# Department of Pharmaceutical Sciences Dr. Harisingh Gour University (A Central University; 'A' Grade by UGC-NAAC)

Sagar (M.P.)-470003



# SCHEME AND SYLLABUS FOR BACHELOR OF PHARMACY (B. PHARM) COURSE

# **B. Pharm Programme**

	Table-I: Course of study for sem	ester l			
Course code	Name of the course		No. of hours	Tuto rial	Credit . points
PHS-CC-1101	Human Anatomy and Physiology I-Theory		3 .	1.	4 .
PHS-CC-1102	Pharmaceutical Analysis I – Theory		3	1	4
PHS-CC-1103	Pharmaceutics I – Theory		3	1	4
PHS-CC-1104	Pharmaceutical Inorganic Chemistry – Theory	•	3	1	4
PHS-CC-1105	Communication skills – Theory *		2	-	2
PHS-EC-1106 Rer	nedial Biology	•	2 .	- •	2 .
OR PHS-EC-1107 Rer	nedial Mathematics – Theory*		2	-	2
PHS-CC-1108	Human Anatomy and Physiology I – Practical	•	4	-	2
PHS-CC-1109	Pharmaceutical Analysis I – Practical		4	-	2
PHS-CC-1110	Pharmaceutics I – Practical	•	4	-	2
PHS-CC-1111	Pharmaceutical Inorganic Chemistry – Practical		4	-	2
PHS-CC-1112	Communication skills – Practical*		2		1
PHS-EC-1113	Remedial Biology – Practical*		2	-	1
	Total		34\$/36#	4	29\$/30#

<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.

Table-II: Course of study for semester II					
Course Code	Name of the course	No. of hours	Tutorial	Credit points	
PHS-CC-2101	Human Anatomy and Physiology II – Theory	3	1	4	
PHS-CC-2102	Pharmaceutical Organic Chemistry I – Theory	3	1	4	
PHS-CC-2103	Physical Pharmaceutics-I – Theory	3	1	4	
PHS-EC-2104	Computer Applications in Pharmacy – Theory *	3	-	3	
PHS-EC-2105	Environmental sciences – Theory *	3	-	3	
PHS-CC-2106	Human Anatomy and Physiology II – Practical	4	-	2	
PHS-CC-2107	Pharmaceutical Organic Chemistry I– Practical	4	-	2	
PHS-CC-2108	Physical Pharmaceutics-I – Practical	4	-	2	
PHS-EC-2109	Computer Applications in Pharmacy – Practical*	2	-	1	
	Total	29	3	25	

Course Code	Table-III: Course of study for semester III  Name of the course	No. of hours	Tutorial	Credit points
PHS-CC-3101	Pharmaceutical Organic Chemistry II – Theory	3	1	4
PHS-CC-3102	Biochemistry – Theory	3	1	4
PHS-CC-3103	Pharmaceutical Microbiology – Theory	3	1	4
PHS-CC-3104	Pharmaceutical Engineering – Theory	3	1	4
PHS-CC-3105	Pathophysiology – Theory	3	1	4
PHS-CC-3106	Pharmaceutical Organic Chemistry II – Practical	4	-	2
PHS-CC-3107	Biochemistry – Practical	4	-	2
PHS-CC-3108	Pathophysiology – Practical	4	-	2
PHS-CC-3109	Pharmaceutical Microbiology – Practical	4	-	2
PHS-CC-3110	Pharmaceutical Engineering –Practical	4	-	2
	Tota	35	5	30

Table-IV: Course of study for semester IV					
Course Code	Name of the course	No. of hours	Tutorial	Credit points	
PHS-CC-4101	Pharmaceutical Organic Chemistry III – Theory	3	1	4	
PHS-CC-4102	Medicinal Chemistry I – Theory	3	1	4	
PHS-CC-4103	Physical Pharmaceutics II – Theory	3	1	4	
PHS-CC-4104	Pharmacology I – Theory	3	1	4	
PHS-CC-4105	Pharmacognosy and Phytochemistry I– Theory	3	1	4	
PHS-CC-4106	Medicinal Chemistry I – Practical	4	-	2	
PHS-CC-4107	Physical Pharmaceutics II – Practical	4		2	
PHS-CC-4108	Pharmacology I – Practical	4	-	2	
PHS-CC-4109	Pharmacognosy and Phytochemistry I – Practical	4	-	2	
	Total	31	5	28	

Table-V: Course of study for semester V					
Course Code	Name of the course		No. of hours	Tutorial	Credit points
PHS-CC-5101	Medicinal Chemistry II – Theory		3	1	4
PHS-CC-5102	Industrial Pharmacyl- Theory		3	1	4
PHS-CC-5103	Pharmacology II – Theory		3	1	4
PHS-CC-5104	Pharmacognosy and Phytochemistry II– Theory		3	1	4
PHS-CC-5105	Pharmaceutical Jurisprudence - Theory		3	1	4
PHS-CC-5106	Medicinal Chemistry II – Practical		4	-	2
PHS-CC-5107	Industrial Pharmacy I – Practical		4	-	2
PHS-CC-5108	Pharmacology II – Practical		4	-	2
PHS-CC-5109	Pharmacognosy and Phytochemistry II – Practical		4	-	2
		Total	31	5	28

Table-VI: Course of study for semester VI					
Course Code	Name of the course	No. of hours	Tutorial	Credit points	
PHS-CC-6101	Medicinal Chemistry III – Theory	3	1	4	
PHS-CC-6102	Pharmacology III – Theory	3	1	4	
PHS-CC-6103	Cosmetics Science – Theory	3	1	4	
PHS-CC-6104	Pharmaceutical Biotechnology – Theory	3	1	4	
PHS-CC-6105	Quality Assurance –Theory	3	1	4	
PHS-CC-6106	Medicinal chemistry III – Practical	4	-	2	
PHS-CC-6107	Pharmacology III – Practical	4	-	2	
PHS-CC-6108	Cosmetics Science – Practical	4	-	2	
PHS-CC-6109	Pharmaceutical Biotechnology – Practical	4	-	2	
	Total	31	5	28	

Table-VII: Course of study for semester VII					
Course Code	Name of the course	No. of hours	Tutorial	Credit points	
PHS-CC-7101	Instrumental Methods of Analysis – Theory	3	1	4	
PHS-CC-7102	Industrial Pharmacy II – Theory	3	1	4	
PHS-CC-7103	Pharmaceutical Marketing Managements – Theory	3	1	4	
PHS-CC-7104	Novel Drug Delivery System – Theory	3	1	4	
PHS-CC-7105	Social and Preventive Pharmacy-Theory	3	1	4	
PHS-CC-7106	Instrumental Methods of Analysis - Practical	4	-	2	
PHS-CC-7107	Novel Drug Delivery System – Practical	4	-	2	
PHS-CC-7108	Practice School*	12	-	6	
	Total	35	5	30	

Course Code	Name of the course	No. of hours	Tutorial	Credit points
PHS-CC-8101	Biostatistics and Research Methodology	3	1	4
PHS-CC-8102	Pharmacy Practice	3	1	4
PHS-CC-8103	Biopharmaceutics and Pharmacokinetics-Theory	3	1	4
PHS-CC-8104	Herbal Drug Technology-Theory	3	1	4
PHS-CC-8105	Biopharmaceuics and Pharmacokinetics- Practical	4	-	2
PHS-CC-8106	Herbal Drug Technology-Practical	4	-	2
PHS-CC-8107	Project Work	12	-	6
PHS-EC	Elective	3	1	4
	Tota	35	4	30

Elective Subjects:

PHS-EC-8108	Pharmaceutical Regulatory Science			
PHS-EC-8109	Pharmacovigilance			
PHS-EC-8110	Quality Control and Standardization of Herbal			
PHS-EC-8111	Computer Aided Drug Design			
PHS-EC-8112	Cell and Molecular Biology	3	1	4
PHS-EC-8113	Cosmetic Science			
PHS-EC-8114	Experimental Pharmacology			
PHS-EC-8115	Advanced Instrumentation Techniques			
PHS-EC-8116	Dietary Supplements and Nutraceuticals			

# PHS-CC-1101:HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

45 Hours

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

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

- Explain the gross morphology, structure and functions of various organs of the human body.
- 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.
- Appreciate coordinated working pattern of different organs of each system.

### LOCF:

Upon successful completion of the course, the student will be able to:

- Describe general principles of cell communication and Forms of intracellular signaling. Will gain information on tissue level of organization
- 02 Explain the skeletal system including Joints, physiology of muscle contraction and Forms of intracellular signaling.
- Describe body fluids, blood, blood related disorders and lymphatic system.
- 04 Explain peripheral nervous system of the human body and anatomy and physiology of special senses.
- Describe Cardiovascular system and regulation of blood pressure.

### **Course Content:**

### Unit I 10 hours

# 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 tissues.

Unit II 10 hours

### 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 10 hours

### Body fluids and blood

Body fluids, composition and functions of blood, hemopoeisis, 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 08 hours

### 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 07 hours

• 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 heart beat, its regulation by autonomic nervous system, cardiac ou tput, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

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

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

### Reference Books (Latest Editions)

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

**Scope**: This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs. **Objectives**: Upon completion of the course student shall be able to understand the principles of volumetric and electrochemical analysis carryout various volumetric and electrochemical titrations develop analytical skills.

### LOCF:

Upon successful completion of the course, the student will be able to:

- Describe the an alysis, preparation and standardization of various solutions. In addition students they will also understand about errors, accuracy, precision and information of different pharmacopoeia's
- Classify the use of indicators for titrations specially Non aqueous solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate.
- Describe different methods of titration as well as classification, demasking and indicators of different regents, Gravitmetry principle analysis and basic methods of diazotisation titration.
- Explain types of redox titration as well as concept of oxidation and reduction.
- Describe different Electrochemical methods of analysis i.e., Potentiometry, conductometry and polarography

### Course Content:

Unit I 10 hours

Pharmaceutical analysis-Definition and scope

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

**(b)**Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures **(c)** Pharmacopoeia, Sources of impurities in medicinal agents, limit tests.

Unit II 10 hours

- Acid base titration: Theories of acid base indicators, classification ofacid 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 10 hours

**Precipitation titrations**: Mohr's method, Volhard's Modified Volhard's, Fajans method, estimation of sodium chloride. **Complexometric titration**: Classification, metal ion indicators, maskingand 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 08 hours

### **Redox titrations**

- a. Concepts of oxidation and reduction.
- b. 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, Conductometrictitrations, applications.
- Potentiometry -Electrochemical cell, construction and workingof reference (Standard hydrogen, silver chloride
  electrode and calomel electrode) and indicator electrodes (metal elec trodes and glass electrode), methods to
  determine end point of potentiometric titration and applications.

07 hours

 Polarography - Principle, Ilkovic equation, construction andworking of dropping mercury electrode and rotating platinum electrode, applications.

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

- 1. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
- 2. Bentley and Driver's Textbook of Pharmaceutical Chemistry
- 3. John H. Kennedy, Analytical chemistry principles
- 4. Indian Pharmacopoeia.

45 Hours

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

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

- 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

# LOCF:

Upon successful completion of the course, the student will be able to:

- Know the historical background and development of profession of pharmacy, Dosage forms, Prescription and Posology.
- 02 Will be learn about the Pharmaceutical calculations.
  - Know the Powders and liquid dosages forms with their formulation, method of preparation, advantages, disadvantages and pharmaceutical application.
- Familiar with the Monophasic and Biphasic liquids including gargles, mouthwashes, throat paint, ear drops, nasal drops, enemas, syrups, elixirs, liniments, lotions, suspension and emulsion.
- Know the suppositories with their formulation, method of preparation, advantages, disadvantages and pharmaceutical application. And pharmaceutical incompatibilities in detail.
- Familiar with the semisolid dosage forms including their classification, mechanisms and factors influencing dermal penetration of drugs.

### **Course Content:**

UNIT – I 10 Hours

**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 Ex 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 10 Hours

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 6

UNIT – III 10 Hours

**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 Emuls ion, Methods of preparation & stability problems and methods to overcome.

UNIT – IV 08 Hours

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 07 Hours

Semisolid dosage forms: Definitions, classification, mechanisms and factors inf luencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms

### Recommended Books: (Latest Editions)

- 1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and
  - a. Walkins, New Delhi.
- M.E. Aulton, Pharmaceutics, The Science Dosage Form Design, Churchill Livingstone, Edinburgh.
- 3. Indian pharmacopoeia.
- British pharmacopoeia.
- 5. Lachmann. Theory and Practice of Industrial Pharmacy, Lea& Febiger Publisher, The University of Michigan.
- Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New
  - a. Delhi.
- E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
- 8. Bentley's Text Book of Pharmaceutics -S. K. Jain and Vandana Soni
- 9. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
- 10. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
- 11. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

45 Hours

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

Objectives: Upon completion of course student shall be able to

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

### LOCF:

Upon successful completion of the course, the student will be able to:

- 01 Explain impurity present in pharmaceuticals substances and describe the heavy metal impurities.
- Describe the acid, base and buffers and importance of buffers in pharmaceutical preparations and be familiar with The role of electrolytes in human's body.
- 03 Describe the dental products in detail.
- Describe the role of expectorant, emetics, haematinics, poison and antidote and astringents as pharmaceutical substances.
- 05 Explain the radio active compounds and their importance and applications in pharmaceutical field.

### Course Content:

UNIT I 10 Hours

**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 10 Hours

**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 majorphysiological 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 10 Hours

### 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 of Potassium permanganate, Boric acid, Hydrogen peroxide\*, Chlorinated lime\*, Iodine and its preparations

UNIT IV 08 Hours

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, Sodium nitrite

Astringents: Zinc sulphate, Potash alum

UNIT V 07 Hours

 $\label{eq: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.$ 

# **Recommended Books (Latest Editions)**

- 1. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition
- 2. M.L Schroff, Inorganic Pharmaceutical Chemistry
- 3. Bentley and Driver's Textbook of Pharmaceutical Chemistry
- 4. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
- 5. IndianPharmacopoeia

# PHS-CC-1105:COMMUNICATION SKILLS (Theory)

30 Hours

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

### Objectives:

Upon completion of the course the student shall be able to

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

# LOCF:

Upon successful completion of the course, the student will be able to:

- Explain the behavioral needs for a pharmacist to function effectively in the areas of pharmaceutical operation.
- O2 Communicate effectively (Verbal and Non-Verbal)
- Describe the effective management of the team as a team player
- 04 Explain method(s) of developing the interview skills
- Describe the process involved for developing the leadership qualities and essentials

### Course content:

UNIT – I 07 Hours

**Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context

**Barriers to Commun** ication: Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers

**Perspectives in Communication:** Introduction, Visual Perception, Language, Other fa ctors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment.

