesthetics

**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, Dipiperdon, Dibucaine.\*

**Recommended Books (Latest Editions)**

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry, 12<sup>th</sup> edition, Lippincotts William & Wilson.
2. Foye's Principles of Medicinal Chemistry, 7<sup>th</sup> edition 2013, Wolters Kluwer Health/Lippincott Williams & Wilkins
3. Burger's Medicinal Chemistry, Vol I to IV, 8<sup>th</sup> edition 2021, Wiley Publication.
4. Introduction to principles of drug design- Smith and Williams, 4<sup>th</sup> edition 2005, CRC Publication.
5. Remington's Pharmaceutical Sciences, 21<sup>st</sup> edition 2006, Lippincott Williams & Wilkins
6. Martindale's extra pharmacopoeia, 3<sup>rd</sup> edition 1993, Pharmaceutical Press
7. Organic Chemistry by I.L. Finar, Vol. II, 5<sup>th</sup> edition 1956, Pearson education.
8. Indian Pharmacopoeia, 9<sup>th</sup> edition 2022, Indian Pharmacopoeia Commission

9. Text book of practical organic chemistry- A.I.Vogel, 5<sup>th</sup> edition 2011, Pearson Education.

## **FPUCBP502T / Industrial Pharmacy I (Theory)**

### **COURSE OUTCOMES:**

1. Upon completion of the course the student shall be able to
2. Know the various pharmaceutical dosage forms and their manufacturing techniques.
3. Know various considerations in development of pharmaceutical dosage forms
4. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

### **UNIT-I**

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

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

**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:**

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

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

**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.

**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

### **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 parenterals 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; labeling, 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.



### **FPUCBP502P / Industrial Pharmacy I (Practical)**

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

### **Recommended Books: (Latest Editions)**

1. Pharmaceutical dosage forms-Tablets, volume 1-3 by H.A. Liberman, Leon Lachman & J.B.Schwartz, 3<sup>rd</sup> edition 2010, CRC Press.
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman &Lachman, 2<sup>nd</sup> edition 2018, CRC Press.
3. Pharmaceutical dosage form disperses system VOL-1 by Liberman & Lachman, 2<sup>nd</sup> edition 2020, CRC Press.
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 4<sup>th</sup> Edition 2002, CRC Press.
5. Remington's Pharmaceutical Sciences, 21<sup>st</sup> edition 2006, Lippincott Williams & Wilkins
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman, 4<sup>th</sup> Edition 2020, CRC Press.
7. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger,Philadelphia, 9<sup>th</sup>edition, 2011, Lippincott Williams & Wilkins.

**FPUCBP503T / PHARMACOLOGY-II (Theory)****COURSE OUTCOME:**

Upon completion of this course the student should be able to

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 correlation of pharmacology with related medical sciences

**UNIT-I**

Pharmacology of drugs acting on cardio vascular system. Introduction to hemodynamic and electrophysiology of heart.

**Drugs used in congestive heart failure:** Anti-hypertensive drugs. Anti-anginal drugs. Anti-arrhythmic drugs. Anti-hyperlipidemic drugs.

**UNIT-II****Pharmacology of drugs acting on cardio vascular system**

Drug used in the therapy of shock. Hematinics, coagulants and anticoagulants.

Fibrinolytics and anti-platelet drugs. Plasma volume expanders

Pharmacology of drugs acting on urinary system. Diuretics Anti-diuretics.

**UNIT-III****Autocoids and related drugs**

Introduction to autocoids and classification

Histamine, 5-HT and their antagonists. Prostaglandins, Thromboxanes and Leukotrienes. Angiotensin, Bradykinin and Substance. Non-steroidal anti-inflammatory agents. Anti-gout drugs. Antirheumatic drugs.

**UNIT-IV****Pharmacology of drugs acting on endocrine system**

Basic concepts in endocrine pharmacology.

