#### JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD BACHELOR OF PHARMACY COURSE STRUCTURE AND SYLLABUS

#### Effective from Academic Year 2022-23 Admitted Batch

#### I Year I semester

S.	Course Code	Subject	L	Т	P	Credits
No						
1	PS101	Human Anatomy and Physiology I	3	1	-	4
2	PS102	Pharmaceutical Analysis I	3	1	-	4
3	PS103	Pharmaceutics	3	1	-	4
4	PS104	Pharmaceutical Inorganic Chemistry	3	1	-	4
5	HS105	Communication skills	2	-	-	2
6	BS106/BS107	Remedial Biology <sup>#</sup> / Remedial Mathematics <sup>\$</sup>	2#/3\$	-	-	2#/3\$
7	PS108	Human Anatomy and Physiology-I lab	-	-	4	2
8	PS109	Pharmaceutical Analysis I lab	-	-	4	2
9	PS110	Pharmaceutics lab	-	-	4	2
10	PS111	Pharmaceutical Inorganic Chemistry lab	-	-	4	2
11	HS112	Communication skills lab	-	-	2	1
12	BS113	Remedial Biology lab	-	-	2	1
		Total	16/17	4	20	30#/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.

S.	Course	Subject	L	Т	Р	Credits
No	Code					
1	PS201	Human Anatomy and Physiology II	3	1	-	4
2	PS202	Pharmaceutical Organic Chemistry-I	3	1	-	4
3	BS203	Biochemistry	3	1	-	4
4	BS204	Pathophysiology	3	1	-	4
5	CS205	Computer Applications in Pharmacy	3	-	-	3
6	PS206	Human Anatomy and Physiology II lab	-	-	4	2
7	PS207	Pharmaceutical Organic Chemistry-I Lab	-	-	4	2
8	BS208	Biochemistry lab	-	-	4	2
9	CS209	Computer Applications in Pharmacy lab	-	-	2	1
10	*MC200	NSS	-	-	-	-
		Total	15	4	14	26

#### I Year II semester

#### **II YEAR I SEMESTER**

S. No	Course Code	Course Title	L	т	Р	Credits
1	PS301	Pharmaceutical Organic Chemistry-II	3	1	0	4
2	PS302	Physical Pharmaceutics-I	3	1	0	4
3	BS303	Pharmaceutical Microbiology	3	1	0	4
4	PC304	Pharmaceutical Engineering	3	1	0	4

5	PS305	Pharmaceutical Organic Chemistry-II Lab	0	0	4	2
6	PS306	Physical Pharmaceutics-I Lab	0	0	4	2
7	BS307	Pharmaceutical Microbiology Lab	0	0	4	2
8	PC308	Pharmaceutical Engineering Lab	0	0	4	2
10	*MC300	NSO	0	0	0	0
		Total Credits	12	04	16	24

### **II YEAR II SEMESTER**

S. No	Course Code	Course Title	L	т	Ρ	Credits
1	PS401	Pharmaceutical Organic Chemistry-III	3	1	0	4
2	PC402	Physical Pharmaceutics-II	3	1	0	4
3	PS403	Pharmacology-I	3	1	0	4
4	PC404	Pharmacognosy and Phytochemistry-I	3	1	0	4
5	PS405	Pharmaceutical Jurisprudence	3	1	0	4
6	PC406	Physical Pharmaceutics-II Lab	0	0	4	2
7	PS407	Pharmacology-I Lab	0	0	4	2
8	PC408	Pharmacognosy and Phytochemistry-I Lab	0	0	4	2
9	*MC400	Gender Sensitization Lab	1	0	0	0
		Total Credits	16	05	12	26

#### III Year I Semester

S. No.	Course Code	Course Title	L	Т	Р	Credits
1	PS501	Medicinal Chemistry I	3	1	0	4
2	PS502	Industrial Pharmacy - I	3	1	0	4
3	PS503	Pharmacology II	3	1	0	4
4	PS504	Pharmacognosy and Phytochemistry - II	3	1	0	4
5		Open Elective - I	3	1	0	4
	PS505	I. Generic Product Development				
	PS506	II. Green Chemistry				
	PS507	III. Cell and Molecular Biology				
	PS508	IV. Cosmetic science				
6	PC509	Medicinal Chemistry I Lab	0	0	4	2
7	PS510	Industrial Pharmacy – I lab	0	0	4	2
8	PS511	Pharmacology - II lab	0	0	4	2
9	PS512	Pharmacognosy and Phytochemistry - II lab		0	4	2
10	*MC500	Environmental sciences	1	0	0	0
		Total	16	05	16	28

#### **III Year II Semester**

S. No.	Course Code	Course Title	L	Т	Р	Credits
1	PS601	Medicinal Chemistry - II	3	1	0	4
2	PS602	Pharmacology - III	3	1	0	4
3	PS603	Herbal Drug Technology	3	1	0	4
4	PS604	Biopharmaceutics and Pharmacokinetics	3	1	0	4
5		Open Elective - II	3	1	0	4
	PS605	I. Pharmaceutical Quality Assurance				
	PS606	II. Pharmaceutical Biotechnology				
	PS607	III. Bioinformatics				
	PS608	IV. Screening Methods in Pharmacology				
6	PS609	Medicinal chemistry - II lab	0	0	4	2

7	PS610	Pharmacology - III lab	0	0	4	2
8	PS611	Herbal Drug Technology lab	0	0	4	2
9	PS612	Biopharmaceutics and Pharmacokinetics Lab	0	0	4	2
10	*MC600	Human Values and Professional Ethics	1	0	0	0
		Total	16	05	16	28

### IV Year I Semester

S.No	Course Code	Course Title	L	т	Р	Credits
1	PS701	Instrumental Methods of Analysis	3	1	0	4
2	PS702	Industrial Pharmacy-II	3	1	0	4
3	PS703	Pharmacy Practice	3	1	0	4
4	PS704	Medicinal Chemistry - III	3	1	0	4
5		Open Elective - III	3	1	0	4
	PS705	i. Pharmaceutical Marketing				
	PS706	ii. Pharmaceutical Regulatory Science				
	PS707	iii. Pharmacovigilance				
	PS708	iv. Quality Control and Standardization of Herbals				
6	PS709	Instrumental Methods of Analysis Lab	0	0	4	2
7	PS710	Practice School	0	0	4	2
8	PS711	Industrial Training	0	0	4	2
		Total	15	5	12	26

#### **IV Year II Semester**

S.No	Course Code	Course Title	L	т	Р	Credits
1	PS801	Biostatistics and Research Methodology		1	0	4
2	PS802	Social and Preventive Pharmacy	3	1	0	4
3	PS803	Novel Drug Delivery System	3	1	0	4
4		Open Elective - IV	3	1	0	4
	PS804	i. Computer Aided Drug Design				
	PS805	ii. Nano Technology				
	PS806	iii. Experimental Pharmacology				
	PS807	iv. Advanced Instrumentation Techniques				
5	PS808	Novel Drug Delivery System Lab	0	0	4	2
6		Project Work	0	0	6	3
		Total	12	4	10	21

\*MC - Mandatory Course - Satisfactory/ Unsatisfactory.

### PS101: HUMAN ANATOMY AND PHYSIOLOGY - I

### B. Pharm. I Year I Sem

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.

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

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

### UNIT-I

### Introduction to human body

Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

### Cellular level of organization

Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine

#### Tissue level of organization

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

### UNIT – II

Integumentary system Structure and functions of skin Skeletal system

Divisions of skeletal system, types of bone, salient features, and functions of bones of axial and appendicular skeletal system

Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction

### .loints

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

### UNIT – III

### Nervous system

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. Structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)

#### UNIT - IV

#### Peripheral nervous system:

Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system. Origin and functions of spinal and cranial nerves.

**Special senses**: Structure and functions of eye, ear, nose and tongue and their disorders.

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#### UNIT – V

#### 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.

#### TEXT 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
- Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
- 4. Text book of Medical Physiology- Arthur C, Guyton and John.E. Hall. Miamisburg, OH, U.S.A.
- 5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
- 6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
- 7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
- 8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

#### **REFERENCE BOOKS: (Latest Editions)**

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

#### PS102: PHARMACEUTICAL ANALYSIS - I

#### B. Pharm. I Year I Sem

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

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

- understand the principles of volumetric and electro chemical analysis
- carryout various volumetric and electrochemical titrations
- develop analytical skills

#### UNIT - I

- (a) Pharmaceutical analysis- Definition and scope
  - i) Different techniques of analysis
  - ii) Methods of expressing concentration
  - iii) Primary and secondary standards.
  - iv) Preparation and standardization of various molar and normal solutions-Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate
- (b) Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

#### UNIT – II

Acid base titration: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves **Non-aqueous titration**: Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCI

#### UNIT – III

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

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

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

#### UNIT – IV

#### **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, Conductometric titrations, applications.

**Potentiometry -** Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.

**Polarography** - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications

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**10 Hours** 

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#### **TEXT BOOKS: (Latest Editions)**

- 1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
- 2. Introduction to Pharmaceutical Analysis by Badwaik Hemant R. published by Pharma Med Press
- 3. A.I. Vogel, Text Book of Quantitative Inorganic analysis
- 4. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
- 5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
- 6. John H. Kennedy, Analytical chemistry principles
- 7. Indian Pharmacopoeia.
- 8. Badwaik Hemant R., Introduction to Pharmaceutical Analysis, Pharma Med Press

B. Pharm. | Year | Sem

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

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations

**PS103: PHARMACEUTICS** 

**Scope:** This course is designed to impart a fundamental knowledge on the preparatory pharmacy with

- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

#### UNIT – I

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

Dosage forms: Introduction to dosage forms, classification and definitions

**Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription. **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

#### UNIT – II

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

**Powders:** Definition, classification, advantages and disadvantages, Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.

**Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

#### UNIT – III

**Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.

#### **Biphasic liquids:**

**Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.

**Emulsions:** Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

#### UNIT – IV

**Suppositories**: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.

**Pharmaceutical incompatibilities**: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

#### UNIV – V

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

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#### **TEXT BOOKS: (Latest Editions)**

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

#### PS104: PHARMACEUTICAL INORGANIC CHEMISTRY

B. Pharm. I Year I Sem	L	т	Ρ	С	
	3	1	0	4	
Seens: This subject deals with the monographs of inergenic drugs and phermasouticals					

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

Course 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 •

#### UNIT – I

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

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

#### UNIT – II

Acids, Bases and Buffers: Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.

Major extra and intracellular electrolytes: Functions of major Physiological ions, Electrolytes used in the replacement therapy: Sodium chloride\*, Potassium chloride, Calcium gluconate\* and Oral Rehydration Salt (ORS), Physiological acid base balance.

**Dental products**: Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

#### UNIT – III

#### **Gastrointestinal agents**

Acidifiers: Ammonium chloride\* and Dil. HCl

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

Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

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

#### UNIT - IV

#### Miscellaneous compounds

Expectorants: Potassium iodide, Ammonium chloride\*. Emetics: Copper sulphate\*, Sodium potassium tartarate Haematinics: Ferrous sulphate\*, Ferrous gluconate Poison and Antidote: Sodium thiosulphate\*, Activated charcoal, Sodiumnitrite333 Astringents: Zinc Sulphate, Potash Alum

#### UNIT – V

Radiopharmaceuticals: Radio activity, Measurement of radioactivity, Properties of á, â, ã radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I<sup>131</sup>, Storage conditions, precautions & pharmaceutical application of radioactive substances.

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#### 10 Hours

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- 1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4<sup>th</sup> edition.
- 2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
- 3. P. GunduRao, Inorganic Pharmaceutical Chemistry, 3<sup>rd</sup> 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
- 8. Algarsamy V. Pharmaceutical Inorganic Chemistry, 2nd Ed. Pharma Med Press
- 9. Rao Somasekhar, Pharmaceutical Inorganic Chemistry, Pharma Med Press

#### HS105: COMMUNICATION SKILLS

#### B. Pharm. | Year | Sem

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.

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

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

#### UNIT – I

Hours

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

Barriers to communication: Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers

Perspectives in Communication: Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

#### UNIT – II

#### 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

#### 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

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

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

#### TEXT BOOKS: (Latest Editions)

- 1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2<sup>nd</sup> Edition, Pearson Education, 2011
- 2. Communication skills, Sanjay Kumar, Pushpalata, 1<sup>st</sup> Edition, Oxford Press, 2011
- 3. Organizational Behaviour, Stephen. P. Robbins, 1st Edition, Pearson, 2013
- 4. Brilliant- Communication skills, Gill Hasson, 1st Edition, Pearson Life, 2011
- 5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, GopalaSwamy Ramesh, 5<sup>th</sup> Edition, 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, Konarnira, 2<sup>nd</sup> Edition, New arrivals PHI, 2011
- 8. Personality development and soft skills, Barun K Mitra, 1<sup>st Edition</sup>, Oxford Press, 2011
- 9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning India pvt. ltd, 2011
- 10. Soft skills and professional communication, Francis Peters SJ, 1<sup>st</sup> Edition, McGraw Hill Education, 2011
- 11. Effective communication, John Adair, 4th Edition, Pan Mac Millan, 2009
- 12. Bringing out the best in people, Aubrey Daniels, 2<sup>nd</sup> Edition, McGraw Hill, 1999
- 13. Rao Bhaskara, Communication Skills, BS Publications

#### **BS106: REMEDIAL BIOLOGY**

#### B. Pharm. | Year | Sem

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

Course 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

UNIT - I Living world:

- Definition and characters of living organisms
- Diversity in the living world
- **Binomial nomenclature** •
- Five kingdoms of life and basis of classification. Salient features of Monera, 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

#### Body fluids and circulation

Composition of blood, blood groups, coagulation of blood, Composition and functions of lymph Human circulatory system, Structure of human heart and blood vessels, Cardiac cycle, cardiac output and ECG

#### **Digestion and Absorption**

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

#### Breathing and respiration

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

#### UNIT – III

#### Excretory products and their elimination

Modes of excretion, Human excretory system- structure and function, Urine formation, Rennin angiotensin system

#### Neural control and coordination

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

#### Chemical coordination and regulation

Endocrine glands and their secretions, Functions of hormones secreted by endocrine glands Human reproduction

Parts of female reproductive system, Parts of male reproductive system, Spermatogenesis and Oogenesis, Menstrual cycle

#### UNIT - IV

Plants and mineral nutrition:

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#### 07 Hours

07 Hours

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

#### Photosynthesis:

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

#### UNIT – V

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### 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:**

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

#### **BS107: REMEDIAL MATHEMATICS**

#### B. Pharm. | Year | Sem

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

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

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

#### UNIT – I

#### Matrices and Determinant:

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants, Product of determinants, Singular and nonsingular matrices, Inverse of a matrix, Solution of system of linear of equations using Gauss Elimination method.

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

#### Function:

UNIT-II

Real Valued function, Classification of real valued functions

#### UNIT – III

### Calculus

#### Limits and continuity:

Introduction, Limit of a function, Definition of limit of a function

#### Differentiation:

Introductions, properties of derivatives, Finding derivative of a function usinf Standard Derivatives, 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. Related problem.

#### UNIT - IV

#### Integration:

Introduction, Definition, Standard formulae, Rules of integration, Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

#### UNIT – V

#### **Differential Equations:**

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

#### **TEXT BOOKS: (Latest Edition)**

- 1. Differential Calculus by Shanthinarayan
- 2. Intermediate telugu academy mathematics text book
- 3. Integral Calculus by Shanthinaravan
- 4. Higher Engineering Mathematics by Dr.B.S. Grewal
- 5. A Text Book of Remedial Mathematics by P seshagiri Rao, Pharmamed Press.

06 Hours

06 Hours

#### 06 Hours

## 06 Hours

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#### PS108: HUMAN ANATOMY AND PHYSIOLOGY- I Lab

#### B. Pharm. I Year I Sem

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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.

#### List of Experiments:

- 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. To study the integumentary and special senses using specimen, models, etc.,
- 7. To study the nervous system using specimen, models, etc.,
- 8. To study the endocrine system using specimen, models, etc
- 9. To demonstrate the general neurological examination
- 10. To demonstrate the function of olfactory nerve
- 11. To examine the different types of taste.
- 12. To demonstrate the visual acuity
- 13. To demonstrate the reflex activity
- 14. Recording of body temperature
- 15. To demonstrate positive and negative feedback mechanism.

#### PS109: PHARMACEUTICAL ANALYSIS - I Lab

B. Pharm. I Year I Sem	LT	РС
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List of Experiments:		

#### 1. Preparation and standardization of

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

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

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

#### 3. 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

#### **REFERENCE:**

1. Pharmaceutical Analysis: A Practical Manual by Randhir Singh Dahiya, Navpreet Kaur, Lalit Kishore, Pharmamed.

#### **PS110: PHARMACEUTICS LAB**

#### B. Pharm. | Year | Sem L T P C 0 0 4 2

### List of Experiments:

#### 1. Syrups

- a) Syrup IP
- b) Paracetamol pediatric syrup

#### 2. Elixirs

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

#### 3. Linctus a) Simple Linctus BPC

#### 4. Solutions

- a) Strong solution of ammonium acetate
- b) Cresol with soap solution

#### 5. Suspensions

- a) Calamine lotion
- b) Magnesium Hydroxide mixture

#### 5. Emulsions

- a) Turpentine Liniment
- b) Liquid paraffin emulsion

#### 6. Powders and Granules

- a) ORS powder (WHO)
- b) Effervescent granules c) Dusting powder

#### 7. Suppositories

- a) Glycero gelatin suppository
- b) Soap glycerin suppository

#### 8. Semisolids

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

#### 9. Gargles and Mouthwashes

- a) Potassium chlorate gargle
- b) Chlorhexidine mouthwash

#### **REFERENCES BOOKS:**

- 1. Pharmaceutics-I (General Pharmacy) A Practical Manual by Mishra Vijay, Pharmamed Press
- 2. Pharmaceutics: A Practical Manual for B PHARM & PHARM D Courses, Abraham Sindhu by Pharmamed Press.