UNIT – II 07 Hours

**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 07 Hours

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 05 Hours

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 04 Hours

**Group Discussion:** Introduction, Communication skills in group discussion, Do's and Dont's of group discussion.

# Recommended Books: (Latest Edition)

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

# PHS-EC-1106: REMEDIAL BIOLOGY (Theory)

30 Hours

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

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

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

### LOCF:

Upon successful completion of the course, the students will be able to:

- 01 Describe the features of living world, binomial nomenclature, five kingdom classifications & morphology of flowering plants.
- 02 Explain the human circulatory system, digestive system & respiratory system.
- Describe the regulation & functioning of human excretory system, neural system, endocrine system & reproductive system;
- Describe the nutritional requirement of plants and importance of photosynthesis.
- 05 Explain the process of plant respiration, role of plant growth regulators, physiology & functions of cell & tissues.

Content

UNIT-I 07 Hours

### 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, Potista, 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 & Dicotylidones.

UNIT - II 07 Hours

### 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 07 Hours

### 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 05 Hours

### 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 04 Hours

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

### Plant growth and development

Phases and rate of plant growth, Condition of growth, Introduction to plant growth Regulators.

### Cell - The unit of life

Structure and functions of cell and cell organelles. Cell division

### Tissues

Definition, types of tissues, location and functions.

### **Text Books**

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

# Reference Books

- A Text book of Biology by B.V. Sreenivasa
- 2. Naidu b. A Text book of Biology by Naidu and Murthy
- 3. Botany for Degree students By A.C.Dutta.
- 4. Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.
- 5. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

# PHS-EC-1107: REMEDIAL MATHEMATICS (Theory)

30 Hours

on.

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

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

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

### LOCF:

Upon successful completion of the course, the student will be able to:

- 01 Solve mathematical problems/questions based on syllabus.
- 02 Articulate the use of mathematical equations and calculations in pharmaceutical field.

### **Course Content:**

UNIT – I 06 Hours

### 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  $(\in -\delta)$  definition,  $\lim_{x\to a} \frac{x^n - a^n}{x - a} = na^{n-1}$ ,  $\lim_{\theta\to 0} \frac{\sin\theta}{\theta} = 1$ ,

UNIT -II 06 Hours

### **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 06 Hours

### 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 xn w.r.t. x, where n is any rational number, Derivative of ex, Derivative of loge x, Derivative of ax, 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 06 Hours

# **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 f ractions, Integration by parts, definite integrals, application

UNIT-V 06 Hours

- 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, Applic ation to solve Linear differential equations, Application in solving Chemical kinetics and Pharmacokinetics equations

# Recommended Books (Latest Edition)

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

# PHS-CC-1108: HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4- Hours/week

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

### LOCF:

Upon successful completion of the course, the student will be able to:

- O1 Describe different parts and functions of compound microscope.
- 02 Explain the epithelial, connective tissue and muscular tissues, nervous tissue.
- O3 Describe the anatomy and physiology of axial bones, appendicular bones.
- Describe the hematological tests (RBC count, WBC count, bleeding time, clotting time, hemoglobin count, blood group, ESR and related disorders
- Explain the methods to determine the blood pressure, heart rate, pulse rate and respiratory volumes
- 1. Study of compound microscope.
- 2. Microscopic study of epithelial and connective tissue
- 3. Microscopic study of muscular and nervous tissue
- 4. Identification of axial bones.
- 5. Identification of appendicular bones.
- 6. Introduction to hemocytometry.
- 7. Enumeration of white blood cell (WBC) count.
- 8. Enumeration of total red blood corpuscles (RBC) count.
- 9. Determination of bleeding time.
- 10. Determination of clotting time.
- 11. Estimation of hemoglobin content.
- 12. Determination of blood group.
- 13. Determination of erythrocyte sedimentation rate (ESR).
- 14. Determination of heart rate and pulse rate.
- 15. Recording of blood pressure.

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

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

### Reference Books (Latest Editions)

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

# PHS-CC-1109: PHARMACEUTICAL ANALYSIS-I (Practical)

4 Hours / Week

# LOCF:

Upon successful completion of the course, the student will be able to:

- Perform the limit tests of different chemical compounds.
- O2 Perform experiments based on preparation and standardization of different chemical compounds.
- O3 Carry out the assay of various compounds along with standardization of titrant as per syllabus.
- 04 Perform experiments based on determination of normality by electro-analytical methods

# 1. Limit Test of the following

- 1. Chloride
- 2. Sulphate
- 3. Iron
- 4. Arsenic

# 2. Preparation and standardization of

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

# 3. Assay of the following compounds along with Standardization of Titrant

- Ammonium chloride by acid base titration
- 2. Ferrous sulphate by Cerimetry
- 3. Copper sulphate by lodometry
- 4. Calcium gluconate by complexometryHydrogen peroxide by Permanganometry
- 5. Sodium benzoate by non-aqueous titration
- 6. Sodium Chloride by precipitation titration

# 4. Determination of Normality by electro-analytical methods

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

### Recommended Books: (Latest Editions)

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

### LOCF:

Upon successful completion of the course, the student will be able to:

- Prepare Syrups like Syrup IP'66, Compound syrup of Ferrous Phosphate BPC'68, Elixirs like Piperazine citrate elixir & Paracetamol pediatric elixir and Linctus like Terpin Hydrate Linctus IP '66 & Iodine Throat Paint (Mandles Paint)
- O2 Prepare Solutions such as Strong solution of ammonium acetate, Cresol with soap solution, Lugol's solution and Suspensions
- O3 Prepare Emulsions like Liquid paraffin emulsion and Turpentine Linime
- O4 Prepare Powders and Granules ORS powder (WHO), Effervescent granules, Dusting powder, divided powders and suppositories like Glycero gelatin suppository, Coca butter suppository, Zinc Oxide suppository etc.
- Prepare semisolids dosage forms like Sulfur ointment, Non staining -iodine ointment with methyl salicylate Carbopal gel, Gargles and Mouthwashes, iodine gargle and Chlorhexidine mouthwash.

# a. Syrups

- i. Syrup IP'66
- ii. Compound syrup of Ferrous Phosphate BPC'68
- iii. Elixirsa) Piperazine citrate elixir
- iv. Paracetamol pediatric elixir
- b. Linctus a) Terpin Hydrate Linctus IP'66
  - 1. b) Iodine Throat Paint (Mandles Paint)

### c. Solutions

- i. Strong solution of ammonium acetate
- ii. Cresol with soap solution
- iii. Lugol's solution

### d. Suspensions

- i. Calamine lotion
- ii. Magnesium Hydroxide mixture
- iii. Aluminimum Hydroxide gel
- e. Emulsions a) Turpentine Liniment
  - 1. Liquid paraffin emulsion

### f. Powders and Granules

- i. ORS powder (WHO)
- ii. Effervescent granules
- iii. c)Dusting powder
- iv. d)Divded powders

# g. Suppositories

- i. Glycero gelatin suppository
- ii. Coca butter suppository
- iii. Zinc Oxide suppository

### h. Semisolids xn 🗈 📠 n 🗓

- i. Sulphur ointment
- i. Non staining-iodine ointment with methyl salicylate

Carbopal gel

Gargles and Mouthwashes lodine gargle

Chlorhexidine mouthwash

# Recommended Books: (Latest Editions)

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

# LOCF:

Upon successful completion of the course, the student will be able to:

- Perform limit test for determining the impurities by heavy metals ions.
- O2 Identify the inorganic compounds present in unknown samples.
- O3 Perform the experiments based on test for purity of inorganic compounds.
- 04 Perform experiments based on preparation of inorganic pharmaceuticals compounds.

# Limit tests for following ions

- 1. Limit test for Chlorides and Sulphates
- 2. Modified limit test for Chlorides and Sulphates Limit test for Iron
- 3. Limit test for Heavy metals
- 4. Limit test for Lead
- 5. Limit test for Arsenic

### **Identification test**

- 1. Acidic and basic radicals in given inorganic sample
- 2. Magnesium hydroxide
- 3. Ferrous sulphate
- Sodium bicarbonate
- 5. Calcium gluconate
- 6. Copper sulphate

### Test for purity

- 1. Swelling power of Bentonite
- 2. Neutralizing capacity of aluminum hydroxide gel
- 3. Determination of potassium iodate and iodine in potassium lodide

# Preparation of inorganic pharmaceuticals

- 1. Boric acid
- 2. Potash alum
- 3. Ferrous sulphate

# **Recommended Books (Latest Editions)**

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

# LOCF:

Upon successful completion of the course, the student will be able to:

- 01 Describe basic communication skills. covering the following topics.
- Describe the effective processes for meeting people, asking questions, making true friends.
- 03 Explain the Do's and Don't's for quality communication.
- 04 Explain the correct pronunciations with reference to Consonant Sounds, Nouns and Vowel Sounds.

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

### Basic communication covering the following topics

Meeting People

**Asking Questions** 

Making Friends

What did you do?

Do's and Dont's

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

# PHS-EC-1113:REMEDIAL BIOLOGY (Practical)

03 Hours/Week

# LOCF:

Upon successful completion of the course, the student will be able to:

- 01 Explain the functioning of microscope, sectioning & staining techniques.
- 02 Describe the cell, cell-organelles, characteristic features of different parts of plant.
- Describe the internal body organs of frog, identification features of different bones.
- 04 Explain the internal organization of different parts of plant.
- Describe the blood group, measurement of the blood pressure and tidal volume.
- 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
- Determination of tidal volume

# **Reference Books**

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

### Semester -II

### PHS-CC-2101: HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

### 45 Hours

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

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

- 1. Explain the gross morphology, structure and functions of various organs of the human body.
- 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, haemoglobin 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.

# LOCF:

Upon successful completion of the course, the student will be able to:

- Describe the structure and functions of the nervous system, Digestive system and its energetics, Respiratory system, Urinary system, Endocrine system, Reproductive system and its genetics of the human body.
- Explain the gross morphology, structure and functions of various organs of the human body.
- Describe the hematological tests like blood cell counts, hemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.
- Appreciate coordinated working pattern of different organs of each system.
   Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

# **Course Content:**

Unit I 10 hours

### **Nervous system**

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophys iology, 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 06 hours

# **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 10 hours

# 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 10 hours

# **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 09 hours

# 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

# Recommended Books (Latest Editions)

- Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypeebrothers medical publishers, New Delhi
- 2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
- Text book of Medical Physiology- Arthur C, Guytonand John. E. Hall. Miamisburg, OH, U.S.A.
- 4. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
- 5. Textbook of Human Histology by Inderbir Singh, Jaypeebrothers medical publishers, New Delhi.
- 6. Textbook of Practical Physiology by C.L. Ghai, Jaypeebrothers medical publishers, New Delhi.

# **Reference Books:**

- 1. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
- 2. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

# PHS-CC-2102: PHARMACEUTICAL ORGANIC CHEMISTRY -I (Theory)

45 Hours

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

**Objectives:** Upon completion of the course the student shall be able to write the structure, name and the type of isomerism of the organic compound write the reaction, name the reaction and orientation of reactions account for reactivity/stability of compounds, identify/confirm the identification of organic compound

### LOCF:

Upon successful completion of the course, the student will be able to:

- Explain IUPAC nomenclature of organic compounds, name and the type of isomerism of the organic compounds.
- Describe the sp2 and sp3 hybridization in alkenes, E1 & E2 reaction kinetics, order of reactivity of alkyl halides, stability of conjugated dienes, Diel -Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement.
- Describe the SN1 and SN2 reactions, structure and uses of ethyl chloride, Chloroform, Trichloroethylene, Tetrachloroethylene, Dichloromethane, Tetrachloromethane, iodoform, Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol.
- Describe the Nucleophilic addition, Cannizzaro reaction ,Electromeric effe ct, Condensation (Aldol, Crossed, Benzoin, Perkin), and structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde.
- Explain the acidity of carboxylic acids, 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, Benzoic acid, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid, and effect of substituent on Basicity, qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine.

# **Course Content:**

General methods of preparation and reactions of compounds superscripted with asterisk (\*) to be explained. To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT-I 07 Hours

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 10 Hours

### Alkanes\*, Alkenes\* and Conjugated dienes\*

sp3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins. Stabilities of alkenes, sp2 hybridization in alkenes

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

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

UNIT-III 10 Hours

# Alkyl halides\*

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

SN1 versus SN2 reactions, Factors affecting SN1 and SN2 reactions

Structure and uses of 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 10 Hours

# 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 08 Hours

# 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, Benzoic acid, Benzoic acid, 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

# **Recommended Books (Latest Editions)**

- 1. Organic Chemistry by Morrison and Boyd
- 2. Organic Chemistry by I.L. Finar , Volume-I
- 3. Textbook of Organic Chemistry by B.S. Bahl&ArunBahl.
- 4. Organic Chemistry by P.L.Soni
- 5. Text Book of Organic name reaction by S. K. Kashaw and Vikash Mishra.

### PHS-CC-2103: PHYSICAL PHARMACEUTICS-I (Theory)

45Hours

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

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

- 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 nad determination of expiry date of formulations
- 3. Demonstrate use of physicochemical properties in the formulationdevelopment and evaluation of dosage forms.