Anterior Pituitary hormones- analogues and their inhibitors. Thyroid hormones- analogues and their inhibitors. **Hormones regulating plasma calcium level-** Parathormone, Calcitonin and Vitamin-D.

Insulin, Oral Hypoglycemic agents and glucagon. ACTH and corticosteroids.

**UNIT-V****Pharmacology of drugs acting on endocrine system**

Androgens and Anabolic steroids. Estrogens, progesterone and oral contraceptives. Drugs acting on the uterus. Bioassay Principles and applications of bioassay. Types of bioassays, Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT.

**FPUCBP503P/ PHARMACOLOGY-II (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 matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of  $PA_2$  value of prazosin using rat anococcygeus muscle (by Schild's plot method).
12. Determination of  $PD_2$  value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

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

**Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, 8<sup>th</sup> edition 2014 Churchill Livingstone Elsevier publisher.
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, 16<sup>th</sup> edition 2023, Tata McGraw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics. 14<sup>th</sup> Edition, Tata McGraw-Hill
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, 9<sup>th</sup> Edition 2008, Lippincott Williams & Wilkins.
5. K.D.Tripathi, Essentials of Medical Pharmacology, 5<sup>th</sup> Edition 2018, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
6. Sharma H. L., Sharma K. K., Principles of Pharmacology, 4<sup>th</sup> edition 2023, Paras medical publisher

**FPUCBP504T / PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)****COURSE OUTCOME:**

1. Upon completion of the course, the student shall be able
2. To know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
3. To understand the preparation and development of herbal formulation.
4. To understand the herbal drug interactions
5. To carry out isolation and identification of phytoconstituents

**UNIT-I****Metabolic pathways in higher plants and their determination**

Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.

Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

**UNIT-II**

General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of 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****Isolation, Identification and Analysis of Phytoconstituents**

**Terpenoids:** Menthol, Citral, Artemisin

**Glycosides:** Glycyrrhetic acid & Rutin

**Alkaloids:** Atropine, Quinine, Reserpine, Caffeine

**Resins:** Podophyllotoxin, Curcumin

**UNIT-IV**

**Industrial production, estimation and utilization of the following phytoconstituents:** Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

**UNIT V**

**Basics of Phytochemistry**

Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crudedrugs.

### **FPUCBP504P / PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)**

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

#### **Recommended Books: (Latest Editions)**

1. W.C.Evans, Trease and Evans Pharmacognosy, 16<sup>th</sup> edition 2009, W.B. Saunders & Co., London.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, 2<sup>nd</sup> Edition 2019, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae, 37<sup>th</sup> Edition 2007, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary, 1<sup>st</sup> Edition 1996, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition 2007, Birla publications, New Delhi.
6. A.N. Kalia, Textbook of Industrial Pharmacognosy, 2005 CBS Publishers, New Delhi.

**FPUCBP505T / PHARMACEUTICAL JURISPRUDENCE (Theory)****COURSE OUTCOME:**

1. Upon completion of the course, the student shall be able to understand:
2. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
3. Various Indian pharmaceutical Acts and Laws
4. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
5. The code of ethics during the pharmaceutical practice

**UNIT-I****Drugs and Cosmetics Act, 1940 and its rules 1945:**

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

**Manufacture of drugs** – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

**UNIT-II****Drugs and Cosmetics Act, 1940 and its rules 1945.**

Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

**Labeling & Packing of drugs-** General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. 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 & 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)

**Recommended books: (Latest Edition)**

1. Forensic Pharmacy by B. Suresh, 7<sup>th</sup> Edition 2010, Birla Publication.
2. Text book of Forensic Pharmacy by B.M. Mithal, 10<sup>th</sup> Edition 1999, Birla Prakashan.
3. A text book of Forensic Pharmacy by N.K. Jain, 8<sup>th</sup> Edition 2014, Birla Publication
4. Drugs and Cosmetics Act/Rules by Govt. of India publications.
5. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
6. Narcotic drugs and psychotropic substances act by Govt. of India publications
7. Drugs and Magic Remedies act by Govt. of India publication
8. Bare Acts of the said laws published by Government, 3 October 2020, Reference books (Theory)



**SEMESTER VI**

**FPUCBP601T / MEDICINAL CHEMISTRY – III (Theory)****COURSE OUTCOME:**

Upon completion of the course student shall be able to

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.