#### PS111: PHARMACEUTICAL INORGANIC CHEMISTRY - LAB

B. Pharm. I Year I Sem	L	т	Ρ	С
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#### Limit tests for following ions

- a) Limit test for Chlorides and Sulphates Modified limit test for Chlorides and Sulphates Limit test for Iron
- b) Limit test for Heavy metals Limit test for Lead
- c) Limit test for Arsenic

**Identification test** Magnesium hydroxide Ferrous sulphate Sodium bicarbonate Calcium gluconate Copper sulphate

#### Test for purity

- a) Swelling power of Bentonite
- b) Neutralizing capacity of aluminum hydroxide gel
- c) Determination of potassium iodate and iodine in potassium lodide

#### Preparation of inorganic pharmaceuticals

- a) Boric acid
- b) Potash alum
- c) Ferrous sulphate

#### **REFERENCE BOOK:**

1. Practical Pharmaceutical In-Organic Chemistry, by Bayya Subba Rao, Pharmamed Press.

#### HS112: COMMUNICATION SKILLS - LAB

B. Pharm. I Year I Sem	L	т	Ρ	С
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The following 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

#### **REFERENCE BOOK:**

1. Successful Career Soft Skills and Business English Personality Development and Career Path by Varanasi Bhaskara Rao, Y. Kameswari

#### BS113: REMEDIAL BIOLOGY LAB

B. Pharm. I Year I Sem	L	т	Ρ	С
	0	0	2	1
List of Experiments:				

- 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 and its modifications
- 4. Detailed study of frog by using computer models
- 5. Microscopic study and identification of tissues
- 6. Identification of bones
- 7. Determination of blood group
- 8. Determination of blood pressure
- 9. Determination of tidal volume

#### **REFERENCE BOOKS:**

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

#### PS201: HUMAN ANATOMY AND PHYSIOLOGY-II

#### B. Pharm. I Year II Sem

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.

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

- Explain the gross morphology, structure, and functions of various organs of the human body. •
- Describe the various homeostatic mechanisms and their imbalances. •
- Identify the various tissues and organs of different systems of human body. •
- Perform the 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 ٠
- Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

#### UNIT – I

#### 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 – II

#### 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 output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

#### UNIT – III

#### **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 intestineand large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

#### **Respiratory system**

Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration

#### UNIT - IV

#### **Respiratory system**

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.

### 06 hours

### 10 hours



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#### 10 hours

10 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

#### TEXT 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
- Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
- 4. Text book of Medical Physiology- Arthur C, Guyton and John.E. Hall. Miamisburg, OH, U.S.A.
- 5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
- 6. Textbook of Human Histology by Inderbir Singh, Jaypeebrothers medical publishers, New Delhi.
- 7. Human Anatomy and Physiology-II by Singh Amteshwar Jaggi, Pharmamed Press

#### **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

09 hours

#### PS202: PHARMACEUTICAL ORGANIC CHEMISTRY -I

#### B. Pharm. I Year II Sem

# **4 1 0 4 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.

**Course 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

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

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

#### UNIT - I

#### Classification, nomenclature and isomerism

Brief review of structural theory of organic chemistry, hybridization, bond length, bond angle, bond energy; inductive effect, electromeric effect, resonance, hyperconjugationand their application in the analysis of strength of organic acids, bases and stability of organic compounds; structure, shape and reactivity of nucleophiles, electrophiles and free radicals; cleavage of bonds-homolysis and heterolysis **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

**Types of organic reactions:** Addition reactions-electrophilic, nucleophilic and free radical; Substitution reactions-electrophilic, nucleophilic and free radical; elimination and rearrangement reactions

#### UNIT – II

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

Functional group approach for the following reactions (preparations & reactions) to be studied in context to their structure

**Alkanes:** Preparation: Catalytic hydrogenation, Wurtz reaction, Kolbe's synthesis, from Grignard reagent. Reactions: Free radical Substitution: Halogenation, Synthesis of cycloalkanes and different kinds of strains in cycloalkanes

**Alkenes:** Preparation: Elimination reactions: Dehydration of alkenes and dehydrohalogenation of alkyl halides (Saytzeff's rule); cis alkenes (Partial catalytic hydrogenation) and trans alkenes (Birch reduction). Reactions: cis-addition (alk. KMnO4) and trans-addition (bromine), Addition of HX (Markownikoff's and anti-Markownikoff's addition), Hydration, Ozonolysis, oxymecuration-demercuration, Hydroboration-oxidation, stability of alkenes

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

**Alkynes**: Preparation: Acetylene from CaC2 and conversion into higher alkynes; by dehalogenation of tetra halides and dehydrohalogenation of vicinal-dihalides. Reactions: formation of metal acetylides, addition of bromine and alkaline KMnO4, ozonolysis and oxidation with hot alk. KMnO4

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#### 10 Hours

07 Hours

### Page **25** of **136**

### UNIT – III

#### Alkyl halides\*

SN1 and SN2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations, SN1 versus SN2 reactions, Factors affecting SN1 and SN2 reactions, Preparation: from alkenes and alcohols. Reactions: hydrolysis, nitrite & nitro formation, nitrile & isonitrile formation.

**Alcohols:** Preparation of alcohols: using Grignard reagent, Ester hydrolysis, Reduction of aldehydes, ketones, carboxylic acid and esters. Reactions: With sodium, HX (Lucas test), esterification, oxidation reactions.

#### UNIT – IV

#### Carbonyl compounds\* (Aldehydes and ketones)

Preparation: from acid chlorides and from nitriles. Reactions: Reaction with HCN, ROH, NaHSO3, NH2-G derivatives. Aldol Condensation, Cannizzaro's reaction, Wittig reaction, Benzoin condensation, Clemensen reduction and Wolff Kishner reduction, Meerwein-Pondorff Verley reduction, Analysis of aldehydes and ketones: haloform test, 2,4-DNP test, Tollens and Fehling test.

#### UNIT - V

Carboxylic acids\*(aliphatic and aromatic)

Preparation and reactions of carboxylic acids.

Carboxylic acid derivatives (aliphatic): Preparation: Acid chlorides, Anhydrides, Esters and Amides from acids and their interconversion.

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

#### Aliphatic amines\* -

Preparation: from alkyl halides, Gabriel's Phthalimide synthesis, Hofmann Bromamide reaction. Reactions: Hofmann vs. Saytzeff elimination, Quaternary ammonium salts, Carbylamine test. Basicity, effect of substituent on Basicity. Qualitative tests.

#### TEXT BOOKS: (Latest Editions)

- 1. Organic Chemistry by Morrison and Boyd
- 2. Organic Chemistry by I.L. Finar, Volume-I
- 3. Algarsamy V., Pharmaceutical organic Chemistry, Pharma Med Press
- 4. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
- 5. Organic Chemistry by P.L. Soni
- 6. Practical Organic Chemistry by Mann and Saunders.
- 7. Vogel's text book of Practical Organic Chemistry
- 8. Advanced Practical organic chemistry by N.K. Vishnoi.
- 9. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
- 10. Pharmaceutical organic Chemistry-1, Pooja Chawla.
- 11. McMurry E. John, Organic Chemistry, Cengage

10 Hours

## 10 Hours

### 08 Hours

08 Hours

#### **BS203: BIOCHEMISTRY**

#### B. Pharm. I Year II Sem

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.

Course Objectives: Upon completion of course, student shell 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 ٠ synthesis of RNAs and proteins.

#### UNIT – I

#### 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 – II

#### Lipid metabolism

a-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.