# LOCF:

Upon successful completion of the course, the student will be able to:

- Explain solute solvent interactions and various laws associated with it.
- Describe properties of matter as well as physiochemical properties of drug molecules affecting the design of dosage forms.
- Explain interfacial phenomenon and its applications in the formulation of dosage forms..
- 04 Describe complexions and its Pharmaceutical applications.
- Explain the electromotive force, pH, oxidation reduction systems and buffered isotonic systems

# **Course Content:**

UNIT-I 10 Hours

**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 10Hours

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 10 Hours

**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

UNIT-IV 08 Hours

**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 07 Hours

**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, mixing, material of pharmaceutical plant construction, distillation.

# Recommended Books: (Latest Editions)

- 1. Physical Pharmacy by Alfred Martin
- 2. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
- 3. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
- 4. Physical Pharmaceutics by Ramasamy C and ManavalanR.
- 5. Physical Pharmaceutics by C.V.S. Subramanyam
- 6. Test book of Physical Phramacy, by Gaurav Jain &Roop K. Khar

# PHS-EC-2104: COMPUTER APPLICATIONS IN PHARMACY (Theory)

30 Hours

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

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

- 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

# LOCF:

Upon successful completion of the course, the student will be able to:

- 4.
- Describe the number system of computers, basis of information system and software.
- Explain the web technologies, programming, servers and databases including pharmacy drug data base.
- Describe the multiple applications of computer in pharmacy including information storage, drug modeling, drug designing, medicine identification, patient monitoring and automated dispensing.
- Describe the concept of bioinformatics, its databases and impact in vaccine discovery.
- Explain the application of computers for data analysis in preclinical development like as chromatographic analysis and information management systems.

### **Course content:**

UNIT –I 06 hours

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

Concept of Information Systems and Software: Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

UNIT →I 06 hours

**Web technologies:** Introduction to HTML, XML,CSS and Programming languages, introduction to web servers and Server Products Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

UNIT – III 06 hours

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 autom ated dispensing of drugs, mobile technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

UNIT –IV 06 hours

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

UNIT-V 06 hours

Computers as data analysis in Preclinical development: Chromatographic data analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMS)

### Recommended books (Latest edition):

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

# PHS-EC-2105: ENVIRONMENTAL SCIENCES (Theory)

30 hours

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

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

- 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.

# LOCF:

Upon successful completion of the course, the student will be able to:

- Describe the natural resources and their associated problems, renewable and non-renewable resources.
- Explain the structure and function of ecosystem.
- Describe the environmental pollution, air, water and soil pollution.

# **Course content:**

Unit-I 10 hours

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 10 hours

# **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 10 hours

• Envioronmental Pollution: Air Pollution, Water Pollution, Soil Pollution

# PHS-CC-2106: HUMAN ANATOMY AND PHYSIOLOGY-II (Practical)

4 Hours/week

### LOCF:

Upon successful completion of the course, the student will be able to:

- Describe the anatomy and physiology of integumentary system, Nervous system, Endocrine system, digestive, respiratory, cardiovascular systems, urinary and reproductive systems.
- 02 Explain the different types of taste buds, different parts of eye.
- Perform experiments based on measurement of body temperature and disorders related to high and low body temperature.
- O4 Perform experiments based on basal mass index with the use of body weight and height of an individual.
- 05 Perform experiments based on total blood cells count in the blood sample.

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

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

### Reference Books:

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

### PHS-CC-2107: PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)

4 Hours / week

# LOCF:

Upon successful completion of the course, the student will be able to:

- Perform experiments based on Preliminary tests including Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, and Detection of elements like Nitrogen, Sulfur and Halogen by Lassaigne's test.
- Perform experiments based on functional group test including Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
- Perform experiments based on identification of the unknown compound from the literature using melting point/ boiling point.
- Perform experiments based on preparation of derivatives and confirmation of the unknown compound by melting point/ boiling point.
- 05 Perform experiments based on preparation of solid derivatives from organic compounds.

# Systematic qualitative analysis of unknown organic compounds like

Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.

Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test

### Solubility test

Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.

Melting point/Boiling point of organic compounds

Identification of the unknown compound from the literature using melting point/ boiling point.

Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.

Minimum 5 unknown organic compounds to be analysed systematically.

Preparation of suitable solid derivatives from organic compounds

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&ArunBahl.
- 4. Organic Chemistry by P.L.Soni
- 5. Practical Organic Chemistry by Mann and Saunders.
- Vogel's text book of Practical Organic Chemistry
- 7. Advanced Practical organic chemistry by N.K.Vishnoi.
- 8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
- 9. Reaction and reaction mechanism by Ahluwaliah/Chatwal.

# LOCF:

Upon successful completion of the course, the student will be able to:

- 01 Interpret the significance of physical properties such as solubility, surface tension, partition coefficient and pKa in the design of dosage forms.
- O2 Perform experiments based on determination of Refractive index, optical rotation, dielectric constant, dipole moment, and dissociation constant.
- Test and compare the surface tension of various samples.
- Perform experiments based on the protein binding of various types of drugs.
- Perform experiments based on estimation of stability constants of complexes by solubility and pH titration methods.
- 1. Determination the solubility of drug at room temperature
- 2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
- 3. Determination of Partition co- efficient of benzoic acid in benzene and water
- 4. Determination of Partition co- efficient of lodine in CCI4 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
- Determination of Freundlich and Langmuir constants using activated char coal
- 9. Determination of critical micellar concentration of surfactants
- 10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
- 11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

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

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

## PHS-EC-2109: COMPUTER APPLICATIONS IN PHARMACY (Practical)

02 Hours/Week

### LOCF:

Upon successful completion of the course, the student will be able to:

- 01 Perform experiments based on word processing and able to collect information.
- 02 Perform experiments based on HTML.
- 03 Perform experiments based on various online tools, web pages and XML pages.
- 04 Perform experiments based on principles and application of MS Access.
- 05 Perform experiments based on printing the files.
- 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

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

#### SEMESTER III

## PHS-CC-3101: PHARMACEUTICAL ORGANIC CHEMISTRY -II (Theory)

45 Hours

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

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

- 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.

#### LOCF:

Upon successful completion of the course, the student will able to:

- Describe the aromatic nature of benzene, reaction and effects of substituent on reactivity and orientation of monosubstituted benzene com- pounds towards electrophilic substitution reaction
- Describe the nature, reaction, structure, and uses of phenol, amine, and aromatic acid.
- 03 Explain reactions and analytical constant of fatty acids and oils.
- Describe the synthesis, reactions, structure and medicinal uses of polynuclear hydrocarbons.
- Describe different theories used to explain stability of Cycloalkanes.

#### **Course Content:**

General methods of preparation and reactions of compounds superscripted with asterisk (\*) to be explained To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I 10 Hours

#### 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

Structure and uses of DDT, Saccharin, BHC and Chloramine

UNIT II 10 Hours

**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 10 Hours

#### **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 08 Hours

## Polynuclear hydrocarbons:

Synthesis, reactions

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

UNIT V 07 Hours

# 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.

- 1. Organic Chemistry by Morrison and Boyd
- 2. Organic Chemistry by I.L. Finar, Volume-I
- 3. Textbook of Organic Chemistry by B.S. Bahl&ArunBahl.
- 4. Organic Chemistry by P.L.Soni

45 Hours

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

Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.

Understand the metabolism of nutrient molecules in physiological and pathological conditions.

Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

#### LOCF:

Upon successful completion of the course, the student will able to:

- Describe the carbohydrates, lipids, nucleic acid, amino acids and protein. They will be able to know about the free energy, enthalpy, entropy and know about ATP
- O2 Describe the carbohydrate's metabolism, different biochemical cycle/pathways involve in metabolism of carbohydrate and their significance. They will also know about biological oxidation.
- O3 Explain the lipid metabolism, biological significance of cholesterol, disorders of lipid metabolism, metabolism of amino acids in addition to some diseases including hypercholesterolemia, atherosclerosis, phenyl ketonuria, albinism, hyperbilirubinemia and jaundice.
- O4 Describe the metabolism of nucleic acids. Complete knowledge about genetic information DNA, RNA genetic code and protein synthesis.
- 05 Explain the enzymes, kinetics of enzyme, regulation of enzyme and therapeutic and diagnostic application of enzymes **Course Content:**

UNIT I 08 Hours

#### **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 10 Hours

#### 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 level phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers

UNIT III 10 Hours

### Lipid metabolism

β-Oxidation of saturated fatty acid (Palmitic acid)

Formation and utilization of ketone bodies; ketoacidosis De novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

#### Amino acid metabolism

General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia) Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline Catabolism of heme; hyperbilirubinemia and jaundice

UNIT IV 10 Hours

### 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 07 Hours

### **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

- 1. Principles of Biochemistry by Lehninger.
- 2. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
- 3. Biochemistry by Stryer.
- 4. Biochemistry by D. Satyanarayan and U.Chakrapani
- 5. Textbook of Biochemistry by Rama Rao.
- 6. Textbook of Biochemistry by Deb.
- 7. Outlines of Biochemistry by Conn and Stumpf

# PHS-CC-3103: PHARMACEUTICAL MICROBIOLOGY (Theory)

45Hours

**Scope:** Study of all categories of microorganisims especially for the production of alchol antibiotics, vaccines, vitamins enzymes etc..

Objectives: 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 sterlization 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.

### LOCF:

Upon successful completion of the course, the student will able to:

- Describe the history and scope of microbiology, principles & methods of identification, cultivation and preservation of various microorganisms.
- Describe the identification of bacteria using staining techniques, sterilization methods and evaluation of the efficiency of sterilization methods.
- Explain the morphology, classification, reproduction/replication and cultivation of fungi and viruses. Also understand the classification, evaluation and mode of action of disinfectants, sterility testing of products according to IP, BP and USP.
- Describe the clean area classification, designing of aseptic area, laminar flow equipment, sources of contamination in aseptic area and methods of prevention in addition to the principles and methods of microbiological assays, standardization of antibiotics, vitamins and amino acids.
- Describe the preservation of pharmaceutical products using antimicrobial agents and evaluation of microbial stability of formulations in addition to the cell culture and its applications in pharmaceutical industry and research.

#### Course content:

Unit I 10 Hours

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 constrast microscopy, dark field Microscopy and electron microscopy.

Unit II 10 Hours

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 10 Hours

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 08 Hours

Designing of aseptic area, laminar flow equipments; study of differentsources of contamination in an aseptic area and methods of prevention, clean area classification.

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

Unit V 07Hours

Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations. Application of cell cultures in pharmaceutical industry and research.

- 1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
- 2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
- 3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
- 4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
- 5. Rose: Industrial Microbiology.
- 6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
- 7. Peppler: Microbial Technology.
- 8. I.P., B.P., U.S.P.- latest editions.
- 9. Ananthnarayan: Text Book of Microbiology, Orient-Longman, Chennai
- 10. Edward: Fundamentals of Microbiology.
- 11. N.K.Jain: Pharmaceutical Microbiology, VallabhPrakashan, Delhi

## PHS-CC-3104: PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

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

**Objectives:** Upon completion of the course student shall be able:

- 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.

### LOCF:

Upon successful completion of the course, the student will able to:

- O1 Explain fundamentals of material and energy balance, mechanisms of size reduction and size separation,
- 02 Describe heat transfer mechanisms and concerned laws, evaporators and distillation techniques.
- Demonstrate mechanism drying process and dryers as well as various mixers.
- 04 Explain theories of filtration and constructions and working of the filters as well as centrifugation principle and applications.
- 05 Elaborate corrosion and various corrosion preventive methods in pharmaceutical industries.

### Course content:

UNIT-I 10 Hours

**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, Air separator, Bag filter & elutriation tank. **UNIT-II**10 Hours

**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 10 Hours

**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 b ed dryer, vacuum dryer, freeze dryer.

**Mixing:** Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, I iquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone bl ender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

UNIT-IV 08 Hours

**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 07 Hours

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.

- 1. Introduction to chemical engineering Walter L Badger & Julius Banchero, Latest edition.
- 2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson-Latest edition.
- 3. Unit operation of chemical engineering Mcabe Smith, Latest edition.
- 4. Pharmaceutical engineering principles and practices C.V.S Subrahmanyam et al., Latest edition.
- 5. Remington Practice of Pharmacy- Martin, Latest edition.
- 6. Theory and Practice of Industrial Pharmacy by Lachmann., Latest edition.
- 7. Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.

### PHS-CC-3105: PATHOPHYSIOLOGY (THEORY)

45 Hours

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

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

- 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.

#### LOCF:

Upon successful completion of the course, the student will able to:

- Describe the Basic principles of Cell injury, Adaptation and basic mechanism involved in the process of inflammation and repair.
- Explain the disorders related to cardiovascular, respiratory and renal system of the human body.
- Describe the etiology and pathogenesis, signs and symptoms and complications of the diseases related to Hematology, endocrine and gastrointestinal system.
- O4 Explain the diseases of bones and joints. Students will also acquire knowledge about on Principles of cancer and inflammatory bowel diseases, jaundice, hepatitis, alcoholic liver disease
- 05 Describe etiology and pathogenesis, signs and symptoms and complications of all the infectious diseases.

#### Course content:

Unit I 10 Hours

## 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

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#### 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, Pathop hysiology of Atherosclerosis.

Unit II 10 Hours

#### 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 10 Hours

Haematological Diseases:

Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, 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 8 Hours

- 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 07 Hours

Infectious diseases: Meningitis, Typhoid, Leprosy, Tuberculosis Urinary Tract Infections

Sexually transmitted diseases: AIDS, Syphilis, Gonorrhea

### Recommended Books (Latest Editions)

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.

- 2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
- 3. Laurence B, Bruce C, Bjorn K.; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
- 4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states; William and Wilkins, Baltimore;1991 [1990 printing].
- 5. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
- Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
- 7. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey;
- 8. Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
- 9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
- 10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

#### **Recommended Journals**

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

#### LOCF:

Upon successful completion of the course, the student will able to:

- 01 Explain the structure, name and the type of isomerism of the organic compound.
- 02 Perform experiments based on reaction, name the reaction and orientation of reactions.
- 03 Perform experiments based on reactivity/stability of compounds.
- O4 Perform experiments based on preparation of organic compounds.