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

**UNIT – I****Antibiotics**

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

**β-Lactam antibiotics:** Penicillin, Cephalosporins, β- Lactamase inhibitors, Monobactams

**Aminoglycosides:** Streptomycin, Neomycin, Kanamycin

**Tetracyclines:** Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

**UNIT – II****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.

**Prodrugs:** Basic concepts and application of prodrugs design.

**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**

**Anti-tubercular Agents**

**Synthetic anti tubercular agents:** Isoniozid\*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid. \*

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

**Urinary tract anti-infective agents**

**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****08 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

### Introduction to Drug Design

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis.

Pharmacophore modeling and docking techniques.

**Combinatorial Chemistry:** Concept and applications chemistry: of combinatorial solid phase and solution phase synthesis.

## FPUCBP601P / MEDICINAL CHEMISTRY- III (Practical)

### **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
- 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 class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)**

### **Recommended Books (Latest Editions)**

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry, Publisher Wolters Kluwe, Edition 12<sup>th</sup>.

2. Foye's Principles of Medicinal Chemistry Publisher : Lippincott Williams & Wilkins; 7th edition (8 March 2012)
3. Burger's Medicinal Chemistry, Vol I to IV. Publisher : Wiley-Blackwell; 6th Edition.
4. Introduction to principles of drug design- Smith and Williams., Publisher : CRC Press; 4th edition.
5. Remington's Pharmaceutical Sciences. Publisher : ELSEVIER EXCLUSIVE SPECIAL PRICE; 23rd edition.
6. Martindale's extra pharmacopoeia. Publisher : Pharmaceutical Press; 31st Revised edition
7. Organic Chemistry by I.L. Finar, Vol. II. Publisher : Pearson Education India; 5th edition
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5. Publisher : Wiley-Interscience; 1st edition
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel. Publisher : Pearson India; 5th edition

## FPUCBP602T / PHARMACOLOGY-III (Theory)

### **COURSE OUTCOME:**

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

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 poisonings and
3. appreciate correlation of pharmacology with related medical sciences.

### **UNIT-I**

#### **Pharmacology of drugs acting on Respiratory system**

Anti -asthmatic drugs

Drugs used in the management of COPD

Expectorants and antitussives

Nasal decongestants

Respiratory stimulants

#### **Pharmacology of drugs acting on the Gastrointestinal Tract**

Antiulcer agents.

Drugs for constipation and diarrhoea.

Appetite stimulants and suppressants.

Digestants and carminatives.

Emetics and anti-emetics.

### **UNIT-II**

#### **Chemotherapy**

General principles of chemotherapy.

Sulfonamides and cotrimoxazole.

Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolones, tetracycline and aminoglycosides

### **UNIT-III**      10hours

#### **Chemotherapy**

Antitubercular agents

Antileprotic agents

Antifungal agents

Antiviral drugs.

Anthelmintics

Antimalarial drugs

Antiamoebic agents

#### **UNIT-IV**

##### **Chemotherapy**

Urinary tract infections and sexually transmitted diseases.

Chemotherapy of malignancy.

##### **Immunopharmacology**

Immunostimulants

Immunosuppressant

Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

#### **UNIT-V**

##### **Principles of toxicology**

Definition and basic knowledge of acute, subacute and chronic toxicity.

Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity

General principles of treatment of poisoning

Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning.

##### **Chronopharmacology**

Definition of rhythm and cycles.

Biological clock and their significance leading to chronotherapy.