#### UNIT – III

#### Amino acid metabolism

General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cvcle 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

#### 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

#### 10 Hours

10 Hours

10 Hours

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Structure of DNA and RNA and their functions DNA replication (semi conservative model) Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

#### UNIT – V

#### Enzymes

Introduction, properties, nomenclature, and IUB classification of enzymes Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

Enzyme inhibitors with examples

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

Therapeutic and diagnostic applications of enzymes and isoenzymes Coenzymes –Structure and biochemical functions

#### TEXT BOOKS: (Latest Editions)

- 1. Principles of Biochemistry by Lehninger
- 2. Algarsamy V. Pharmaceutical Biochemistry, Pharma Med Press.
- 3. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
- 4. Biochemistry by Stryer.
- 5. Biochemistry by D. Satyanarayan and U. Chakrapani
- 6. Textbook of Biochemistry by Rama Rao.
- 7. Textbook of Biochemistry by Deb.
- 8. Outlines of Biochemistry by Conn and Stumpf
- 9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)

**08 Hours** 

#### **BS204: PATHOPHYSIOLOGY**

#### B. Pharm. I Year II Sem

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

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

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

#### UNIT – I

#### Basic principles of Cell injury and Adaptation:

Introduction, definitions, Homeostasis, Components and Types of Feedback systems, causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis &Alkalosis, Electrolyte imbalance

#### Basic mechanism involved in the process of inflammation and repair:

Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of

WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis

#### UNIT – II

#### Cardiovascular System:

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

**Respiratory system:** Asthma, Chronic obstructive airways diseases.

Renal system: Acute and chronic renal failure

#### UNIT - III

#### Haematological Diseases:

Iron deficiency, megaloblastic 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

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

#### 10 Hours

10 Hours

#### 10 Hours

#### UNIT – V

**Infectious diseases:** Meningitis, Typhoid, Leprosy, Tuberculosis, Urinary tract infections, SARS virus including COVID 19, Conjunctivitis, Measles

Sexually transmitted diseases: AIDS, Syphilis, Gonorrhea

#### TEXT 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; 12<sup>th</sup> edition; New York; McGraw-Hill; 2011.
- 4. Sujesh M., Pathophysiology for Pharmacy A Concise Review, Pharma Med Press
- 5. 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;
- 6. William and Wilkins, Baltimore; 1991 [1990 printing].
- Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21<sup>st</sup> edition; London; ELBS/Churchill Livingstone; 2010.
- Guyton A, John. E Hall; Textbook of Medical Physiology; 12<sup>th</sup> edition; WB Saunders Company; 2010.
- Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9<sup>th</sup> edition; London; McGraw-Hill Medical; 2014.
- 10. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6<sup>th</sup> edition; Philadelphia; WB Saunders Company; 1997.
- 11. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3<sup>rd</sup> edition; London; Churchill Livingstone publication; 2003.

#### **CS205: COMPUTER APPLICATIONS IN PHARMACY**

#### B. Pharm. I Year II Sem

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

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

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

#### UNIT – I

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

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

#### UNIT-II

Web technologies: Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

#### UNIT – III

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology, and adherence monitoring

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

#### UNIT - IV

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

#### **UNIT-V**

#### 06 hours

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

#### **TEXT BOOKS: (Latest edition):**

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

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#### PS206: HUMAN ANATOMY AND PHYSIOLOGY -II LAB

#### B. Pharm. I Year II Sem

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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.

#### List of Experiments:

- 1. Introduction to hemocytometry.
- 2. Enumeration of white blood cell (WBC) count
- 3. Enumeration of total red blood corpuscles (RBC) count
- 4. Determination of bleeding time
- 5. Determination of clotting time
- 6. Estimation of hemoglobin content
- 7. Determination of blood group.
- 8. Determination of erythrocyte sedimentation rate (ESR).
- 9. Determination of heart rate and pulse rate.
- 10. Recording of blood pressure.
- 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.

#### **REFERENCE BOOKS:**

- 1. Textbook of Practical Physiology by C.L. Ghai, Jaypeebrothers medical publishers, New Delhi.
- 2. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

#### PS207: PHARMACEUTICAL ORGANIC CHEMISTRY -I LAB

#### B. Pharm. I Year II Sem

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#### List of Experiments:

- a) Systematic qualitative analysis of unknown organic compounds like
  - 1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
  - 2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
  - 3. Solubility test

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

- 5. Melting point/Boiling point of organic compounds
- 6. Identification of the unknown compound from the literature using melting point/ boiling point.

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

- 8. Minimum 5 unknown organic compounds to be analysed systematically.
- b) Preparation of suitable solid derivatives from organic compounds
- c) Construction of molecular models

#### **RECOMMENDED BOOKS (Latest Editions)**

- 1. Practical Organic Chemistry by Mann and Saunders.
- 2. Advanced Practical organic chemistry by N.K. Vishnoi.

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#### **BS208: BIOCHEMISTRY LAB**

#### B. Pharm. I Year II Sem

#### List of Experiments:

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

#### **RECOMMENDED BOOKS (Latest Editions)**

- 1) Biochemistry: A Practical Manual, Bose Sharad Chandra
- 2) Practical Biochemistry by R.C. Gupta and S. Bhargavan.
- 3) Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
- 4) Practical Biochemistry by Harold Varley.

#### CS209: COMPUTER APPLICATIONS IN PHARMACY LAB

#### B. Pharm. I Year II Sem

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#### List of Experiments:

- 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

#### PS301: PHARMACEUTICAL ORGANIC CHEMISTRY - II

#### B. Pharm. II Year I Sem

Course Objectives: 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.

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

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

#### UNIT - I

#### Benzene and its derivatives

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

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

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

#### UNIT - II

Phenols\* - preparation and reactions, Acidity of phenols, effect of substituents on acidity, qualitative tests.

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

Nitro Compounds: Preparations and reactions, Classification, Reactivity: Halogenation using nitrous acid, Nef reaction, Michael Addition, Henry Reaction, Aromatic Nitro hydrocarbons, Preparation of Nitrobenzene from diazonium salt and direct nitration, Reactivity and reduction of nitrobenzene in different media.

Ethers (aliphatic and aromatic): Introduction, synthesis and reactions of ethers

#### UNIT - IV

#### Polynuclear hydrocarbons:

- a) Synthesis, reactions
- b) Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

#### UNIT – V

Cyclo alkanes: Stabilities - Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane

#### **RECOMMENDED BOOKS (Latest Editions)**

- 1. Organic Chemistry by Morrison and Boyd
- 2. Organic Chemistry by I.L. Finar, Volume-I
- Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.

#### 07 Hours

# 08 Hours

#### 10 Hours

10 Hours

10 Hours

#### LT P C 3 1 0 4
- 4. Pharmaceutical organic Chemistry by V Algarsamy, Pharmamed Press
- 5. Organic Chemistry by P.L. Soni
- 6. Practical Organic Chemistry by Mann and Saunders.
- 7. Vogel's text book of Practical Organic Chemistry
- 8. Advanced Practical organic chemistry by N.K. Vishnoi.
- 1. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

#### PS302: PHYSICAL PHARMACEUTICS - I

B. Pharm. II Year I Sem

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**Course Objectives:** The course deals with the various physical, physicochemical properties and principle involved in dosage forms, formulations. Theory and practical components of the subject help the student to get a better insight in to various areas of formulation research and development and stability studies of pharmaceuticals.

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

- Understand various physicochemical properties of drug molecules in the designing the dosage form.
- Know the principles of chemical kinetics & to use them in assigning expiry date for formulation.
- Demonstrate use of physicochemical properties in evaluation of dosage forms.
- Appreciate physicochemical properties of drug molecules in formulation research and development.

#### UNIT – I

**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 – II

**Solubility of drugs:** Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, Dissolution & drug release, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions, azeotropic mixtures, fractional distillation. Partially miscible liquids, Critical solution temperature (CST) and applications. Distribution law, its limitations and applications

#### UNIT - III

**Micromeretics:** Particle size and distribution, average 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 – IV

**Complexation and protein binding:** Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants.

#### UNIT – V

**pH, buffers and Isotonic solutions:** Sorensen's pH scale, pH determination ectrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions. Isotonicity, Colligative properties and determination of tonicity of a system.

#### 10 Hours

10 Hours

#### 08 Hours

10 Hours

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

### BS303: PHARMACEUTICAL MICROBIOLOGY

B. Pharm. II Year I Sem

**Course Objectives:** In the broadest sense, scope of microbiology is the study of all organisms that are invisible to the naked eye- that is the study of microorganisms. Microorganisms are necessary for the production of bread, cheese, beer, antibiotics, vaccines, vitamins, enzymes etc. Microbiology has an impact on medicine, agriculture, food science, ecology, genetics, biochemistry, immunology etc.

**Course Outcomes:** Upon completion of the subject student shall be able to;

- Understand methods of identification, cultivation and preservation of various microorganisms
- Importance of sterilization in microbiology. and pharmaceutical industry
- Learn sterility testing of pharmaceutical products.
- Microbiological standardization of Pharmaceuticals.
- Understand the cell culture technology and its applications in pharmaceutical industries.

#### UNIT – I

Introduction, history of microbiology, its branches, scope and its importance. Introduction to Prokaryotes and Eukaryotes. Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count). Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.

#### UNIT - II

Identification of bacteria using staining techniques (simple, Gram's & Acid fast staining) and biochemical tests (IMViC). Study of principle, procedure, merits, demerits and applications of Physical, chemical and mechanical method of sterilization. Evaluation of the efficiency of sterilization methods. Equipments employed in large scale sterilization. Sterility indicators.

#### UNIT – III

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Virus. Classification and mode of action of disinfectants. Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions. Evaluation of bactericidal & Bacteriostatic. Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

#### UNIT – IV

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification. Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic and testing of antimicrobial activity of a new substance. General aspects-environmental cleanliness.