# Experiments involving laboratory techniques

- Recrystallization
- Steam distillation

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

- Acid value
- Saponification value
- lodine value

### 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-napthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
- Cinnammic acid from Benzaldehyde by Perkin reaction
- P-lodo benzoic acid from P-amino benzoic acid

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

### LOCF:

Upon successful completion of the course, the student will able to:

- Perform experiments based on detection of carbohydrates, peptide bond in proteins, reducing sugars (DNSA method).
- Perform experiments based on urine analysis including detection of protein in urine, abnormal constituents in urine and creatinine levels. Also, some experiments on sugar in blood.
- Perform experiments based on measurement of LDL ("bad" cholesterol), HDL ("good" cholesterol), and triglycerides in order to determine the total blood cholesterol, serum cholesterol.
- O4 Prepare buffer solutions and measure the pH as the conditions like acidosis/alkalosis intimates us about metabolic disorders in our body.
- 05 Perform experiments based on hydrolysis of starch and effect of temperature on enzyme activity.
- 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

- Principles of Biochemistry by Lehninger.
- 2. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
- 3. Biochemistry by Stryer.
- 4. Biochemistry by D. Satyanarayan and U.Chakrapani
- 5. Textbook of Biochemistry by Rama Rao.
- Textbook of Biochemistry by Deb.
- 7. Outlines of Biochemistry by Conn and Stumpf
- 8. Practical biochemistry by O.P. Agrawal

## LOCF:

Upon successful completion of the course, the student will able to:

- Perform experiments based on the physical parameters, different cells to analyze a normal urine and comparing it with diseased sample.
- Perform experiments based on different methods to detect blood sugar level and diseases related to abnormal blood sugar level in blood.
- Describe the symptoms of a possible heart problem, such as chest pain, palpitations (suddenly noticeable heartbeats), dizziness and shortness of breath.
- Perform experiments based on evaluation of diagnosis of asthma, chronic obstructive pulmonary disease (COPD) and other conditions that affect breathing

  Perform experiments based on different muscle fatigue detecting techniques for e.g. surface Electromyography
- 05 (sEMG) and Mechanomyography (MMG) and will be able to know about recording the electrical activity signal from the muscle.
- Perform experiments based on different diagnostic tests performed in laboratory related to human samples.
- 1. Physical analysis of urine.
- 2. Clinical analysis of urine.
- 3. Estimation of sugar content
- Microscopic examination of analysis urine sediment.
- 5. ECG interpretation.
- 6. Hematology and laboratory and laboratory tests.
- 7. Experiments based on spirometry.
- Experiments based on muscle fatigue.
- 9. Experiments based on histology.
- 10. Common laboratory and diagnostic tests.

### Recommended Books:

- 1. Vinay Kumar, Abdul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia Edition; India; Elsevier; 2014.
- 2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
- 3. Laurence B, Bruce C, Bjorn K..; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12<sup>th</sup> edition; New York; Mc Graw Hill; 2011.
- Pathophysiology A Practical Approach, Lachel Story, Jones & Bartlett Learning; 3 Edition (March 15, 2007) ISBN-13: 978-1284120196.
- 5. An Essential Guide to Pathophysiology: Practical & Oral Examinations, M.K. Chaudhuri, New Central Book Agency (P) Limited, 2005, ISBN-817381337X, 9788173813375.
- 6. A Text Book of Pathophysiology, Dr. S. L. Bodhankar, Dr. N. S. Vyawahare, Nirali Prakashan, ISBN -9788196396169

#### LOCF

Upon successful completion of the course, the student will able to:

- Perform experiments based on 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
- 02 Perform experiments based on sterilize glassware, preparation and sterilization of media.
- O3 Perform experiments based on preparation of nutrient stabs and slants preparations.
- Perform experiments based on staining (Simple, Grams staining and acid -fast staining) and isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
- Perform experiments based on microbiological assay of antibiotics by cup plate method and other methods, bacteriological analysis of water and sterility testing of pharmaceuticals.
- 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

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

#### **LOCF**

Upon successful completion of the course, the student will able 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.
- Determine overall heat transfer coefficient by heat exchanger and calculate the distillation. efficiency of steam
- 03 Demonstrate the factors affecting the drying and mixing
- O4 Analyze the factors affecting rate of filtration and centrifugation.
- 05 Assess the types of corrosion.
  - 1. Determination of radiation constant of brass, iron, unpainted and painted glass.
  - 2. Steam distillation To calculate the efficiency of steam distillation.
  - 3. To determine the overall heat transfer coefficient by heat exchanger.
  - 4. Construction of drying curves (for calcium carbonate and starch).
  - 5. Determination of moisture content and loss on drying.
  - 6. Determination of humidity of air i) From wet and dry bulb temperatures –use of Dew point method.
  - 7. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
  - 8. Size analysis by sieving To evaluate size distribution of tablet granulations Construction of various size frequency curves including arithmetic and logarithmic probability plots.
  - 9. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
  - 10. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such othermajor equipment.
  - 11. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
  - 12. To study the effect of time on the Rate of Crystallization.
  - 13. To calculate the uniformity Index for given sample by using Double Cone Blender.
  - 14. Determination of flow of fluid by using Pitot tube/Reynold's Venturimeter.
  - 15. Interpretation and Study of different equipment and processing of:
  - 16. Dryer/Ball mill venturimeter/Pitot tube/ Orifice meter/ Pellet machine/ distillation plant/ sigma blade mixer and other equipment used in pharmaceutical engineering.

# Semester IV

## PHS-CC-4101: PHARMACEUTICAL ORGANIC CHEMISTRY -III (Theory)

45 Hours

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

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

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

#### LOCF

Upon successful completion of the course, the student will able to:

- Explain the stereo chemical aspects of organic compounds and stereo chemical reactions.
- Describe the methods of determination of configuration of geometrical isomers and conformational isomerism in alkanes and bicyclic compounds.
- Explain nomenclature, classification, synthesis, reactions and medicinal uses of heterocyclic compounds.
- 04 Describe the synthesis, reactions and medicinal uses of Pyrimidine, Purine, azepines and their derivatives
- 05 Explain the reactions of synthetic importance such as reduction, rearrangement and oxidation reactions.

#### **Course Content:**

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

UNIT-I 10 Hours

#### 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 10 Hours

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 10 Hours

#### 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 8 Hours

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrazole, Imidazole, Oxazole and Thiazoles.

Pyridine, Quinoline, Isoquinoline, Acridine and Indole.

Basicity of pyridine

Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

UNIT-V 07 Hours

## Reactions of synthetic importance

Metal hydride reduction (NaBH4 and LiAlH4), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement.

Claisen-Schmidt condensation

- 1. Organic chemistry by I.L. Finar, Volume-I & II.
- 2. A text book of organic chemistry Arun Bahl, B.S. Bahl.
- 3. Heterocyclic chemistry by Raj K. Bansal
- 4. Organic chemistry by Morrison and Boyd
- 5. Heterocyclic chemistry by T.L. Gilchrist
- 6. Text Book of Organic name reaction by S. K. Kashaw and Vikash Mishra.

## PHS-CC-4102: MEDICINAL CHEMISTRY-I (Theory)

45 Hours

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

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

- understand the chemistry of drugs with respect to their pharmacological activity
- 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

### LOCF

Upon successful completion of the course, the student will be able to:

- Describe the basic concept and development of medicinal chemistry, various physiological parameters affecting drug action, concept of drug metabolism, its principle and factors influencing metabolism along with stereo -chemical aspects
- Explain the drug acting on ANS with biosynthetic pathway and its catabolism of catecholamines, SAR of different sympathomimetic agent and detailed study of different adrenergic antagonists.
- Describe various cholinergic neurotransmitters along with SAR of various parasympathomimetic agents (direct and indirect acting agents) and synthetic cholinergic blocking agents.
- Describe the classification of various medicinal agent with mode of action acting on central nervous system (CNS)such sedative and hypnotics, Antipsychotics, Anticonvulsants
- Describe the medicinal agent acting on (CNS) such as general anesthetics, narcotic and non -narcotic and anti -inflammatory agents.

### **Course Content:**

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

UNIT- I 10 Hours

**Introduction to Medicinal Chemistry** 

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

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

#### Drug metabolism

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

UNIT- II 10 Hours

**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 10 Hours

### 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 (Reversible) (

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, Cyclopentolatehydrochloride, Clidinium bromide, Dicyclominehydrochloride\*, Glycopyrrolate, Methantheline

bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine

hydrochloride, Procyclidine hydrochloride\*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

UNIT- IV 08 Hours

### **Drugs acting on Central Nervous System**

#### A. Sedatives and Hypnotics:

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

Barbiturtes: SAR of barbiturates, Barbital\*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital

Miscelleneous:

Amides & imides: Glutethmide.

Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

**B.** Antipsychotics

Phenothiazeines: SAR of Phenothiazeines - Promazine hydrochloride, Chlorpromazine hydrochloride\*,

Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.

Ring Analogues of Phenothiazeines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride

C. Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action

**Barbiturates:** Phenobarbitone, Methabarbital. **Hydantoins:** Phenytoin\*, Mephenytoin, Ethotoin

Oxazolidine diones: Trimethadione, Paramethadione

**Succinimides:** Phensuximide, Methsuximide, Ethosuximide\* **Urea andmonoacylureas:** Phenacemide, Carbamazepine\*

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate

UNIT – V 07 Hours

**Drugs acting on Central Nervous System** 

General anesthetics:

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

Ultra short acting barbitutrates: Methohexital sodium\*, Thiamylal 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, Anilerdine 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, Zomepriac, Diclofenac, Ketorolac, Ibuprofen\*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

- 1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
- 2. Foye's Principles of Medicinal Chemistry.
- 3. Burger's Medicinal Chemistry, Vol I to IV.
- 4. Introduction to principles of drug design- Smith and Williams.
- 5. Remington's Pharmaceutical Sciences.
- Martindale's extra pharmacopoeia.
- 7. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
- 8. Indian Pharmacopoeia.

## PHS-CC-4103: PHYSICAL PHARMACEUTICS-II (Theory)

45Hours

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

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

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

### **LOCF**

Upon successful completion of the course, the student will be able to:

- 01 Compare the types and properties of colloids and macromolecular systems
- 02 Explain Newtonian and Non-Newtonian systems and role of thixotropy in the formulation of the stable formulations.
- Demonstrate flocculated and deflocculated suspensions as well as stability of the emulsions.
- Elaborate the concepts of fundamental and derived properties of powders and its role in the formulation of stable pharmaceutical solid dosage forms.
- 05 Assess Accelerated stability of pharmaceutical dosage forms.

Course Content:

UNIT-I 07 Hours

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 10 Hours

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temper ature, 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 10 Hours

Coarse dispersion: Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of floccul ated and deflocculated suspensions. Emulsions and theories of emulsificat ion, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formulation by HLB method.

UNIT-IV 10Hours

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

UNIT-V 08 Hours

Drug stability: Reaction kinetics: zero, pseudo -zero, first & second order, units of basic rate constants, determination of reaction ord er. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic str ength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agent s against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Pho tolytic degradation and its prevention

- 1. Physical Pharmacy by Alfred Martin, Sixth edition
- 2. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
- 3. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
- 4. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
- 5. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

### PHS-CC-4104: PHARMACOLOGY-I (Theory)

45 Hrs

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

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

- 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

#### LOCF

Upon successful completion of the course, the student will be able to:

- Describe the basic principles of pharmacology and branches of pharmacology in addition to the pharmacokinetic parameters of the drug.
- Explain the basic principles of pharmacodynamic parameters of the drug and principles and mechanisms of drug action, receptor theories & classification of receptors.
- 03 Describe the Pharmacology of drugs acting on peripheral nervous system and drugs acting on ANS.
- Describe the Pharmacology of drugs acting on central nervous system neurotransmission and specific neurotransmitters of CNS.
- 05 Describe detailed information of drugs acting on CNS like Psychopharmacological agents, CNS stimulants.

#### **Course Content:**

# UNIT-I 08 hours

#### **General Pharmacology**

- a) Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, Antagonists (competitive and non-competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.
  - b) Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs. Enzyme induction, enzyme inhibition, kinetics of elimination

# UNIT-II 12 Hours

### **General Pharmacology**

**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 10 Hours

### Pharmacology of drugs acting on peripheral nervous system

- a. Organization and function of ANS.
- b. Neurohumoral transmission, co-transmission and classification of neurotransmitters.
- c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.
- d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).
- e. Local anesthetic agents.
- f. Drugs used in myasthenia gravis and glaucoma

UNIT-IV 08 Hours

- a) Pharmacology of drugs acting on central nervous system
- b) Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.
- c) General anesthetics and pre-anesthetics.
- d) Sedatives, hypnotics and centrally acting muscle relaxants.
- e) Anti-epileptics
- f) Alcohols and disulfiram

UNIT-V 07 Hours

### Pharmacology of drugs acting on central nervous system

- 1. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
- 2. Drugs used in Parkinsons disease and Alzheimer's disease.
- 3. CNS stimulants and nootropics.
- 4. Opioid analgesics and antagonists
- 5. Drug addiction, drug abuse, tolerance and dependence.

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

45 Hours

**Scope:** The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals and their medicinal properties.

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

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

#### LOCF

Upon successful completion of the course, the student will be able to:

- 01 Explain introduction of Pharmacognosy and various techniques used in the cultivation & production of crude drugs as per syllabus
- 02 Describe the classification of crude drugs, their uses and phytochemical characteristics.
- 03 Explain plant tissue culture and its application in phyto pharmaceutical development.
- 04 Describe the microscopic and morphological evaluation of crude drugs and describe various evaluation techniques used for herbal drugs.
- 05 Explain the importance of pharmacognosy in various traditional medicines and production of plant derived products.

#### **Course Content:**

UNIT-I 10 Hours

#### Introduction to Pharmacognosy:

- a) Definition, history, scope and development of Pharmacognosy
- b) 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 sero taxonomical classification of drugs

#### **Quality Control of Drugs of Natural Origin:**

Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties. Quantitative microscopy of crude drugs including lycopodium spore method, leafconstants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT-II 10 Hours

### 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 07 Hours

### 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 10 Hours

### 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 08 Hours

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.