**FPUCBP602P / PHARMACOLOGY-III (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 effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens ( rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

\*Experiments are demonstrated by simulated experiments/videos

**Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics, McGraw-Hill Education
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, publisher : Lippincott Williams & Wilkins
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. Vallabh Prakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.edition1st ed.[Shyam Prakashan](#)

**FPUCBP603T / HERBAL DRUG TECHNOLOGY (Theory)****COURSE OUTCOME:**

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

1. understand raw material as source of herbal drugs from cultivation to herbal drugproduct
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .

**UNIT-I****Herbs as raw materials**

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation  
Source of Herbs

Selection, identification and authentication of herbal materials  
Processing of herbal raw material

**Biodynamic Agriculture**

Good agricultural practices in cultivation of medicinal plants including Organic farming.  
Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

**Indian Systems of Medicine**

Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy  
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 Gastro intestinal diseases.

Study of 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.

**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, disintegrants, flavors & 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:**

Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy

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.

## **FPUCBP603P / HERBAL DRUG TECHNOLOGY (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

### **Recommended Books: (Latest Editions)**

1. Textbook of Pharmacognosy by Trease & Evans. Publisher : W B Saunders Co Ltd; 16th edition
2. Textbook of Pharmacognosy by Tyler, Brady & Robber. Publisher : Lea & Febiger, U.S.; 7th Revised edition
3. Pharmacognosy by Kokate, Purohit and Gokhale, Publisher : Nirali Prakashan
4. Essential of Pharmacognosy by Dr.S.H.Ansari, Publisher : BIRLA PUBLICATIONS PVT. LTD.
5. Pharmacognosy & Phytochemistry by V.D.Rangari, Publisher : Career Publications; 2nd Revised edition
6. Pharmacopoeial 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.



## FPUCBP604T / BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

### COURSE OUTCOME:

Upon completion of the course student shall be able to:

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, elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. Understand various pharmacokinetic parameters, their significance & applications.

### 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 -  $K_E$ ,  $t_{1/2}$ ,  $V_d$ ,  $AUC$ ,  $K_a$ ,  $Cl_t$  and  $CL_R$ - definitions methods of eliminations, understanding of their significance and application

#### 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.

Michaelis-menton method of estimating parameters, Explanation with example of drugs.

#### **Recommended Books: (Latest Editions)**

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi, Publisher : Pharma Book Syndicate; 4th edition
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari, Publisher : Dekker (Marcel) Inc.,U.S.
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. Merceel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott byADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick, Publisher : Lea & Febiger,U.S.
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebert F Notari Marcel Dekker Inn, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company,Pennsylvania



## **FPUCBPFUCBP605T / PHARMACEUTICAL BIOTECHNOLOGY (Theory)**

### **COURSE OUTCOME:**

Upon completion of the subject student shall be able to;

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

### **Unit I**

Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.

Enzyme Biotechnology- Methods of enzyme immobilization and applications.

Biosensors- Working and applications of biosensors in Pharmaceutical Industries.

Brief introduction to Protein Engineering.

Use of microbes in industry. Production of Enzymes- General consideration -Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.

Basic principles of genetic engineering.

### **Unit II**

Study of cloning vectors, restriction endonucleases and DNA ligase.

Recombinant DNA technology. Application of genetic engineering in medicine.

Application of r DNA technology and genetic engineering in the production of:

i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin.

Brief introduction to PCR

### **Unit III**

Types of immunity- humoral immunity, cellular immunity

Structure of Immunoglobulins

Structure and Function of MHC

Hypersensitivity reactions, Immune stimulation and Immune suppressions.

General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.

Storage conditions and stability of official vaccines

Hybridoma technology- Production, Purification and Applications

Blood products and Plasma Substitutes.

#### **Unit IV**

Immuno blotting techniques- ELISA, Western blotting, Southern blotting.

Genetic organization of Eukaryotes and Prokaryotes

Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.

Introduction to Microbial biotransformation and applications.

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.