#### UNIT – V

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.

Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations. Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures. Application of cell cultures in pharmaceutical industry and research.

### 10 Hours

10 Hours

10 Hours

#### 08 Hours

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3	1	0	4

- 1. Rafi MD, Text book of biochemistry for undergraduates, 3<sup>rd</sup> edition, Universities press, 2017.
- 2. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
- 3. Prescott and Dunn, Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
- 4. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
- 5. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
- 6. Rose: Industrial Microbiology.
- 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. I.P., B.P., U.S.P.- latest editions.
- 11. Edward: Fundamentals of Microbiology.
- 12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
- 13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
- 14. Ananthanarayan and Paniker's textbook of Microbiology tenth edition
- 15. Ravi Kumar, Pharmaceutical Microbiology: A Comprehensive Approach, 2nd Ed. Pharma Med Press

#### PC304: PHARMACEUTICAL ENGINEERING

#### B. Pharm. II Year I Sem

### **08 Hours**

# 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

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

Crystallization: Objectives, applications, & theory of crystallization. Solubility curves, principles, construction, working, uses, merits and demerits of Agitated batch crystallizer, Swenson Walker Crystallizer, Krystal crystallizer, Vacuum crystallizer. Caking of crystals, factors affecting caking & prevention of caking.

#### UNIT – III

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.

Heat Transfer: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers. List of equipment by name and their functions.

#### UNIT - IV

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

Distillation: Objectives, applications & types of distillation. principles, construction, working, uses, merits and demerits of (lab scale and industrial scale) Simple distillation, preparation of purified water and water for injection BP by distillation, flash distillation, fractional distillation, distillation under reduced

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

Course Outcomes: Upon completion of the course student shall be able:

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

### UNIT – I

Ρ С pressure, steam distillation & molecular distillation

#### UNIT - V

#### 07 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 Seitz filter. HEPA filters for controlled pollution. **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.

- 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 DK Tripathi, Pharma Med Press
- 5. Pharmaceutical engineering principles and practices C.V.S Subrahmanyam et al., Latest edition.
- 6. Remington practice of pharmacy- Martin, Latest edition.
- 7. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
- 8. Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
- 9. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.
- 10. Derle, Essentials of Pharmaceutical Engineering (Unit Operations), 2nd Ed. Pharma Med Press

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#### PS305: PHARMACEUTICAL ORGANIC CHEMISTRY - II LAB

B. Pharm. II Year I Sem	L	т	Ρ
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#### I Experiments involving laboratory techniques

Recrystallization Steam Distillation

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

Acid value Saponification value Iodine value

#### III Preparation of compounds

- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
- 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/ Acetanilide by halogenation (Bromination) reaction.
- 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
- Benzoic acid from Benzyl chloride by oxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-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. Practical Organic Chemistry by Mann and Saunders.
- 2. Durai Ananda Kumar T., Experimental Organic and Medicinal Chemistry Principles & Practice, Pharma Med Press.
- 3. A Microscale Approach to Organic Laboratory Techniques, Pavia, Lampman, Cengage BSP Books.

#### PS306: PHYSICAL PHARMACEUTICS - I LAB

#### B. Pharm. II Year I Sem

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#### List of Experiments

- 1. Determination the solubility of drug at room temperature at different pH conditions
- 2. Determination of pKa value by Half Neutralization/ Henderson Hassel Balch equation
- 3. Determination of Partition co- efficient of benzoic acid in benzene and water
- 4. Determination of Partition co- efficient of lodine in  $CCI_4$  and water
- 5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
- 6. Determination of particle size, particle size distribution using sieving method
- 7. Determination of particle size, particle size distribution using Microscopic method
- 8. Determination of bulk density, true density and porosity
- 9. Determine the angle of repose and influence of lubricant on angle of repose
- 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

- 1. Experimental pharmaceutics by Eugene, Parott.
- 2. Pharmaceutical Calculation, D K Tripathi.
- 3. Laboratory manual of physical pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
- 4. Mohanta Guru Prasad. Physical Pharmacy Practical text, 3rd Revised Ed., Pharma Med Press

#### BS307: PHARMACEUTICAL MICROBIOLOGY LAB

#### B. Pharm. II Year I Sem

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#### List of Experiments:

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

- 1. Jyostna, Manual of Practical Microbiology, Pharma Med Press
- 2. Pharmaceutical Microbiology: A Laboratory manual by Prasad G.Shyam & K.Srisailam,

#### PC308: PHARMACEUTICAL ENGINEERING LAB

#### B. Pharm. II Year I Sem

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#### List of Experiments:

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

- 1. Pharmaceutical Engineering : Practical Manual (Unit Operations), Sudhakara Reddy,Pharmamed Press.
- 2. Remington practice of pharmacy- Martin, Latest edition.

#### PS401: PHARMACEUTICAL ORGANIC CHEMISTRY - III

#### B. Pharm. II Year II Sem

**Course Objectives:** 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.

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

- Understand the methods of preparation and properties of organic compounds
- Explain the stereo chemical aspects of organic compounds and stereo chemical reactions
- Know the medicinal uses and other applications of organic compounds

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

#### UNIT - I

#### Stereo isomerism

Optical isomerism – Optical activity, enantiomerism, diastereoisomerism, meso compounds Elements of symmetry, chiral and achiral molecules, DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers, Reactions of chiral molecules. Racemic modification and resolution of racemic mixture Asymmetric synthesis: partial and absolute

#### UNIT – II

#### Geometrical isomerism

Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems) Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane. Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity. Stereospecific and stereoselective reactions

UNIT – III

#### Heterocyclic compounds with one hetero atom

Nomenclature and classification

Synthesis, reactions and medicinal uses of compounds/derivatives: Pyrrole, Furan, and Thiophene Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

#### UNIT – IV

#### Heterocyclic compounds with two hetero atoms

Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrazole, Imidazole, Oxazole and Thiazole. Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

#### UNIT – V

#### **Reactions of synthetic importance**

Metal hydride reduction (NaBH4 and LiAlH4), Clemmensen reduction, Birch reduction, Wolff Kishner reduction. Oppenauer-oxidation and Dakin reaction. Beckmanns rearrangement and Schmidt rearrangement, Pinocol-Pinocolone rearrangement Claisen-Schmidt condensation

#### **RECOMMENDED BOOKS (Latest Editions)**

- 1. Organic chemistry by I.L. Finar, Volume-I & II.
- 2. A text book of organic chemistry Arun Bahl, B.S. Bahl.
- 3. Heterocyclic Chemistry by Raj K. Bansal
- 4. Organic Chemistry by Morrison and Boyd
- 5. Heterocyclic Chemistry by T.L. Gilchrist
- 6. Rama Rao Nadendla, Principles of Pharmaceutical Organic Chemistry, 2nd Ed., Pharma Med Press

# 10 Hours

### 10 Hours

# 08 Hours

07 Hours

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#### **PS402: PHYSICAL PHARMACEUTICS - II**

#### B. Pharm. II Year II Sem

Course Objectives: The course deals with the various physical, physicochemical properties and principle involved in dosage forms, formulations. Theory and practical components of the subject help the student to get a better insight in to various areas of formulation research and development and stability studies of pharmaceuticals.

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

- Understand various physicochemical properties of drug molecules in the designing the dosage form
- Know the principles of chemical kinetics & to use them in assigning expiry date for Formulation
- Demonstrate use of physicochemical properties in evaluation of dosage forms.
- Appreciate physicochemical properties of drug molecules in formulation research and Development •

#### UNIT - I

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

#### UNIT - II

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatants, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers

Deformation of solids: Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus

#### UNIT – III

**Coarse dispersion:** Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Physical stability of emulsions, preservation of emulsions, rheological properties of emulsions, phase equilibria and emulsion formulation.

#### UNIT - IV

Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions, surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface.

#### UNIT – V

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.

#### **RECOMMENDED BOOKS: (Latest Editions)**

- 1. Physical Pharmacy by Alfred Martin, Sixth edition
- 2. Experimental pharmaceutics by Eugene, Parott.
- 3. Tutorial pharmacy by Cooper and Gunn.

#### 07 Hours

# 10 Hours

**08 Hours** 

10 Hours

#### Page 49 of 136

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- 4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
- 5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume 1-3, Marcel Dekkar Inc.
- 6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
- 7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.
- 8. Vidyadhara et al. Physical Pharmaceutics II, Pharma Med Press.

#### PC403: PHARMACOLOGY - I

#### B. Pharm. II Year II Sem

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

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

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

#### UNIT – I

#### 1. General Pharmacology

- a) Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration.
- b) 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.
- c) Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs. Enzyme induction, enzyme inhibition, kinetics of elimination

#### UNIT – II

#### Adverse Drug Reactions and Drug Interactions

a. Agonists, antagonists (competitive and noncompetitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.