- 1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
- 2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
- 3. Text Book of Pharmacognosy by T.E. Wallis
- Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
- Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
- 6. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
- 7. Anatomy of Crude Drugs by M.A. Iyengar

### PHS-CC-4106: MEDICINAL CHEMISTRY -I (Practical)

#### 4 Hours/Week

## **LOCF**

Upon successful completion of the course, the student will be able to:

- Perform experiments based on preparation of drug and their mechanisms of action, structure -activity relationships (SAR), acid-base and physicochemical properties.
- Perform assay of the drugs, measuring the presence, amount, or functional activity of a t arget entity (Drugs)to determine its effectiveness or potency in preventing illness.
- Perform experiments based on pharmacokinetic profile of the drug such as absorption, distribution, metabolism and excretion.
- O4 Prepare, characterize and find out percentage yield of the drugs containing different heterocyclic nucleus.

## I Preparation of drugs/ intermediates

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

## II Assay of drugs

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

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

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

## **LOCF**

Upon successful completion of the course, the student will be able to:

- 01 Characterize the various properties of colloids.
- 02 Determine the viscosity of liquids using Ostwald's and Brookfield's viscometer.
- Recognize the micromeritics of powder, determine the globule size of an emulsion and the effect of phase volume ratio on stability of emulsion.
- 04 Perform experiments based on particle size and its distribution using various size determination methods.
- 05 Relate the accelerated stability testing of tablet formulations.
- 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

- 1. Physical Pharmacy by Alfred Martin, Sixth edition
- Experimental pharmaceutics by Eugene, Parott.
- 3. Tutorial pharmacy by Cooper and Gunn.
- 4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
- 5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
- Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2,
   Marcel Dekkar Inc.
- 7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

4Hrs/Week

### **LOCF**

Upon successful completion of the course, the student will be able to:

- Demonstrate preclinical and clinical study designs in a stepwise phase of investigations and the importance of the experimental animals used in pharmacological experiments
- 02 Demonstrate different experimental instruments used in pharmacology laboratory for different activities of animals
- 03 Perform experiments based on blood withdrawal, serum and plasma separation methods
- Perform experiments based on different routes of drugs administration used in different animals specifically mice/rats.
- Perform experiments based on effect of barbiturates, skeletal muscle relaxants, CNS acting drugs ,stimulation of sympathetic and parasympathetic nerves by the drugs, anxiolytic drugs etc.
  - 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.
  - 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
  - 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

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

### PHS-CC-4109: PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

4 Hours/Week

#### **LOCF**

Upon successful completion of the course, the student will be able to:

- O1 Carry out analytical protocols and chemical tests for test materials including Tragacanth, Acacia, Agar, Gelatin, Starch, Honey and Castor oil.
- Perform and describe the quantitative microscopic evaluation using parameters like stomatal index, vein islet number, vein termination number, palisade ratio of organized drugs as per syllabus of course code PHS-CC-4105.
- 03 CarryoutandexplainthepowdermicroscopyofcrudedrugsaspersyllabusofcoursecodePHS -CC-4105.

#### Perform experiments based

- onthemicroscopicandmorphologicalevaluationofcrudedrugsanddescribevariousevaluationtechniquesusedforher baldrugs.
- 05 Perform experiments based onextractive and ashvalues of crudeherbal material of medicinal importance.
  - 1. Analysis of crude drugs by chemical tests: (i)Tragaccanth (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 paliside 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

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

## SEMESTER V

PHS-CC-5101: MEDICINAL CHEMISTRY - II (Theory)

45 Hours

which is

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

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

- 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 of different class of drugs
- 4. Study the chemical synthesis of selected drugs

### LOCF

agents.

Upon successful completion of the course, the student will be able to:

- Explain the underlying principles like mechanism of action, synthesis of drug and their site of receptor or tar get. Get familiar with classification, uses and side effects of drugs like Antihistaminic, Proton pump inhibitors, Anti -neoplastic
- Describe the classification, synthesis, mechanism of action, structure activity relationship the uses of drug used in the management of heart related disorders like Anti-anginal, Diuretics and anti-hypertensive agents.
- Explain understand the role of various drugs in the management of cardiac disorders like arrythmia, CHF and supporting drugs like anti-lipidemic and anti-coagulants and their classification or their synthesis.
- Explain synthesis, mechanism of action, stereochemistry of drug acting on endocrine system and related disorders. Role of sex hormones.
- Explain the synthesis and role of insulin in the management of diabetes. Classification, synthesis, mechanism of action, structure activity relationship the uses of drug which is used in the management of diabetes.

#### **Course Content:**

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

UNIT- I 10 Hours

Antihistaminic agents: Histamine, receptors and their distribution in the humanbody

**H1–antagonists:** Diphenhydramine hydrochloride\*, Dimenhydrinate, Doxylamines cuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidinehydrochloride\*, Phenidamine tartarate, Promethazine hydrochloride\*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

**H2-antagonists:** Cimetidine\*, Famotidine, Ranitidin.

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

Anti-neoplastic agents:

Alkylating agents: Meclorethamine\*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa.

**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 ` 10 Hours

### Anti-anginal:

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

**Calcium channel blockers:** Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

#### **Diuretics:**

Carbonic anhydrase inhibitors: Acetazolamide\*, Methazolamide, Dichlorphenamide. Thiazides: Chlorthiazide\*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide\*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

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

UNIT- III 10 Hours

**Anti-arrhythmic Drugs:** Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate\*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide 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 08 Hours

### **Drugs acting on Endocrine system**

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol

**Corticosteroids:** Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone **Thyroid and antithyroid drugs:** L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

UNIT – V 07 Hours

#### Antidiabetic agents:

Insulin and its preparations

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

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide. Glucosidase inhibitors: Acrabose, 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, Diperodon, Dibucaine.\*

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

## PHS-CC-5102: Industrial Pharmacyl (Theory)

45 Hours

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

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

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

#### LOCF

Upon successful completion of the course, the student will be able to:

- O1 Explain the various pharmaceutical dosage forms and their manufacturing techniques.
- 02 Explain various considerations in the development of pharmaceutical dosage forms.
- Describe the formulation of solid, liquid, and semisolid dosage forms and evaluate them for their quality.

#### Course content:

3 hours/ week

UNIT-I 07 Hours

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

- a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism
- b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs & its significant Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT-II 10 Hours

#### 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 08 Hours

#### 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 10 Hours

Parenteral Products:

a. 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 10 Hours

**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 aeros ol 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.

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

45 Hours

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

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

- 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

## **LOCF**

Upon successful completion of the course, the student will be able to:

- Describe the pharmacology of drugs acting on cardio vascular system namely congestive heart failure, Anti hypertensive drugs, Anti-anginal drugs, Anti-arrhythmic drugs and Anti-hyperlipidemic drugs.
- Explain the pharmacology of drugs acting on cardio vascular system namely Drug used in the therapy of shock., hematinics, coagulants and anticoagulants, fibrinolytics and anti-platelet drugs, Plasma volume expanders Students will also learn about drugs acting on urinary system.
- Explain the Pharmacology of Histamine, 5-HT and their antagonists and related drugs.
- Describe the basic concepts in endocrine pharmacology and hormones secreted from Anterior Pituitary, thyroid glands and hormones effecting calcium balance etc.
- Explain the basic concepts in endocrine pharmacology and Pharmacology of drugs under the category of Androgens and Anabolic steroids and drugs acting on uterus. Students will be able to learn about Principles and applications of bioassay.

#### **Course Content:**

UNIT-I 10 hours

#### Pharmacology of drugs acting on cardio vascular system

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

UNIT-II 10 hours

### Pharmacology of drugs acting on cardio vascular system

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

### Pharmacology of drugs acting on urinary system

- a. Diuretics
- b. Anti-diuretics.

UNIT-III 10 hours

## Autocoids and related drugs

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

- c. Prostaglandins, Thromboxanes and Leukotrienes.
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatory agents
- f. Anti-gout drugs.
- g. Antirheumatic drugs.

UNIT-IV 08 hours

## Pharmacology of drugs acting on endocrine system

- a. Basic concepts in endocrine pharmacology.
- b. Anterior Pituitary hormones- analogues and their inhibitors.
- c. Thyroid hormones- analogues and their inhibitors.
- d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
- e. Insulin, oral hypoglycemic agents and glucagon.
- f. ACTH and corticosteroids.

UNIT-V 07 hours

## Pharmacology of drugs acting on endocrine system

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

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

## PHS-CC-5104: PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

**Scope:** The main purpose of subject is to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

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

- to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
- 2. to understand the preparation and development of herbal formulation.
- 3. to understand the herbal drug interactions
- 4. to carryout isolation and identification of phytoconstituents

### LOCF

Upon successful completion of the course, the student will be able to:

- Describe the metabolic pathways of different secondary metabolites of plants and explain the extraction techniques, characterization & identification procedures used for the herbal crude drugs & phytoconstituents.
- Explain the commercial values of Alkaloids, Phenylpropanoids and Flavonoids, Steroids, Cardiac Glycosides & Triterpenoids, Volatileoils, Tannins, Resins, Glycosides with suitable examples as specifie d in course content.
- Describe herbal drug interactions and its importance in therapeutics involving botanical actives and explain the processes involved in herbal preparations and development of phyto -formulations.
- 04 Understand and explain isolation and identification of phyto -actives of medicinal importance.
- 05 Explain

The extractive and ash values of crude herbal material of medicinal importance and describe the industrial production of phytoleads as enlisted under course content.

#### **Course Content:**

UNIT-I 7 Hours

### Metabolic pathways in higher plants and their determination

- a. Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways-Shikimic acid pathway, Acetate pathways and Amino acid pathway.
- b. Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT-II 14 Hours

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 06 Hours

#### Isolation, Identification and Analysis of Phytoconstituents

- a) Terpenoids: Menthol, Citral, Artemisin
- b) Glycosides: Glycyrhetinic acid & Rutin
- c) Alkaloids: Atropine, Quinine, Reserpine, Caffeine
- d) Resins: Podophyllotoxin, Curcumin

UNIT-IV 10 Hours

Industrial production, estimation and utilization of the following phytoconstituents:

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

UNIT V 8 Hours

### **Basics of Phytochemistry**

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

- 1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
- 2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
- 3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
- 4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
- 5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
- 6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
- 7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
- 8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
- 9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
- 10. Remington's Pharmaceutical sciences.

## PHS-CC-5105: PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

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

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

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

### LOCF

Upon successful completion of the course, the student will be able to:

- 01 Describe the Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
- 02 Explain various Indian pharmaceutical Acts and Laws.
- Describe the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.
- Describe the code of ethics during the pharmaceutical practice.

## Course Content:

UNIT-I 10 Hours

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 10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945.

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 10 Hours

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 08 Hours

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, 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 07 Hours

Code of Pharmaceutical ethics D efinition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath Right to Information Act

Introduction to Intellectual Property Rights (IPR):

Patent/Copyright/Trademark/IC/Trade secret/G.I

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

## **LOCF**

Upon successful completion of the course, the student will be able to:

- Perform the experiments based on mechanism of organic reaction involved in the synthesis of compounds as enlisted in theory subject (PHS-CC-5101).
- Perform the experiments based on synthesis of Methylphenobarbital, Barbital Nikethamide, Pantaprazol, Diclofenamide, phenobarbitone, and phenothiazine.
- Perform the experiments bas ed on mechanism of reaction of synthesis of furosemide, Levodopa, Chlorpromazine, phenytoin, Aspirin and their uses.
  - Explain importance and the benefits of green chemistry over conventional method of synthesis those are like less
- of formation of hazardous byproducts, to prevent water pollution due to hazardous chemical and production of safer consumable products.
- Synthesize various rearrangement reactions including Benzil-Benzilic acid rearrangement, mechanism of Photoreduction and concept of solid-state synthesis.

### Synthesis of

- 1. Methylphenobarbital
- 2. Barbital Nikethamide
- 3. Pantaprazol
- 4. Diclofenamide
- 5. Phenobarbitone
- 6. Phenothiazine
- 7. Furosemide
- 8. Levodopa
- 9. Chlorpromazine
- 10. Phenytoin
- 11. Aspirin

### Synthesis of the following compounds via green chemistry method

- 1. Synthesis of acetanilide
- 2. Synthesis of dibenzal propanone
- 3. Diels-Alder reaction between furan and maleic acid
- 4. Benzil- Benzilic acid rearrangement
- 5. Nitration of phenol
- 6. Bromination of acetanilides
- 7. Photoreduction of benzophenone to benzopinacol
- 8. Synthesis of benzopinacol
- 9. Synthesis of adipic acid
- 10. Clay catalyzed solid state synthesis of 7-hydroxy-4-methyl coumarin
- 11. Synthesis of dihyropyrimidinone
- 12. Synthesis of 1,1-bis-2-napthol
- 13. Manganese (III) acetylacetonate
- 14. Iron (III) acetylacetonate

#### Books recommended:

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

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## **LOCF**

Upon successful completion of the course, the student will be able to:

- O1 Perform the experiments based on pre-formulation studies of drugs for developing pharmaceutical formulations.
- Perform the experiments based on preparation and evaluation of various types of pharmaceutical dosage forms including tablet, capsule, parenteral, eye drops, eye ointments, creams (cold cream and vanishing cream).
- Perform the experiments based on tablet coating procedures.
- 04 Perform the experiments based on quality control testing of marketed products (tablets and capsules).
- Perform the experiments based on evaluation of glass containers (as per IP).
  - 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)

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

## **LOCF**

Upon successful completion of the course, the student will be able to:

- Perform the experiments based on *in-vitro* studies involving experimental animals used in pharmacological investigations and use of physiological salt solution in experimental protocols.
- Perform the experiments based on effects of drugs on isolated hear t preparation with the help of using specific pharmacological software.
- Perform the experiments based on different methods of recording blood pressure and heart rate of dog and other animals using pharmacological software.
- Perform the experiments based on evaluation of diuretic activity using pharmacological software.
- Perform the experiments based on histamine, serotonin, oxytocin. the DRC curve of graded responses to Acetylcholine, physostigmine, atropine, atropine, atropine, histamine, serotonin, oxytocin.
  - 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 PA2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
  - 12. Determination of PD2 value using guinea pig ileum.
  - 13. Effect of spasmogens and spasmolytics using rabbit jejunum.
  - 14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
  - 15. Analgesic activity of drug using central and peripheral methods

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

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

### PHS-CC-5109: PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

## **LOCF**

Upon successful completion of the course, the student will be able to:

- O1 Carry out analytical protocols and powder characterization of Cinchona, Cinnamon, Senna, Clove, Ephedra ,Fennel and Coriander.
- O2 Perform the experiments based on chromatographic profile of herbal materials.
- Perform TLC based experiments and explain the separation processes involved in chromatographic protocols
- Carry out the hydro -distillation based experiments and explain volatile oils contents of plants
- 05 Perform the experiments based on qualitative chemical profile herbal material of medicinal importance.
  - 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
  - Distillation of volatile oils and detection of phytoconstitutents by TLC
  - 10. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

- 1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
- 2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
- 3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
- 4. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.
- Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
- 6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
- 7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
- 8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
- 9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
- 10. The formulation and preparation of cosmetic, fragrances and flavours.
- 11. Remington's Pharmaceutical sciences.