#### **Recommended Books (Latest edition):**

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology, Publisher : WH Freeman; 8th ed. 2018 edition
3. J.W. Goding: Monoclonal Antibodies, Publisher : Academic Press Inc; 3rd edition
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degrand, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

## **FPUCBP606T / PHARMACEUTICAL QUALITY ASSURANCE (Theory)**

### **COURSE OUTCOME:**

Upon completion of the course student shall be able to:

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

### **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.

**Equipments 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.

## **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

### **Recommended Books: (Latest Edition)**

1. Quality Assurance Guide by organization of Pharmaceutical Products of India. Publisher : World Health Organization
2. Good Laboratory Practice Regulations, 2<sup>nd</sup> 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. Publisher : Vandana Pub
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh, Publisher : Singh, S K
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, Publisher : Marcel Dekker Inc
9. ICH guidelines, ISO 9000 and 14000 guidelines

**SEMESTER VII**

## **FPUCBP701T INSTRUMENTAL METHODS OF ANALYSIS (Theory)**

### **COURSE OUTCOME:**

Upon completion of the course the student shall be able to

1. Understand the interaction of matter with electromagnetic radiations 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.

### **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- Phototube, Photo multiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications – Spectrophotometric titrations, Single component and multicomponent 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, Thermistor, Pyroelectric detector and applications

**Flame Photometry**- Principle, interferences, instrumentation and applications

**Atomic absorption spectroscopy**- Principle, interferences, instrumentation and applications

**Nephelometry**- Principle, instrumentation and applications

### **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, ionexchange resins, properties, mechanism of ionexchange process, factors affecting ion exchange, methodology and applications

**Gel chromatography-** Introduction, theory, instrumentation and applications

**Affinity chromatography-** Introduction, theory, instrumentation and applications

**FPUCBP701P INSTRUMENTALMETHODSOFANALYSIS (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 sulfanilamide by colorimetry
- 4 Simultaneous estimation of ibuprofen and paracetamol by UVspectroscopy
- 5 Assay of paracetamol by UV-Spectrophotometry
- 6 Estimation of quinine sulfate by fluorimetry
- 7 Study of quenching of fluorescence
- 8 Determination of sodium by flame photometry
- 9 Determination of potassium by flame photometry
- 10 Determination of chlorides and sulphates by nephelo turbidometry
- 11 Separation of amino acids by paper chromatography
- 12 Separation of sugars by thin layer chromatography
- 13 Separation of plant pigments by column chromatography
- 14 Demonstration experiment on HPLC
- 15 Demonstration experiment on Gas Chromatography

**Recommended Books(LatestEditions)**

1. Instrumental Methods of Chemical Analysis by B.K.Sharma 24<sup>th</sup> edition revised edition, goel Publishing House.
2. Organic spectroscopy by Y.R.Sharma, 5<sup>th</sup> edition, S.Chand and Company Pvt. Ltd.
3. Textbook of Pharmaceutical Analysis by Kenneth A.Connors, 3<sup>rd</sup> edition, jain book Agency.
4. Vogel's Textbook of Quantitative Chemical Analysis by A.I.Vogel, 7<sup>th</sup> impression 2008, Pearson
5. Practical Pharmaceutical Chemistry by A.H.Beckett and J.B.Stenlake, 4<sup>th</sup> edition, the athlone press London.



## FPUCBP702T INDUSTRIAL PHARMACY-II (Theory)

### COURSE OUTCOME:

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

1. Know the process of pilot plant and scaleup 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 pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

### UNIT-I

**Pilotplant scaleup techniques:** General considerations- including significance of personnel requirements, space requirements, raw materials, Pilotplant scaleup considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to plat form 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 TTProcess (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 (casestudies), TT agencies in India- APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI;TT related documentation -confidentiality agreement, licensing, MoUs, legalissues

### 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 ISO9000 series of quality systems standards, ISO14000, NABL, GLP

#### **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.

#### **Recommended Books:(Latest Editions)**

1. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
2. Ajay Semalty, Industrial Pharmacy -1, 4<sup>th</sup> edition, Pharma med Press.
3. Roop K Khar, SP Vyas, Farhan J Ahmad, Gaurav K Jain. The theory and practice of Industrial Pharmacy, 4<sup>th</sup> edition, CBS Publisher and distributors.