- b. Adverse drug reactions.
- c. Drug interactions (pharmacokinetic and pharmacodynamic)
- d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

#### UNIT – III

#### 2. Pharmacology of 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

### 3. Pharmacology of central nervous system - I

a. Neurohumoral transmission in the C.N.S. special emphasis on importance of various

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neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.

- b. General anesthetics and pre-anesthetics.
- c. Sedatives, hypnotics and centrally acting muscle relaxants.
- d. Anti-epileptics
- e. Alcohols and disulfiram

#### UNIT – V

#### Pharmacology of central nervous system - II

- Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, antimanics and hallucinogens.
- b. Drugs used in Parkinsons disease and Alzheimer's disease.
- c. CNS stimulants and nootropics.
- d. Opioid analgesics and antagonists
- e. Drug addiction, drug abuse, tolerance and dependence.

#### **RECOMMENDED BOOKS (Latest Editions)**

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
- 2. A Pharmacology Primer: Theory Applications and Methods, 3<sup>rd</sup> edition, Terry P. Kenakin, Elsevier
- 3. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
- 4. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
- 5. Basic Knowledge of Pharmacology BY Roland Seifert, Springer
- 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
- 7. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
- 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
- 11. Ravishankar. K & Kiranmayi G.V.N, Pharmacology: A Comprehensive Approach, Pharma Med Press

#### PC404: PHARMACOGNOSY AND PHYTOCHEMISTRY - I

#### B. Pharm. II Year II Sem

**Course Objective:** The subject involves the fundamentals of Pharmacognosy like scope, classification ofcrude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

Course Outcomes: Upon completion of the course, the student shall be able

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

#### UNIT - I

**Introduction to Pharmacognosy:** Definition, history, scope and development of Pharmacognosy (a) Sources of Drugs – Plants, Animals, Marine & Tissue culture

(b) 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 classification of drugs

#### UNIT – II

#### Cultivation, Collection, Processing and storage of drugs of natural origin:

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

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

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

#### UNIT – III

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

#### UNIT - IV

#### Pharmacognosy in various systems of medicine:

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

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#### Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

#### UNIT - V

**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

- 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
- 4. 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.
- 6. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
- 7. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
- 8. Anatomy of Crude Drugs by M.A. Iyengar
- 9. SL Deore, Pharmacognosy and Phytochemistry I, Pharma Med Press

#### PS405: PHARMACEUTICAL JURISPRUDENCE

#### B.Pharm. II Year II Sem.

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

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

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

#### UNIT – I

#### Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the act and rules Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs - Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

#### UNIT – II

#### Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA)

Sale of Drugs - Wholesale, Retail sale and Restricted license. Offences and penalties

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

Administration of the act and rules - Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

#### UNIT – III

**Pharmacy Act - 1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; its constitution and functions, Registration of Pharmacists, Offences and

Penalties

**Medicinal and Toilet Preparation Act -1955:** Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.

**Narcotic Drugs and Psychotropic substances Act-1985 and Rules:** Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

#### UNIT – IV

**Study of Salient Features of Drugs and magic remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties

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**Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

#### UNIT – V

#### 07 Hours

**Pharmaceutical Legislations** – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee

**Code of Pharmaceutical ethics** - Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath

Medical Termination of pregnancy act Right to information Act Introduction to Intellectual Property Rights (IPR)

- 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)
- 10. Kokate C. K. Textbook of Forensic Pharmacy, 2nd Ed. Pharma Med Press

#### PC406: PHYSICAL PHARMACEUTICS - II LAB

B. Pharm. II Year II Sem	L	т	Ρ	С
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#### List of Experiments:

- 1. Determination of surface tension of given liquids by drop count and drop weight method
- 2. Determination of HLB number of a surfactant by saponification method
- 3. Determination of Freundlich and Langmuir constants using activated char coal
- 4. Determination of critical micellar concentration of surfactants
- 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
- 12. Preparation and evaluation of Colloids

- 1. Physical Pharmacy by Alfred Martin, Sixth edition
- 2. Experimental pharmaceutics by Eugene, Parott.
- 3. Tutorial pharmacy by Cooper and Gunn.
- 4. Physical Pharmacy Practical text, 3rd Revised Ed.by Mohanta Guru Prasad
- 5. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

#### PS407: PHARMACOLOGY - I LAB

#### B. Pharm. II Year II Sem

#### List of Experiments:

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

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

#### **RECOMMENDED BOOKS (Latest Editions)**

1) Essentials of Experimental Pharmacology, General Concepts by Bothra Sunil

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#### PC408: PHARMACOGNOSY AND PHYTOCHEMISTRY - I LAB

#### B. Pharm. II Year II Sem

#### List of Experiments:

- 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 length and width of Phloem fibres of Cinchona & Cinnamon.
- 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
- 11. Determination of acid value, ester value, Saponification value and iodine lab of fixed oils mentioned in theory.

- 1. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
- 2. Practical Pharmacognosy, T. E. Wallis, Pharmamed Press
- 3. Anatomy of Crude Drugs by M.A. Iyengar

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#### MC400: GENDER SENSITIZATION LAB

B. Pharm. II Year II Sem	LΤ
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#### COURSE DESCRIPTION

This course offers an introduction to Gender Studies, an interdisciplinary field that asks critical questions about the meanings of sex and gender in society. The primary goal of this course is to familiarize students with key issues, questions and debates in Gender Studies, both historical and contemporary. It draws on multiple disciplines – such as literature, history, economics, psychology, sociology, philosophy, political science, anthropology and media studies – to examine cultural assumptions about sex, gender, and sexuality.

This course integrates analysis of current events through student presentations, aiming to increase awareness of contemporary and historical experiences of women, and of the multiple ways that sex and gender interact with race, class, caste, nationality and other social identities. This course also seeks to build an understanding and initiate and strengthen programmes combating gender-based violence and discrimination. The course also features several exercises and reflective activities designed to examine the concepts of gender, gender-based violence, sexuality, and rights. It will further explore the impact of gender-based violence on education, health and development.

#### **Objectives of the Course**

- To develop students' sensibility with regard to issues of gender in contemporary India.
- To provide a critical perspective on the socialization of men and women.
- To introduce students to information about some key biological aspects of genders.
- To expose the students to debates on the politics and economics of work.
- To help students reflect critically on gender violence.
- To expose students to more egalitarian interactions between men and women.

#### Learning Outcomes

- Students will have developed a better understanding of important issues related to gender in contemporary India.
- Students will be sensitized to basic dimensions of the biological, sociological, psychological and legal aspects of gender. This will be achieved through discussion of materials derived from research, facts, everyday life, literature and film.
- Students will attain a finer grasp of how gender discrimination works in our society and how to counter it.
- Students will acquire insight into the gendered division of labor and its relation to politics and economics.
- Men and women students and professionals will be better equipped to work and live together as equals.
- Students will develop a sense of appreciation of women in all walks of life.
- Through providing accounts of studies and movements as well as the new laws that provide protection and relief to women, the textbook will empower students to understand and respond to gender violence.

#### Unit-I: UNDERSTANDING GENDER

Introduction: Definition of Gender-Basic Gender Concepts and Terminology-Exploring Attitudes towards Gender-Construction of Gender-Socialization: Making Women, Making Men - Preparing for Womanhood. Growing up Male. First lessons in Caste.

#### Unit – II: GENDER ROLES AND RELATIONS

Two or Many? -Struggles with Discrimination-Gender Roles and Relations-Types of Gender Roles-Gender Roles and Relationships Matrix-Missing Women-Sex Selection and Its Consequences-Declining Sex Ratio. Demographic Consequences-Gender Spectrum: Beyond the Binary

#### Unit – III: GENDER AND LABOUR

Division and Valuation of Labour-Housework: The Invisible Labor- "My Mother doesn't Work." "Share the Load."-Work: Its Politics and Economics -Fact and Fiction. Unrecognized and Unaccounted work. - Gender Development Issues-Gender, Governance and Sustainable Development-Gender and Human Rights-Gender and Mainstreaming

#### Unit - IV: GENDER - BASED VIOLENCE

The Concept of Violence- Types of Gender-based Violence-Gender-based Violence from a Human Rights Perspective-Sexual Harassment: Say No!-Sexual Harassment, not Eve-teasing- Coping with Everyday Harassment- Further Reading: "*Chupulu*".

Domestic Violence: Speaking Outls Home a Safe Place? -When Women Unite [Film]. Rebuilding Lives. Thinking about Sexual Violence Blaming the Victim-"I Fought for my Life...."

#### Unit – V: GENDER AND CULTURE

Gender and Film-Gender and Electronic Media-Gender and Advertisement-Gender and Popular Literature- Gender Development Issues-Gender Issues-Gender Sensitive Language-Gender and Popular Literature - Just Relationships: Being Together as Equals

Mary Kom and Onler. Love and Acid just do not Mix. Love Letters. Mothers and Fathers. Rosa Parks-The Brave Heart.