## SEMESTER VI

PHS-CC-6101: MEDICINAL CHEMISTRY - III (Theory)

45 Hours

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

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

- 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.

### LOCF

Upon successful completion of the course, the student will be able to:

- Describe the historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation, classification and important products of the β-Lactam antibiotics, Aminoglycosides, and Tetracyclines.
- Describe the historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation, classification and important products of the Macrolide, quinolines, biquanides, dihydrotriazines.
- Describe the historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation, classification and important products of the anti-tubercular drugs, Urinary tract anti-infective agents, and Antiviral agents.
- Describe historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degrada tion, classification and important products of the antifungal agents, anti -protozoal Agents, anthelmintics, sulphonamides and sulfones, folate reductase inhibitors.
- Explain various approaches of drug design, synthesis of drugs using solvent phase and s olid phase synthesis and parameters used in quantitative structure activity relationship (QSAR).

## **Course Content:**

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

UNIT – I 10 Hours

#### Antibiotics

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

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

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II 10 Hours

#### **Antibiotics**

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification an dimportant 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, Artesunete, Artemether, Atovoquone.

UNIT – III 10 Hours

### **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 Tioconozole, Miconazole\*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate\*.

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

Anthelmintics: Diethylcarbamazine citrate\*, Thiabendazole, M ebendazole\*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

### **Sulphonamides and Sulfones**

Historical development, chemistry, classification and SAR of Sulfonamides:

Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide\*, Sulphapyrid ine, Sulfamethoxaole\*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim\*, Cotrimoxazole.

Sulfones: Dapsone\*.

UNIT – V 07 Hours

### Introduction to Drug Design

Various approaches used in drug design.

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

Pharmacophore modeling and docking techniques.

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

- 1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
- 2. Foye's Principles of Medicinal Chemistry.
- 3. Burger's Medicinal Chemistry, Vol I to IV.
- 4. Introduction to principles of drug design- Smith and Williams.
- 5. Remington's Pharmaceutical Sciences.
- Martindale's extra pharmacopoeia.
- 7. Organic Chemistry by I.L. Finar, Vol. II.
- 8. Indian Pharmacopoeia.

## PHS-CC-6102: PHARMACOLOGY-III (Theory)

45 Hours

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

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

- 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.

### LOCF

Upon successful completion of the course, the student will be able to:

- Explain mechanism of drug action and its relevance in the treatment of different infectious diseases of respiratory system and gastrointestinal tract.
- 02 Describe general principles of chemotherapy and get knowledge about different antibiotics.
- Explain mechanism of drugaction and its relevance in the treatment of different infectious diseases.
- Describe mechanism of drug action and its relevance in the treatment of UTI, STD & malignancy and explain the effects of drugs modifying immune mechanism in body.
- 05 Explain principles of toxicology and treatment of various poisonings.

## **Course Content:**

UNIT-I 10 hours

- Pharmacology of drugs acting on Respiratory system
- a. Anti -asthmatic drugs
- b. Drugs used in the management of COPD
- c. Expectorants and antitussives
- d. Nasal decongestants
- e. Respiratory stimulants
- 2. Pharmacology of drugs acting on the Gastrointestinal Tract
- a. Antiulcer agents.
- b. Drugs for constipation and diarrhoea.
- Appetite stimulants and suppressants.
- d. Digestants and carminatives.
- e. Emetics and anti-emetics.

UNIT-II 10 hours

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

UNIT-III 10 hours

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

UNIT-IV 08 hours

- 5. Chemotherapy
- a. Urinary tract infections and sexually transmitted diseases.
- b. Chemotherapy of malignancy.
- 6. Immunopharmacology
- a. Immunostimulants
- b. Immunosuppressant

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

UNIT-V 07 hours

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

Definition of rhythm and cycles.

Biological clock and their significance leading to chronotherapy.

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

45Hours

## **LOCF**

Upon successful completion of the course, the student will be able to:

- 01 Explain the different types of cosmetic and cosmeceutical productand various excipients used in their formulation.
- Describe the principles of formulation and building blocks of skin care products.
- 03 Explain insight on sunscreen and role of herbs in cosmetics.
- 04 Describe the principles of cosmetic evaluation.
- 05 Explain cosmetic problems associated with hair and skin.

UNIT I 10Hours

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 10 Hours

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 cosmecuticals. Antiperspants & 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-phylene 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 10 Hours

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 08 Hours.

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 benfits.

UNIT V 07 Hours

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, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
- 3. Text book of cosmetology by Sanju Nanda & Roop K. Khar, Tata Publishers.

## PHS-CC-6104: PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 hours

## **LOCF**

Upon successful completion of the course, the student will be able to:

- 01 Describe the enzyme, enzyme immobilization and biosensors used in Pharmaceutical Industries.
- Explain various types of cloning vectors and enzymes used in the genetic engineering as well as rDNA technology and its application in enzyme production.
- Describe the immune system, Innate immunity, innate immune cells and mechanism, major histocompatibility complex and autoimmunity and hypersensitive response
- Describe the antigen and antibody structure, types of antibodies and function, production of d iverse and B cell, T Cell maturation process.
- Explain the fermentation process, design and construction of fermenter, types of media and production of various vitamins and drugs involving fermentation process.
- 06 Explain the biotransformation by microbes and its application.

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

**Objectives:** Upon completion of the subject student shall be able to:

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

Unit I 10 Hours

- a. Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.
- b. Enzyme Biotechnology- Methods of enzyme immobilization and applications.
- c. Biosensors- Working and applications of biosensors in Pharmaceutical Industries.
- d. Brief introduction to Protein Engineering.
- e. Use of microbes in industry. Production of Enzymes- General consideration Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.
- f. Basic principles of genetic engineering.

Unit II 10 Hours

- a. Study of cloning vectors, restriction endonucleases and DNA ligase.
- b. Recombinant DNA technology. Application of genetic engineering in medicine.
- c. Application of r DNA technology and genetic engineering in the production of:
- d. Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin.
- e. Brief introduction to PCR

#### **Unit III 10 Hours**

Types of immunity- humoral immunity, cellular immunity

- a. Structure of Immunoglobulins
- b. Structure and Function of MHC
- c. Hypersensitivity reactions, Immune stimulation and Immune suppressions.
- d. General method of the preparation of bacterial vaccines,toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.
- e. Storage conditions and stability of official vaccines
- f. Hybridoma technology- Production, Purification and Applications
- g. Blood products and Plasma Substituties.

### **Unit IV 08 Hours**

- a. Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
- b. Genetic organization of Eukaryotes and Prokaryotes.
- c. Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
- d. Introduction to Microbial biotransformation and applications.
- e. Mutation: Types of mutation/mutants.

Unit V 07 Hours

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

- 1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and ApplicationsofRecombinantDNA: ASM Press Washington D.C.
- 2. RA Goldshyet. al., :Kuby Immunology.
- 3. J.W. Goding: Monoclonal Antibodies.
- 4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by RoyalSociety of Chemistry.
- 5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, 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.
- 8. S.P. Vyas, V.K. Dixit, Pharmaceutical Biotechnology, 1st ed. CBS Publishers & Distributors, New Delhi.

## PHS-CC-6105: QUALITY ASSURANCE (Theory)

45 Hours

## **LOCF**

Upon successful completion of the course, the student will be able to:

- Describe the quality control, GMP, QA and quality Management; ICH stability testing guidelines; Quality by design (QbD); ISO certification and NABL accreditation.
- Explain the organization and personnel responsibilities, training; design, and construction of premises, pharmaceutical production plant and equipment selection, maintenance, purchase specifications, and maintenance of stores for ra w materials.
- Describe QC test for containers, rubber closures and secondary packing materials; GLP, Nonclinical Laboratory Studies and disqualification of Testing Facilities.
- Describe the evaluation of complaints, Handling of return goods, recalling and waste disposal and maintenance of documents, SOPs, Quality audit and Review.
- Describe the calibration, qualification and validation, types of validation and validation master plan, Calibration of pH meter, Qualification of UV-Visible spectrophotometer and good warehousing practice, materials management.

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

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

- 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

### Course content:

UNIT – I 10 Hours

Quality Assurance and Quality Management concepts: Definition and concept of Quality

control, Quality assurance and GMP

ICH Guidelines: purpose, participants, process of harmonization, 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 10 Hours

**Organization and personnel:** Personnel responsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmentalcontrol, 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 10 Hours

**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 08 Hours

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling andwaste disposal.

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

UNIT –V 07 Hours

**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

- 1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
- 2. Good Laboratory Practice Regulations, 2<sup>nd</sup> Edition, Sandy Weinberg Vol. 69.
- Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
- 4. A guide to Total Quality Management- KushikMaitra and Sedhan K Ghosh
- 5. How to Practice GMP's P P Sharma.
- 6. ISO 9000 and Total Quality Management Sadhank G Ghosh
- 7. The International Pharmacopoeia Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
- 8. Good laboratory Practices Marcel Deckker Series
- 9. ICH guidelines, ISO 9000 and 14000 guidelines

## PHS-CC-6106: MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

## **LOCF**

Upon successful completion of the course, the student will be able to:

- 01 Explain the preparation of drugs and intermediates.
- Perform the quantitative estimation of drugs using titrations.
- Prepare medicinally important compounds or intermediates by Microwave irradiation technique
- Draw structures and reactions using chem draw®.
- Determine 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).

## 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)

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

## PHS-CC-6107: PHARMACOLOGY-III (Practical)

4Hrs/Week

## **LOCF**

Upon successful completion of the course, the student will be able to:

- O1 Calculate the dose in pharmacological experiments.
- 02 Estimate serum biochemical parameters and LD50 also effect of agonist and antagonists.
- Evaluate anti-ulcer activity and antiallergic activity.
- Determine gastrointestinal motility and hypoglycemic effect.
- Describe acute eye irritation, acute skin irritation.
- 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/video

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

## PHS-CC-6108: COSMETIC SCIENCE (PRACTICAL)

04 Hours/Week

## **LOCF**

Upon successful completion of the course, the student will be able to:

- O1 Prepare and evaluate face washes
- O2 Prepare and evaluate moisturing cream, Cold cream, Vanishing cream
- Prepare and evaluate different types of Shampoos, hair removal cream and bleaching cream
- Prepare and evaluate Dentifrices, Mouth washes, herbal creams,
- Prepare and evaluate lipsticks, nail paint, and other coloring cosmetics.
  - 1. Prepare and evaluate Face wash
  - 2. Prepare and evaluate Moisturing cream
  - 3. Prepare and evaluate Cold cream
  - 4. Prepare and evaluate Vanishing cream
  - 5. Prepare and evaluate Shampoo
  - 6. Prepare and evaluate Anti-dandruff shampoo
  - 7. Prepare and evaluate Tooth paste
  - 8. Prepare and evaluate Tooth powder
  - 9. Prepare and evaluate Mouth wash
  - 10. Prepare and evaluate Aloe vera cream
  - 11. Prepare and evaluate Turmeric cream
  - 12. Prepare and evaluate Sunscreen cream
  - 13. Prepare and evaluate Lipstick
  - 14. Prepare and evaluate Nail polish
  - 15. Prepare and evaluate Hair removing cream
  - 16. Prepare and evaluate Bleeching cream

others practicals will be included based on the theory

### PHS-CC-6109: PHARMACEUTICAL BIOTECHNOLOGY (Practical)

04 Hours/Week

## **LOCF**

Upon successful completion of the course, the student will be able to:

- 01 Perform protein estimation by UV spectrophotometric, Lowry and Bradford method
- Perform experiments based on isolation of DNA from cheek cells& onion, concentration and purity of protein in a sample and Ethanol production by fermentation.
- Perform experiments based on preparation of nutrient broth and agar medium.
- Perform experiments based on extraction of enzyme from yeast and immobilization of different enzymes in alginate beads.
- Perform experiments based on effect of temperature, pH and substrate concentration on enzyme activity.
- 1. Estimation of the given protein sample by UV spectrophotometric method.
- 2. Preparation of standard curve of given protein by UV spectrophotomertic, Lowry and Bradford method and determine the concentration of given protein sample by all the three methods.
- 3. Isolation and characterisation of DNA from cheek cell.
- 4. Preparation of standard curve of DNA by UV spectrophotomeric method and determine it concentration and purity of given protein sample.
- 5. Isolation and characterization of DNA from onion.
- 6. Fermentation from yeast cell and determination of the concentration of ethanol produced.
- 7. Preparation and sterilization of nutrient broth and agar medium.
- 8. Protein electrophoresis using western blot techniques
- 9. Extraction and estimation of tyrosin enzyme from yeast.
- 10. Immobilization of given enzymes in alginate beads.
- 11. Elucidate the effect of temperature pH and substrate concentration on enzyme activity.
- 12. Comparison of the activity of enzyme in its native and immobilized form.
- 13. Meristem explant collection and callus culture
- 14. Preparation of culture media its sterilization and performing plant tissue culture

#### **Books Recommended:**

- Methods in biotechnology and Bioengineering, By Vyas, S.P. and Kohli, D.V. CBS Publishers and Distributors, New Delhi.
- Laboratory Manual in Biochemistry By Jayaraman, J. New Age International Publishers, New Delhi.
- Pharmaceutical Biotechnology, Vyas S. P. and Dixit V. K. CBS Publishers and Distributors, New Delhi.