**FPUCBP703T PHARMACY PRACTICE(Theory)****COURSE OUTCOME:**

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

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

**UnitI:****Hospital and it's organization**

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

**Hospital pharmacy and its organization**

Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

**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.

**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.

**UnitII:**

**Drug distribution system in a hospital**

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

**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.

**Therapeutic drug monitoring**

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

**Medication adherence**

Causes of medication nonadherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

**Patient medication history interview**

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

**Community pharmacy management**

Financial, materials, staff, and infrastructure requirements.

**UnitIII:**

**Pharmacy and therapeutic committee**

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, in patient and out patient prescription, automatics top order, and emergency druglist preparation.

**Drug information services**

Drug and Poison information centre, Sources of drug information, Computerized services, and storage and retrieval of information.

**Patient counseling**

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

**Education and training programming the hospital**

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

**Prescribed medication order and communication skills**

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

**UnitIV**

**Budget preparation and implementation**

Budget preparation and implementation

**Clinical Pharmacy**

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

Over the counter (OTC) sales

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

**Unit V****Drug store management and inventory control**

Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure

**Investigational use of drugs**

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

**Interpretation of Clinical Laboratory Tests**

Blood chemistry, hematology, and urinalysis

**Recommended Books(Latest Edition):**

1. Merchant S.H. and Dr.J.S.Quadry. A text book of hospital pharmacy, 4<sup>th</sup> ed.Ahmadabad: B.S.Shah Prakakshan; 2001.
2. Partha sarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1<sup>st</sup> ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. Hospital pharmacy, 5<sup>th</sup> ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. Hospital Pharmacy, 1<sup>st</sup> ed.Maharashtra: Career Publications; 2008.
5. Scott LT. Basic skills in interpreting laboratory data, 4<sup>th</sup> ed. American Society of Health System Pharmacists Inc;2009.
6. Parmar N.S.Health Education and Community Pharmacy,18<sup>th</sup> ed.India:CBSPublishers&Distributers; 2008. American journal of health system pharmacy.ISSN:1535-2900(online)
1. Pharmacy times (Monthly magazine)

**FPUCBP704T / NOVEL DRUG DELIVERY SYSTEMS(Theory)****COURSE OUTCOME:**

Upon completion of the course student shall be able

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

**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 ionexchange 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 bioadhesion/mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems

**Implantable Drug Delivery Systems:** Introduction, advantages and disadvantages, concept of implants and osmotic pump

**Unit-III**

**Transdermal Drug Delivery Systems:** Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches.

**Gastro retentive 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.

**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, intraocular barriers and methods to overcome – Preliminary study, ocular formulations and ocuserts

**Intrauterine Drug Delivery Systems:** Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

**Recommended Books: (Latest Editions)**

1. YW.Chien, Novel Drug Delivery Systems, 2<sup>nd</sup>edition, revised and expanded, Marcel Dekker, Inc., NewYork,1992.
2. Robinson,J.R., LeeV.H.L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., NewYork, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/ Weinheim
4. N.K.Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition1997 (reprintin2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery-concepts and advances, Vallabh Prakashan, New Delhi, First edition2002.

**Journals**

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

**SEMESTER VIII**



## FPUCBP801T/ BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)

### COURSE OUTCOME:

Upon completion of the course the student shall be able to

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

### 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 - Pharmaceutical 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, Experimental 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.