# <u>Note</u>: Since it is Interdisciplinary Course, Resource Persons can be drawn from the fields of English Literature or Sociology or Political Science or any other qualified faculty who has expertise in this field from engineering departments.

- Classes will consist of a combination of activities: dialogue-based lectures, discussions, collaborative learning activities, group work and in-class assignments. Apart from the above prescribed book, Teachers can make use of any authentic materials related to the topics given in the syllabus on "Gender".
- ESSENTIAL READING: The Textbook, "Towards a World of Equals: A Bilingual Textbook on Gender" written by A. Suneetha, Uma Bhrugubanda, DuggiralaVasanta, Rama Melkote, Vasudha Nagaraj, Asma Rasheed, Gogu Shyamala, Deepa Sreenivas and Susie Tharu published by Telugu Akademi, Telangana Government in 2015.

ASSESSMENT AND GRADING:

- Discussion & Classroom Participation: 20%
- Project/Assignment: 30%
- End Term Exam: 50%

#### PS501: MEDICINAL CHEMISTRY - I

#### B. Pharm. III Year I Sem

**Course Objectives:** 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.

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

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

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

#### UNIT – I

#### Introduction to Medicinal Chemistry

History and development of medicinal chemistry. Physicochemical properties in relation to biological action (Ionization, Solubility, Partition Coefficient, Hydrogen bonding) Protein binding, Chelation, Bioisosterism, significance of Isomerism in biological activity, Structural modifications in drug discovery. Prodrugs: Basic concepts & application of prodrug design

#### UNIT – II

#### Drugs acting on Autonomic Nervous System

Adrenergic Neurotransmitters: Biosynthesis and catabolism of catecholamine. Adrenergic receptors (Alpha & Beta) and their distribution.

#### Sympathomimetic agents: SAR of Sympathomimetic agents

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

Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.

Agents with mixed mechanism: Ephedrine, Metaraminol.

#### Adrenergic Antagonists:

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

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

#### UNIT – III

Cholinergic neurotransmitters: Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

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

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

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

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

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

#### UNIT – IV

**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 anticonvulsantaction

Barbiturates: Phenobarbitone, Methabarbital.

Hydantoins: Phenytoin, Mephenytoin, Ethotoin

Oxazolidine diones: Trimethadione, Paramethadione

Succinimides: Phensuximide, Methsuximide, Ethosuximide

Urea and monoacylureas: Phenacemide, Carbamazepine

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate

#### UNIT – V

Drugs acting on Central Nervous System

**General anesthetics:** 

**Inhalation anesthetics:** Halothane\*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane. **Ultra short acting barbitutrates:** Methohexital sodium\*, Thiamylalsodium, Thiopental sodium. **Dissociative anesthetics:** Ketamine hydrochloride. \*

Narcotic and non-narcotic analgesics

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

**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.
- 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. Rama Rao Nadendla, Medicinal Chemistry, 2nd Revised Ed. Pharma Med Press

#### PS502: INDUSTRIAL PHARMACY - I

#### B.Pharm. III Year I Sem.

Course Objective: 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.

Course Outcomes: 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 •

#### UNIT - I

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

a. Physical properties: Physical form (Crystalline and amorphous forms: Concepts of polymorphism and its significance in industrial setup), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient).

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs

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

#### UNIT - II

#### Tablets:

- a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.
- b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.
- c. Quality control tests: In process and finished product tests

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

#### UNIT – III

Capsules:

- a. Hard gelatin capsules: Introduction, Extraction of gelatin and production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules. In process and final product quality control tests for capsules.
- b. Soft gelatin capsules: Nature of shell and capsule content, size of capsules, importance of base adsorption and minimum/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets, Fluidised bed coater (FBC)/ extrusion spheronization technique.

#### UNIT – IV

#### **Parenteral Products:**

- a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
- b. Production procedure, production facilities and controls.
- c. Formulation of injections, sterile powders, emulsions, suspensions, large volume parenterals

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and lyophilized products, Sterilization.

d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests.

**Ophthalmic/Otic Preparations:** Introduction, formulation considerations; formulation of eye drops, ear 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 aerosolsystems; 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.

#### TEXT BOOKS: (Latest Editions)

- 1. Pharmaceutical dosage forms Tablets, volume 1 -3 by H. A. Liberman, Leon Lachman & J. B. Schwartz
- 2. Pharmaceutical dosage form Parenteral medication vol- 1&2 by Liberman & Lachman
- 3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
- 4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
- 5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
- 6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
- 7. Pharmaceutics- The science of dosage form design by M.E. Aulton, Churchill Livingstone, Latest edition
- Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia, 5<sup>th</sup> edition, 2005
- 9. Drug stability Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.
- 10. Pharmaceutical Technology 1 &11 BY Gaurav Agarwal CBS Publishers
- 11. Pharmaceutics Basic principles and Formulations by D.K. Tripati Pharma med press
- 12. Semalty Ajay, Industrial Pharmacy I, Pharma med press

#### PS503: PHARMACOLOGY - II

B.Pharm. III Year I Sem.	L	т	Ρ	С
	3	1	0	4

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

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

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

#### UNIT – I

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

- 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

- 1. Pharmacology of drugs acting on cardio vascular system II
  - a. Drug used in the therapy of shock.
  - b. Hematinics, coagulants and anticoagulants.
  - c. Fibrinolytics and anti-platelet drugs
  - d. Plasma volume expanders

#### 2. Pharmacology of drugs acting on urinary system

- a. Diuretics
- b. Anti-diuretics.

#### UNIT - III

#### 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

#### Pharmacology of drugs acting on endocrine system - I

- a. Basic concepts in endocrine pharmacology.
- b. Anterior Pituitary hormones- analogues and their inhibitors.
- c. Thyroid hormones- analogues and their inhibitors.

10 hours

10 hours

10 hours

08 hours

- d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
- e. Insulin, Oral Hypoglycemic agents and glucagon.
- f. ACTH and corticosteroids.

#### UNIT - V

#### 1. Pharmacology of drugs acting on endocrine system - II

07 hours

- a. Androgens and Anabolic steroids.
- b. Estrogens, progesterone and oral contraceptives.
- c. Drugs acting on the uterus.

#### 2. Bioassay

- a. Principles and applications of bioassay.
- b. Types of bioassay
- c. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine

#### TEXT BOOKS (Latest Editions)

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology,
- 2. Churchil Livingstone Elsevier
- 3. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
- 4. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
- 5. Basic Knowledge of Pharmacology BY Roland Seifert, Springer
- 6. 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.
- 7. Mycek M. J, Gelnet S. B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
- 8. K. D. Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
- 9. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
- 10. Modern Pharmacology with clinical Applications, by Charles R. Craig& Robert.
- 11. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
- 12. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

#### PS504: PHARMACOGNOSY AND PHYTOCHEMISTRY - II

#### B.Pharm. III Year I Sem.

**Course Objective:** 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

**Course Outcomes:** Upon completion of the course, the student shall be able

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

#### UNIT - I

#### Metabolic pathways in higher plants and their determination

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

#### UNIT - II

a. General introduction, general methods of extraction (Maceration, Percolatio, Chromatographic methods) and isolation of alkaloids, glycosides, flavanoids and volatile oils.

b. Biological source, microscopical characters, composition, chemistry, analysis, therapeutic uses and commercial applications of the following secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,

#### UNIT - III

General introduction, composition, chemistry & chemical classes, general methods of extraction & analysis, biological sources, therapeutic uses and commercial applications of following secondary metabolites

Tannins: Catechu, Pterocarpus

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

Glycosides: Senna, Aloes, Bitter Almond

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

#### UNIT - IV

#### Isolation, Identification, analysis of phytoconstituents and commercial applications of following

- a. Terpenoids: Menthol, Citral and Artemisin
- b. Glycosides: Glycyrhetinic acid and Rutin
- c. Alkaloids: atropine, Quinine, Reserpine and Caffeine
- d. Resins: Podophyllotoxin and Curcumin

#### UNIT - V

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

08 Hours

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### 10 Hours

#### 10 Hours

#### JNTUH

# 07 Hours

b. Modern methods of extraction (Super critical fluid extraction, counter current extraction, Microwave assisted extraction, ultra sonication assisted extraction

#### TEXT BOOKS: (Latest Editions)

- 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), I<sup>st</sup> 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. The formulation and preparation of cosmetic, fragrances and flavours.
- 11. Remington's Pharmaceutical sciences.
- 12. Text Boo of Biotechnology by Vyas and Dixit.
- 13. Text Book of Biotechnology by R. C. Dubey.
- 14. SL Deore, Pharmacognosy and Phytochemistry II, Pharma Med Press
- 15. Kulkarni A. Vishaka, Pharmacognosy and Phytochemistry II, Pharma Med Press

#### PS505: GENERIC PRODUCT DEVELOPMENT (Open Elective - I)

B.Pharm. III Year I Sem.	L	т	Ρ	С
	3	1	0	4
Course Objectives: To learn the generic drug product development process, dosage for	m d	esi	gn a	and

Course Outcome: The knowledge of the students is enhanced with the clear information about the

### UNIT - I

generic product development.