### **SEMESTER VII**

## PHS-CC-7101: INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

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

**Objectives:** Upon completion of the course the student shall be able to understand the interaction of matter with electromagnetic radiations and its applications in drug analysis

Understand the chromatographic separation and analysis of drugs. Perform quantitative &qualitative analysis of drugs using various analytical instruments.

## **LOCF**

Upon successful completion of the course, the student will be able to:

- 01 Explain the ultra violet spectroscopy and fluorimetry, its application and instrumentation.
- Describe the IR spectroscopy, flame spectroscopy and atomic absorption spectroscopy their instrumentation and applications.
- 03 Explain TLC, Paper chromatography and its methodology and applications.
- Describe the Gas chromatography and HPLC, their principle and applications.
- 05 Explain the basic principle, methodology and application of ion exchange, gel and affinity chromatography.

## **Course Content:**

UNIT -I 10 Hours

#### **UV Visible spectroscopy**

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors-Photo tube,

Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis

## **Fluorimetry**

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT -II 10 Hours

#### IR spectroscopy

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

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer,

Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

UNIT →III 10 Hours

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, Techniquesof paper, gel, capillary electrophoresis, applications

UNIT -IV 08 Hours

**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 07 Hours

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

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

- 1. Organic spectroscopy by Y.R Sharma
- 2. Text book of Pharmaceutical Analysis by Kenneth A. Connors
- 3. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
- 4. Organic Chemistry by I. L. Finar
- 5. Quantitative Analysis of Drugs by D. C. Garrett
- 6. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi

## PHS-CC-7102: INDUSTRIAL PHARMACY-II (Theory)

45 Hours

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

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

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

## **LOCF**

Upon successful completion of the course, the student will be able to:

- 01 Explain the process of pilot plant and scale up of various types of dosage forms.
- Describe the process of technology transfer from lab scale to commercial batch (R &D to production) and documentation.
- Explain the Regulatory Affairs, Regulatory authorities and regulatory requirements for drug products& Investigational New Drug Application.
- Describe the concept of Quality, ISO series and know different Laws and Acts that regulate pharmaceutical industry.
- Describe the Regulatory Requirements in India, Central and State drug Licensing Authority, Certificate of Pharmaceutical Product and regulatory requirements and approval procedures for New Drugs.

#### **Course Content:**

#### UNIT-I 10 Hours

Pilot plant scale up techniques: General considerations - including significance ofpersonnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

### **UNIT-II 10 Hours**

**Technology development and transfer:** WHO guidelines for Technology Transfer(TT):

Terminology, Technology transfer protocol, Quality risk management, Transfer from R &D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials)

Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE /

SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

UNIT-III 10 Hours

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

Regulatory requirements for drug approval: Drug Development Teams, Non -ClinicalDrug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND)

Application, Investiga tor'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 08 Hours

Quality management systems: Quality management & Certifications: Concept of

Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT-V 07 Hours

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.

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

## PHS-CC-7103: PHARMACEUTICAL MARKETING MANAGEMENTS (Theory)

45 Hours

### **LOCF**

Upon successful completion of the course, the student will be able to:

- Describe the sales & Marketing which grooms the people for taking a challenging role in Sales and Product management.
- Describe the product management in pharmaceutical industry.
- 03 Explain various promotional techniques.
- Describe the Pharmaceutical marketing channels and sales representatives.
- Describe the pricing methods and strategies as well as issues in price management in pharmaceutical industry and emerging concepts in marketing.

### Scope:

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

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

Unit I 10 Hours

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 10 Hours

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 10 Hours

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 08 Hours

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 07 Hours

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; RuralMarketing; Consumerism; Industrial Marketing; Global Marketing.

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

## PHS-CC-7104: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

**Scope:** This subject is designed to impart basic knowledge on the area of novel drugdelivery systems.

**Objectives:** 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

### LOCF

Upon successful completion of the course, the student will be able to:

- O1 Describe about c ontrolled drug delivery systems and Polymers: used in the formulation of controlled release drug delivery systems
- 02 Explain microencapsulation techniques as well as Mucosal and Implantable Drug Delivery systems
- 03 Explain the Transdermal, Gastroretentive and Naso-pulmonary drug delivery system.
- 04 Describe the Targeted drug Delivery along with their concepts, approaches, examples, and applications
- Describe the ocular and Intrauterine Drug Delivery Systems.

#### **Course content:**

Unit-I 10 Hours

**Controlled drug delivery systems**: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations **Polymers**: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

Unit-II 10 Hours

**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 10 Hours

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

**Gastroretentive drug delivery systems:** Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications

**Nasopulmonary drug delivery system:** Introduction to Nasal and Pulmonary routes ofdrug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

Unit-IV 08 Hours

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

Unit-V 07 Hours

**Ocular Drug Delivery Systems:** Introduction, intra ocular barriers and methods toovercome —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. Y W. Chien, Novel Drug Delivery Systems, 2<sup>nd</sup> edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
- 2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
- 3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
- 4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
- 5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
- 6. Vyas S.P.Theory and practice in Novel Drug Delivery Systems, CBS, New Delhi

### **Journals**

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

## PHSCC-7105 SOCIAL AND PREVENTIVE PHARMACY (Theory)

Hours: 45

## **LOCF**

Upon successful completion of the course, the student will be able to:

- 01 Describe the concept of health and disease, focusing social health and education.
- 02 Explain the preventive medicines for widely distributed diseases for their prevention and control.
- 03 Explain the objectives of national health programmes for benefit of community for various diseases.
- 04 Describe various national health programmes for mother, child and family for control of various diseases.
- Describe the community services for rural, urban and school health.

### Scope:

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

### Objectives:

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

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

Unit I: 10 Hours

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: 10 Hours

Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, I ymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

Unit III: 10 Hours

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: 08 Hours

National health intervention programme for mother and child, National family welfare programme, National tobacco contro I programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of Indian national program

Unit V: 07 Hours

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

### **Recommended Journals:**

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

### PHS-CC-7106: INSTRUMENTAL METHODS OF ANALYSIS (Practical)

4 Hours/Week

## **LOCF**

Upon successful completion of the course, the student will be able to:

- O1 Perform experiments based on handling of UV spectrophotometer.
- 02 Perform experiments based on quantitative technique used to measure the concentration of a given substance in a solution.
- Perform experiments based on simultaneous estimation of pharmaceutical compounds, separation of amino acids (substances) by paper chromatography.
- Perform experiments based on TLC of sugars, separation plant pigments by column chromatography and quenching of fluorescence.
- 05 Perform experiments based on fluorimetry and assay of drugs.
- 1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
- 2. Estimation of dextrose by colorimetry
- 3. Estimation of sulfanilamide by colorimetry
- 4. Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
- 5. Assay of paracetamol by UV-Spectrophotometry
- 6. Estimation of quinine sulfate by fluorimetry
- 7. Study of quenching of fluorescence
- 8. Determination of sodium by flame photometry
- 9. Determination of potassium by flame photometry
- 10. Determination of chlorides and sulphates by nepheloturbidometry
- 11. Separation of amino acids by paper chromatography
- 12. Separation of sugars by thin layer chromatography
- 13. Separation of plant pigments by column chromatography
- 14. Demonstration experiment on HPLC
- 15. Demonstration experiment on Gas Chromatography

- 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

## PHS-CC-7107: NOVEL DRUG DELIVERY SYSTEM (Practical)

04 Hours/Week

## **LOCF**

Upon successful completion of the course, the student will be able to:

- O1 Prepare and evaluate controlled release drug delivery system of given drug
- 02 Prepare and evaluate polymeric film bearing drug for their physico-chemical properties and drug release
- O3 Prepare and evaluate micro-encapsules bearing drug using co-acervation phase separation technique.
- Perform experiments based on preparation and evaluation of muco -adhesive matrix type drug delivery bearing drug, matrix diffusion controlled transdermal drug delivery system and floating drug delivery system bearing drug.
- Perform experiments based on preparation and evaluation of nasal spray of drugs, osmotic pumps of drugs and micro particles bearing drug using incompatible polymer/cross linking agent.
- 1. To prepare and evaluate controlled release drug delivery system of given drug
- 2. To prepare and evaluate polymeric film bearing drug for their physico-chemical properties and drug release
- 3.To prepared and evaluate micro-encapsules bearing drug using co-ascervation phase separation technique
- 4. To prepare and evaluate muco-adhesive matrix type drug delivery bearing drug for their physico-chemical properties
- 5. To prepare and evaluate matrix diffusion controlled transdermal drug delivery system
- 6. To prepare and evaluate the floating drug delivery system bearing drug
- 7. To prepare and evaluate nasal spray of given drug
- 8. To prepare and evaluate osmotic pumps of given drug
- 9. To prepare and evaluate micro particles bearing drug using incompatible polymer/cross linking agent

Other experiments based on the syllabus of the theory

- 1. Y W. Chien, Novel Drug Delivery Systems, 2<sup>nd</sup> edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
- 2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
- 3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
- 4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
- 5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
- 6. Vyas S.P.Theory and practice in Novel Drug Delivery Systems, CBS, New Delhi

## PHS-CC-7108: PRACTISE SCHOOL

## **LOCF**

Upon successful completion of the course, the student will be able to:

- Dispense medication in the drug stores of the hospitals, private dispensaries and other approved locations of drug ware housing.
- Describe the working environment in pharmaceutical industries.
- 03 Explain the regulatory affairs regulation adopted and maintained in pharmaceutical industries.
- 04 Explain the role and responsibility of pharmacist in professional life.
- 05 Describe the regulatory and ethical responsibility of qualified & registered pharmacy professionals.

Every candidate shall undergo practice school for a period of 150 hours and opt any one of the domains for practice school declared by the program committee from timeto time. At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.

Every candidate shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Ho spital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit , Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. After the Semester – VI and before the commencement of Semester – VII, and shall submit satisfactory report of such work and certificate duly signed by the authority of training organization to the head of the institute.

# **SEMESTER VIII**

## PSC-CC-8101: BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

45 Hours

#### Scope:

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

### **Objectives:**

Upon completion of the course the student shall be able to

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

### LOCF

Upon successful completion of the course, the student will be able to:

- 01 Explain the statistical terms and techniques used to solve statistical problems.
- Explain the regression, sampling techniques and tests used to check the significance of the experimental.
- Explain the non-parametric analysis, basic concepts of research and data presentation.
- 04 Explain various softwares used for statistical analysis of data.
- 05 Explain the optimization techniques and factorial design of experiments.

#### Course content:

Unit-I 10 Hours

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode - Pharmaceutical examples Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples

Unit-II 10 Hours

Regression: Curve fitting by the met hod 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 10 Hours

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Unit-IV 8 Hours

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regressionmodels Introduction to Practical components of Indus trial 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 7 Hours

## **Design and Analysis of experiments:**

Factorial Design: Definition, 22, 23design. Advantage of factorial design Response Surf ace methodology: Central composite design, Historical design, Optimization Techniques

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

# PHS-CC-8102: PHARMACY PRACTICE (Theory)

45 Hours

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

### LOCF

Upon successful completion of the course, the student will be able to:

- Explain the organization of hospital and hospital pharmacy. They will also get to know about the organization and working of wholesale and retail drug store.
- 02 Explain the drug distribution system and hospital formulary in the hospital.
- Explain the pharmacy therapeutic committee, different education and training program in the hospital that are
- beneficial for the community.
- 04 Explain the concept of clinical pharmacy it's functioning and over the counter drugs.
- 05 Describe the drug store management and inventory control.

# Objectives: 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.

### Unit I: 10 Hours

## 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 detectingdrug 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.

# Unit II: 10 Hours

### 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 non-adherence, 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.

Unit III: 10 Hours

### Pharmacy and therapeutic committee

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

### Drug information service

Drug and Poison information centre, Sourcesof drug information, Computerised 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 program in the hospital

Role of pharmacist in the education and training program, Internal and ex ternal 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.

Unit IV 8 Hours 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.

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 7 Hours

### 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 and Methods used for the analysis of the drug expenditure

# Recommended Books (Latest Edition):

- 1. Merchant S.H. and Dr. J.S.Quadry. A textbook of hospital pharmacy, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
- 2. William E. Hassan, Hospital pharmacy, 5th ed. Philadelphia; Lea & Febiger: 1986.
- Tipnis Bajaj. Hospital Pharmacy, 1st ed. Maharashtra: Career Publications; 2008.
- 4. Scott LT. Basic skills in interpreting laboratory data, 4thed. American Society of Health System Pharmacists Inc; 2009.
- Parmar N.S. Health Education and Community Pharmacy, 18th ed. India: CBS Publishers & Distributers; 2008.

### Journals:

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

# PHS-CC-8103: BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

**Scope:** This subject is designed to impart knowledge and skills of Biopharmaceuticsand pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arised therein.

**Objectives:** 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.

### LOCF

Upon successful completion of the course, the student will be able to:

- Explain the process mechanism; interpret various factors affecting drug absorption, distribution, metabolism and excretion of drugs.
- 02 Describe bioavailability and bioequivalence and their assessment.
- Apply the pharmacokinetic models for determination of various pharmacokinetic parameters.
- 04 Explain Kinetics of two compartment models and multiple dosing.
- O5 Analyze the bioavailability parameters of drugs that follows non-linear pharmacokinetics.

### **Course Content:**

UNIT-I 10 Hours

### Introductionto Biopharmaceutics

**Absorption**; Mechanisms of drug absorption through GIT, factors influencing drugabsorption though 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 10 Hours

**Elimination:** Drug metabolism and basic understanding metabolic pathways renalexcretion 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, measu rement 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 10 Hours

**Pharmacokinetics:** Definition and introduction to Pharmacokinetics, Compartmentmodels, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations, Oral administration understanding of their significance to calculate various pharmacokinetic parameters.