### **Unit-IV**

Blocking and confounding system for Two-level factorials

**Regression modeling:** 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

### **Recommended Books (Latest edition):**

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

**FPUCBP802T/ SOCIAL AND PREVENTIVE PHARMACY****COURSE OUTCOME:**

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

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

**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

**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.

**Recommended Books (Latest edition):**

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

**Recommended Journals:**

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

## **FPUCBP803ET/ PHARMA MARKETING MANAGEMENT (Theory)**

### **COURSE OUTCOME:**

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

### **Unit I**

#### **Marketing:**

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

#### **Pharmaceutical market:**

Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and 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 labeling 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.

## **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.

### **Recommended Books: (Latest Editions)**

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche: Marketing Strategy- Planning and Implementation, Tata MC Graw Hill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt: Global Perspective, Indian Context, 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.

## **FPUCBP804ET /PHARMACEUTICAL REGULATORY SCIENCE (Theory)**

### **COURSE OUTCOME:**

Upon completion of the subject student shall be able to;

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

### **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

## Unit V

### Regulatory Concepts

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

### Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5<sup>th</sup> 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



**FPUCBP805ET/ PHARMACOVIGILANCE (Theory)****COURSE OUTCOME:**

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

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

**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, edDRA and Standardised MedDRA queries  
WHO drug dictionary, Eudravigilance medicinal product dictionary

**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**

#### **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**

**Recommended Books (Latest edition):**

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiolog 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 167
12. <http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297>
13. <http://www.ich.org/>
14. <http://www.cioms.ch/>
15. <http://cdsco.nic.in/>
16. [http://www.who.int/vaccine\\_safety/en/](http://www.who.int/vaccine_safety/en/)
17. [http://www.ipc.gov.in/PvPI/pv\\_home.html](http://www.ipc.gov.in/PvPI/pv_home.html)

**FPUCBP806ET/ QUALITY CONTROL AND STANDARDIZATION OF  
HERBALS  
(Theory)**

**COURSE OUTCOME:**

Upon completion of the subject student shall be able to;

1. Know WHO guidelines for quality control of herbal drugs
2. Know Quality assurance in 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

**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

**Recommended Books: (Latest Editions)**

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.

## FPUCBP807ET /COMPUTER AIDED DRUG DESIGN (Theory)

### COURSE OUTCOME:

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

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

### 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 Modeling and virtual screening techniques

**Virtual Screening techniques:** Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

**Molecular docking:** Rigid docking, flexible docking, manual docking, Docking based screening. De novo drug design.

### UNIT-IV

#### Informatics & Methods in drug design

Introduction to Bioinformatics, cheminformatics. ADME databases, chemical,

biochemical and pharmaceutical databases.

### UNIT-V

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

### Recommended Books (Latest Editions)

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

## **FPUCBP808ET / CELL AND MOLECULAR BIOLOGY (Elective subject)**

### **COURSE OUTCOME:**

Upon completion of the subject student shall be able to;

1. Summarize cell and molecular biology history.
2. Summarize cellular functioning and composition.
3. Describe the chemical foundations of cell biology.
4. Summarize the DNA properties of cell biology.
5. Describe protein structure and function.
6. Describe cellular membrane structure and function.
7. Describe basic molecular genetic mechanisms.
8. Summarize the Cell Cycle

### **Unit I**

Cell and Molecular Biology: Definitions theory and basics and Applications.

Cell and Molecular Biology: History and Summation.

Properties of cells and cell membrane.

Prokaryotic versus Eukaryotic

Cellular Reproduction

Chemical Foundations – an Introduction and Reactions (Types)

### **Unit II**

DNA and the Flow of Molecular Information

DNA Functioning

DNA and RNA

Types of RNA

Transcription and Translation

### **Unit III**

Proteins: Defined **and** Amino Acids

Protein Structure

Regularities in Protein Pathways

Cellular Processes

Positive Control and significance of Protein Synthesis

### **Unit IV**

Science of Genetics

Transgenics and Genomic Analysis

Cell Cycle analysis

Mitosis and Meiosis



Cellular Activities and Checkpoints

**Unit V**

Cell Signals: Introduction

Receptors for Cell Signals

Signaling Pathways: Overview

Misregulation of Signaling Pathways

Protein-Kinases: Functioning

**Recommended Books (latest edition):**

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

## FPUCBP809ET /COSMETIC SCIENCE (Theory)

### 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 Color, Hair tensile strength, Hair combing properties

Soaps, and syndet bars. Evolution and skin benefits.