UNIT- IV 08 Hours

Multicompartment models: Two compartment open model. IV bolus and extravascular administration (oral administration). Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their clinical significance UNIT- V 07 Hours

Absorption Kinetics: Curve Fitting, Wagner –Nelcon, LooRiegelman and Deconvoluntion method for elimination of absorption rate constant

**Nonlinear Pharmacokinetics:** a. Introduction, b. Factors causing Non-linearity, c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.

- 1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
- 2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- 3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall Inernational edition. USA
- 4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, VallabhPrakashanPitampura, Delhi
- 5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
- 6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- 7. Biopharmaceutics; By Swarbrick
- 8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
- 9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- 10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- 11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
- 12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvni

# PHS-CC-8104: HERBAL DRUG TECHNOLOGY (Theory)

45 hours

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

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

- 1. understand raw material as source of herbal drugs from cultivation to herbal drug product
- 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.

### LOCF

Upon successful completion of the course, the student will be able to:

- 01 Describe the characteristics of herbal material of medicinal importance and basic principles of Indian system of medicines.
- 02 Explain the commercial values nutraceuticals and international scope of functional phyto -leads used in nutraceutical products.
- 03 Describe the herbal cosmetics and herbal excipients used in cosmetic formulation and development.
- O4 Explain isolation and identification of phyto -actives as per WHO guidelines and patenting & regulatory requirements of natural products.
- 05 Explain the current scope and future prospective of herbal industry with reference to good manufacturing practices of herbal product manufacturing.

### Course content:

UNIT-I 11 Hours

# 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 7 Hours

# **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 lassification. Study of following drugs and their possible side effects and interactions: Hypercium, Kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

UNIT-III 10 Hours

## **Herbal Cosmetics**

Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective age nts, 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 10 Hours

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugsStability 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 ofmanufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT-V 07 Hours

### **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.

- 1. Textbook of Pharmacognosy by Trease & Evans.
- 2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
- 3. Pharmacognosy by Kokate, Purohit and Gokhale
- 4. Essential of Pharmacognosy by Dr.S.H.Ansari
- 5. Pharmacognosy & Phytochemistry by V.D.Rangari
- 6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)

# PHS-CC-8105: BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

04 Hours/Week

### LOCF

Upon successful completion of the course, the student will be able to:

- 01 Explain passive absorption and active absorption of a drug using isolated everted intestine sac method.
- Describe the protein binding of the drug and factors affecting the protein binding.
- Determine the bioavailability and bioequivalence of formulations from the given plasma and urine data.
- 04 Explain compartment model and its uses to determine various pharmacokinetic parameters.
- 05 Describe non-linear pharmacokinetics.
  - 1. To assess passive absorption of a drug using isolated everted intestine sac method
  - 2. To assess active absorption of a drug using isolated everted intestine sac method
  - 3. To report effect of dietary factors on the absorption of drug on oral administration
  - 4. To report protein binding of a drug
  - 5. To report relative bioavailability of given drug product using urinary excretion data
  - 6. To report pharmacokinetic parameter of a drug using urinary excretion data administered via oral route.
  - 7.To report bioequivalence of drug products using urinary excretion data administered via oral routes.
  - Other experiments based on syllabus of the theory

- 1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
- 2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- 3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall Inernational 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 Glbaldi Donald, R. Mercel Dekker Inc.
- 6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- 7. Biopharmaceutics; By Swarbrick
- 8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
- 9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- 10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- 11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
- 12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvni

## **LOCF**

Upon successful completion of the course, the student will be able to:

- O1 Carry out analytical protocols and preliminary phytochemical screening of crude drugs.
- O2 Perform experiments based on physico -chemical profiling of herbal materials and formulations.
- O3 Perform experiments based on herbal cosmetics and evaluation thereof.
- Carryout the experiments to develop herbal syrups, mixtures and tablets and their evaluation as per pharmacopeial requirements.
- Determine and explain the qualitative & quantitative contents of herbal material of medicinal importance.
  - 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

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

# PHS-CC-8107: PROJECT WORK

## PHS-EC 8108: ELECTIVEELECTIVE SUBJECTS:

# PHS-EC-8108: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

# Scope:

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

# **Objectives:**

Upon completion of the subject student shall be able to;

- 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

### Course content:

Unit I 10Hours

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 10Hours

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 10Hours

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 08Hours

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 07Hours

Regulatory Concepts

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

- 1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
- 2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol. 185. Informa Health care Publishers.
- 3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol. 190.
- 4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
- 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.

# Scope:

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

# **Objectives:**

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

- 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
- 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.

# **Course Content**

Unit - I 10 Hours

# 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 10 hours

### Drug and disease classification

Anatomical, therapeutic and chemical classification of drugs

International classification of diseases

Daily defined doses

International Non proprietary Names for drugs

### Drug dictionaries and coding in pharmacovigilance

WHO adverse reaction terminologies

MedDRA and Standardised MedDRA gueries

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** 10 Hours

# 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

8 Hours **Unit IV** 

### Safety data generation

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

#### **ICH Guidelines for**

- 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 IV 7 Hours

# Pharmacogenomics of adverse drug reactions

Genetics related ADR with example focusing PK parameters.

# Drug safety evaluation in special population

**Paediatrics** 

Pregnancy and lactation

Geriatrics

### **CIOMS**

**CIOMS Working Groups** 

CIOMS Form

# CDSCO (India) and Pharmacovigilance

D&C Act and Schedule Y

Differences in Indian and global pharmacovigilance requirements

- 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,
- 8. Sean Hennessy, Wiley Publishers.
- 9. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi,
- 10. Karin NyfortHansen, Milap C. Nahata
- 11. National Formulary of India
- 12. Text Book of Medicine by Yashpal Munial
- 13. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna

# PHS-EC-8110: QUALITY CONTROL AND STANDARDIZATION OF HERBAL PRODUCTS (Theory)

45 Hours

## Scope:

In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs.

The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

# **Objectives:**

Upon completion of the subject student shall be able to;

- 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 10 hours

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 10 hours

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 10 hours

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Unit IV 08 hours

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 07 hours

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

- 1. Pharmacognosy by Trease and Evans
- 2. Pharmacognosy by Kokate, Purohit and Gokhale
- Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I, Carrier Pub., 2006.
- 4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
- EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
- 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.

45 Hours

### Scope:

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

## **Objectives:**

- Upon completion of the course, the student shall be able to understand
- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

#### **Course Content:**

UNIT-I 10 Hours

### **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 10 Hours

### Quantitative Structure Activity Relationship (QSAR)

**SA**R 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, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III 10 Hours

#### 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.

### Informatics & Methods in drug design

**UNIT-IV** 

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

UNIT-V 07 Hours

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

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

- Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
- 2. Martin YC. "Quantitative Drug Design" Dekker, New York.
- Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
- 4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
- 5. Koro Ikovas 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.
- Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

08 Hours

# Scope:

 Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function.

This is done both on a microscopic and molecular level.

Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organisms such as humans, plants, and sponges.

# **Objectives:**

- Upon completion of the subject student shall be able to;
- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

Course content:

Unit I 10Hours

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 10 Hours

DNA and the Flow of Molecular Information

**DNA Functioning** 

DNA and RNA

Types of RNA

Transcription and Translation

Unit III 10 Hours

Proteins: Defined and Amino Acids

Protein Structure

Regularities in Protein Pathways

Cellular Processes

Positive Control and significance of Protein Synthesis

Unit IV 08 Hours

Science of Genetics

Transgenics and Genomic Analysis

Cell Cycle analysis

Mitosis and Meiosis

Cellular Activities and Checkpoints

Unit V 07 Hours

Cell Signals: Introduction Receptors for Cell Signals Signaling Pathways: Overview Misregulation of Signaling Pathways Protein-Kinases: Functioning

- 1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
- 2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
- 3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
- 4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
- 5. Rose: Industrial Microbiology.
- 6. S.P. Vyas and H.D. Kumar. Advances in Pharmaceutical Biotechnology, CBS Publishers, New Delhi.
- 7. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
- 8. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
- 9. Peppler: Microbial Technology.
- 10. Edward: Fundamentals of Microbiology.
- 11. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi.
- 12. S.P. Vyas, V.K. Dixit, Pharmaceutical Biotechnology. CBS Publishers & Distributors, New Delhi, 1998.
- 13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
- 14. B.R. Glick and J.J. Pasternak: Molecular 6: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
- 15. RA Goldshy et. al., : Kuby Immunology.
- 16. Cell and molecular biology by Vyas S. P. and Mehta A.

PHS-EC-8113: COSMETIC SCIENCE (Theory)

45Hours

UNIT I 10Hours

Perfumes and Fragrances in cosmetics:

Fragrances nomenclature, chemistry and Odour types Selection of Fragrances, Fragrances Raw materials, Fragrances Allergenicity, Development of a fragrances, Water soluble Fragnrances, Aromatic Waters, Colognes and Aromatherapy

UNIT II 10 Hours

Botanicals in cosmetics:

Cosmetics in Ayurveda and the Growing Influences of Ayurveda in cosmetics, Standardisation and quality control of Botanicals and use of natural substances other than Botanicals in cosmetics.

Limitations of Botanicals in cosmetics

UNIT III 10 Hours

Surfactants in Cosmetics:

Surfactant Groups like

Amphoteric Surfactant: acyl/dialkyl Ethylene Diamines and Derivatives

N-Alkylamino acids,

Anionic surfactants: Alkylamino Acids, The Acyl Glutamates

Acyl Peptides, Sarcosinates, Taurates, Carboxylic Acids like Alkanoic Acids,

Ester Carboxylic Acids, Ether Carboxylic Acids.

Phosphoric Acid Ester (and Salts),

Sulfonic Acids like Acyl Isethionates, AlkylarylSulfonates, Alkyl sulfonates, Sulfosusccinates, Sulfuric Acid Esters,

Alkyl Ether Sulfates and Alkyl Sulfates

Cationic Surfactants: Alkylamines, Alkyl Imidazolines, Ethoxylated Amines, Quaterneries,

Alkyl Benzyl Dimethyl Ammonium salts,

Alkyl Betaines, Hetero Cyclic Quaternaries, Tetraalkylammonium Salts,

Non-Ionic Surfactants:

Alcohols, Alkanolamides like Alkanol Amine Derived Amides, Ethoxylated Amides, Amine Oxides, Esters like Ethoxylated carboxylic Acids, Ethoxylated Glycerides, Glycol Esters and Derivatives, Monoglycerides, Polyglyceryl Esters, Polyhydric Alcohol Esters and Ethers,

Sorbitan/sorbital Esters, Triesters of Phosphoric Acid, Ethers, Ethoxylated alcohols, EthoxylatedLanoline Derivatives,

EthoxylatedPolysiloxanes, Propoxylated POE Ethers,

UNIT IV 08 Hours.

Polymers and Thickeners in Cosmetics

Natural and Modified Natural Polymers and Thickeners

Synthetic Polymers and Thickeners

UNIT V 07 Hours.

Microbiological Control and Preservation of Cosmetics:

Sources of contamination and their Prevention, Action of Microorganism on Cosmetics

Methods of Preservation of Cosmetics, Preservatives, Ideal Requirements of a Preservatives, Legal Status of Preservatives, Common Preservatives and their Mechanism of Action,

Factors Influencing the Effectiveness of Preservatives and Methods of Predicting Long Term Preservative Efficacy

#### References

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

### PHS-EC-8114

### EXPERIMENTAL PHARMACOLOGY

45 Hours

## Scope:

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

# **Objectives:**

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

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

Unit –I 10 Hours

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 10 Hours

Preclinical screening models

a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study.

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 10 Hours

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

Unit –IV 10 Hours

Preclinical screening models: for CVS activity- antihypertensives,

diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory,

coagulants, and anticoagulants

Preclinical screening models for other important drugs like antiulcer,

antidiabetic, anticancer and antiasthmatics.

UNIT -V 05 Hours

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):

Fundamentals of Experimental Pharmacology-by M.N.Ghosh

Hand book of Experimental Pharmacology-S.K.Kulakarni

CPCSEA guidelines for laboratory animal facility.

Drug Discovery and Evaluation by Vogel H.G.

Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta

ntroduction to biostatistics and research methods by PSS Sundar Rao and J Richard

#### PHS-EC-8115: ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

### Scope:

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

# **Objectives:**

Upon completion of the course the student shall be able to

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

### **Course Content:**

UNIT-I 10 Hours

#### **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 10 Hours

Thermal Methods of Analysis: Principles, instrumentation and applications of ThermogravimetricAnalysis (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 10 Hours

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 08 Hours

Radio immune assay: Importance, various components, Principle, different methods, limitation and applications of Radio immuno assay.

Extraction techniques: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

UNIT-V 07 Hours

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

- 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. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
- 5. Organic Chemistry by I. L. Finar
- 6. Organic spectroscopy by William Kemp
- 7. Quantitative Analysis of Drugs by D. C. Garrett

### PHS-EC-8116: DIETARY SUPPLEMENTS AND NUTRACEUTICALS

No. of hours :3 Tutorial:1 Credit point:4

# Scope:

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

# Objective:

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

- 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 07 hours

- 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.
- 2. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.
- 3. 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 15 hours

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

- a. Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin
- Sulfides: Diallyl sulfides, Allyl trisulfide.
- c. Polyphenolics: Reservetrol
- d. Flavonoids- Rutin, Naringin, Quercitin, Anthocyanidins, catechins, Flavones
- e. Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum
- f. Phyto estrogens: Isoflavones, daidzein, Geebustin, lignans
- g. Tocopherols
- h. Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

UNIT III 07 hours

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

UNIT IV 10 hours

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

UNIT V 06 hours

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

- b. Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
- c. Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

#### References:

- 1. Dietetics by Sri Lakshmi
- 2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
- 3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
- 4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
- 5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
- 6. G. Gibson and C.williams Editors 2000 Functional foods Woodhead Publ.Co.London.
- 7. Goldberg, I. Functional Foods. 1994. Chapman and Hall, New York.
- 8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in Essentials of Functional Foods M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
- 9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
- 10. Shils, ME, Olson, JA, Shike, M. 1994 Modern Nutrition in Health and Disease. Eighth edition. Lea and Febiger