## **UNIT V**

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor.

Antiperspirants and Deodorants- Actives and mechanism of action

### **References**

- 1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
- 2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4<sup>th</sup> Edition, Vandana Publications Pvt. Ltd., Delhi.
- 3) Text book of cosmeticology by Sanju Nanda & Roop K. Khar, Tata Publishers.

## FPUCBP810ET / PHARMACOLOGICAL SCREENING METHODS

### COURSE OUTCOME:

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

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

### 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

#### Preclinical screening models

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.

#### Study of screening animal models for

Diuretics, nootropics, anti-Parkinson's, antiasthmatics,

**Preclinical screening models:** for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease

### Unit –III

**Preclinical screening models:** for ANS activity, sympathomimetics, sympatholytics, parasympathomimetic, parasympatholytic, 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.

**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.

**Recommended Books (latest edition):**

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

**FPUCBP811ET /ADVANCED INSTRUMENTATION TECHNIQUES****COURSE OUTCOME:**

Upon completion of the course the student shall be able to

5. understand the advanced instruments used and its applications in drug analysis
6. understand the chromatographic separation and analysis of drugs.
7. understand the calibration of various analytical instruments
8. know analysis of drugs using various analytical instruments.

**UNIT-I****Nuclear Magnetic Resonance spectroscopy**

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

**Mass Spectrometry-** Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

**UNIT-II**

**Thermal Methods of Analysis:** Principles, instrumentation and applications of Thermo gravimetric 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 solidphase extraction and liquid-liquid extraction

**UNIT-V**

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

**Recommended Books (Latest Editions)**

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



## **FPUCBP812ET / DIETARY SUPPLEMENTS AND NUTRACEUTICALS**

### **COURSE OUTCOME:**

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

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 the application.
4. Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

### **UNIT I**

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.

Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.

Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

### **UNIT II**

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

Carotenoids-  $\alpha$  and  $\beta$ -Carotene, Lycopene, Xanthophylls, leutin

Sulfides: Diallyl sulfides, Allyl trisulfide.

Polyphenolics: Resveratrol

Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones

Prebiotics / Probiotics.: Fructo oligosaccharides, Lactobacillus

Phyto estrogens: Isoflavones, daidzein, Geebustin, lignans

Tocopherols

Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

### **UNIT III**

Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.

Dietary fibres and complex carbohydrates as functional food ingredients.

**UNIT IV**

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. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E,  $\alpha$ -Lipoic acid, melatonin  
Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.  
Functional foods for chronic disease prevention

**UNIT V**

Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.

Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

**References:**

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals 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 2<sup>nd</sup> 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)
10. Shils, ME, Olson, JA, Shike, M. 1994 Modern Nutrition in Health and Disease. Eighth edition. Lea and Febiger

## **FPUCBP813PW / ELECTIVE COURSE ON PHARMACEUTICAL PRODUCT**

### **Unit-I**

Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms

### **Unit-II**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

Solvents and solubilizers

Cyclodextrins and their applications

Non - ionic surfactants and their applications

Polyethylene glycols and sorbitols

Suspending and emulsifying agents

Semi solid excipients

### **Unit-III**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

Tablet and capsule excipients

Directly compressible vehicles

Coat materials

Excipients in parenteral and aerosols products

Excipients for formulation of NDSS

Selection and application of excipients in pharmaceutical formulations with specific industrial applications

### **Unit-IV**

Optimization techniques in pharmaceutical product development. A study of various optimization techniques for pharmaceutical product development with specific examples. Optimization by factorial designs and their applications. A study of QbD and its application in pharmaceutical product development.

### **Unit-V**

Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.

**Recommended Books (Latest editions)**

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