- a. Concept of generic drug product development, Hatch-Waxman act and its amendments.
- b. History of generic product development in US

development, analytical method development and dossier approval process.

#### UNIT - II

Design of dosage form to meet equivalence to reference listed drug, product development steps, formula optimization, process optimization and packaging selection.

#### UNIT - III

Analytical method development for verification and validation for active ingredient and impurities, inprocess samples and finished dosage forms.

#### UNIT - IV

- a. Stability studies on active ingredient and finished dosage forms, accelerated stability studies, stability studies at different conditions, determination of expiration date.
- b. Scale up studies to optimize manufacturing process and execution of exhibit batches.

#### UNIT - V

- a. Bioequivalence studies, various designs of bioequivalence studies, bioequivalence criteria and in-vitro tests to ensure bioequivalence of test product.
- b. Introduction to electronic Common Technical Document (eCTD), various modules and the important information in each module.
- c. Drug product approval process in India and US.

#### **REFERENCE BOOKS:**

- 1. Generic Drug product Development: Solid oral dosage forms-Leon Shargel.
- 2. ICH guidelines.
- 3. Subba Rao Chaganti, Cracking the Generics code Your Single-Source Success Manual for Winning in Multi-Source Product Markets, Pharma Med Press

#### PS506: GREEN CHEMISTRY (Open Elective - I)

B.Pharm. III Year I Sem.	L	т	Ρ	С
	3	1	0	4

**Course Objectives:** To familiarize students about environment benign chemical synthesis. To make students familiarize with principles and importance of various green chemical synthesis. To provide adequate knowledge regarding green reactions, green solvents and other alternative green approaches. To impart adequate information regarding environment pollution, contributing factors and the concerns.

**Course Outcomes:** Upon completion of this course, the students should be able to: Explain the environment pollution factors. Understand the different greener approaches along with their principles.

#### UNIT – I

#### Introduction to green chemistry

Inception of green chemistry: history and development.

Principles of green chemistry: description with examples.

Synthetic approaches of green chemistry: in water, solvent less, microwave, ultrasonic, catalytic and synthesis.

#### UNIT – II

#### In water and solvent less organic reactions

In water reactions: principle and process involved in the Michael reaction and Wartz synthesis Solvent less organic synthesis:

Alternative solvents used in green chemistry strategies

#### UNIT – III

#### Microwave and ultrasonic mediated reactions

Microwave reactions: principles and process involved in the Fries rearrangement, Diels Alder reaction and Metal halide reduction

Ultrasonic reaction: principle and process involved in the Strecker and Reformatsky reactions

#### UNIT – IV

#### Catalytic and solid supported reactions

Catalytic reactions: principle and process involved in the reactions catalyzed by metal catalysts, ionic liquids (Knovenegel ondensatin) and bio catalysts (Villeger reaction) Solid supported reactions: principles and process Alternative reagents used in green chemistry strategies.

#### UNIT – V

Greener synthesis of pharmaceuticals: Principle and procedure of the following synthesis Nicotinic acid, Ibuprofen, paracetamol, Aspirin Future trends in Green chemistry

#### **REFERENCE BOOKS**

- 1. Paul T Anastas, John Charles Warmer. Green chemistry: theory and practice. Oxford university Press, 1988
- 2. Alluwalia V. K, Green chemistry: environmentally benign reactions. 2<sup>nd</sup> edn, Ane Books Pvt Ltd, New Delhi, 2012
- 3. Alluwalia V.K, M. Kidwai, New trends in green chemistry. 2<sup>nd</sup> edn, Anamaya Publishers, New Delhi, 2004.
#### PS507: CELL AND MOLECULAR BIOLOGY (Open Elective - I)

L	Т	Ρ	С
3	1	0	4

**Course Objectives:** 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.

**Course Outcomes:** 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

UN	IT –		10 Hours
	a.	Cell and Molecular Biology: Definitions theory and basics and Applications.	
	b.	Cell and Molecular Biology: History and Summation.	
	C.	Theory of the Cell? Properties of cells and cell membrane.	
	d.	Prokaryotic versus Eukaryotic	
	e.	Cellular Reproduction	
UN	IT –	11	10 Hours
	a.	DNA and the Flow of Molecular Structure	
	b.	DNA Functioning	
	C.	DNA and RNA	
	d.	Types of RNA	
	e.	Transcription and Translation	
UN	IT –		10 Hours
	a.	Proteins: Definition and Amino Acids	
	b.	Protein Structure	
	c.	Regularities in Protein Pathways	
	d.	Cellular Processes	
	e.	Positive Control and significance of Protein Synthesis	
UN	IT –	IV	08 Hours
	a.	Science of Genetics	
	b.	Transgenics and Genomic Analysis	
	C.	Cell Cycle analysis	
	d.	Mitosis and Meiosis	
	e.	Cellular Activities and Checkpoints	
UN	IT –	v	07 Hours
	a.	Cell Signals: Introduction	

- b. Receptors for Cell Signals
- c. Signaling Pathways: Overview
- d. Misregulation of Signaling Pathways
- e. Protein-Kinases: Functioning

#### **RECOMMENDED BOOKS (latest edition):**

- 1. Ananthanarayana and Panikers, Text book of microbiology, 10<sup>th</sup> edition by universities press.
- 2. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
- 3. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
- 4. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
- 5. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
- 6. Rose: Industrial Microbiology.
- 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. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
- 13. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
- 14. RA Goldshy et. al., Kuby Immunology.

#### PS508: COSMETIC SCIENCE (Open Elective - I)

B.Pharm. III Year I Sem.	L	т	Ρ	С
	3	1	0	4
Course Objective: This subject deals with cosmetic products, cosmetic excipients, skin	car	e pr	odu	ucts

#### **Course Outcomes:**

- Upon completion of the course the student shall be able to know the regulations pertaining to cosmetics and cosmetic excipients.
- They will be knowing the preparations of various skin care products like creams, antiperspirants, deodorants, hair care products etc.
- They also know about the role of herbs in sunscreens.

#### UNIT – I

Classification of cosmetic and cosmeceutical products

and their methods of preparation and evaluations.

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application Skin: Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

#### UNIT – II

# Principles of formulation and building blocks of skin care products:

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream their relative skin sensory, advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

#### Principles of formulation and building blocks of Hair care products:

Conditioning shampoo, Hair conditioners, antidandruff 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

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

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as guasi and OTC drugs.

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

#### UNIT – V

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

# 10 Hours

08 Hours

#### 07 Hours

10 Hours

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- Introduction, classification and mechanism of action

#### **REFERENCE BOOKS:**

- 1. Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
- 2. Cosmetics Formulations, Manufacturing and Quality Control, P.P. Sharma, 4<sup>th</sup> Edition, Vandana Publications Pvt. Ltd., Delhi.
- 3. Textbook of Cosmetics by Rajesh Kumar Nema, Kamal Singh Rathore and BK Dubey
- 4. Textbook of Cosmetics by M. Vimaladevi
- 5. Rao Madhusudan, Cosmeceuticals, Pharma Med Press
- 6. Vinita kale, Textbook of Cosmetic science and technology, Pharma Med Press

### PC509: MEDICINAL CHEMISTRY - I LAB

B. Pharm. III Year I Sem	L	т	Ρ	С
	0	0	4	2
List of Experiments:				

#### I. Preparation of drugs/ intermediates

- 1 1,3-pyrazole
- 2 1,3-oxazole
- 3 Benzimidazole
- 4 Benztriazole
- 5 2,3- diphenyl quinoxaline
- 6 Phenothiazine
- 7 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

#### **RECOMMENDED BOOKS (Latest Editions)**

- 1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
- 2. Foye's Principles of Medicinal Chemistry.
- 3. Burger's Medicinal Chemistry, Vol I to IV.
- 4. Introduction to principles of drug design- Smith and Williams.
- 5. Remington's Pharmaceutical Sciences.
- 6. Martindale's extra pharmacopoeia.
- 7. rganic 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
- 11. Raghuprasad, et al., Advanced Medicinal Chemistry A Laboratory Guide, Pharma Med Press

#### PS510: INDUSTRIAL PHARMACY LAB

#### B. Pharm. III Year I Sem

L	Т	Ρ	С
0	0	4	2

#### List of Experiments:

- 1. Preformulation study for prepared granules
- 2. Preparation and evaluation of Paracetamol tablets
- 3. Preparation and evaluation of Aspirin tablets
- 4. Coating of tablets
- 5. Preparation and evaluation of Tetracycline capsules
- 6. Preparation of Calcium Gluconate injection
- 7. Preparation of Ascorbic Acid injection
- 8. Preparation of Paracetamol Syrup
- 9. Preparation of Eye drops
- 10. Preparation of Pellets by extrusion spheronization technique
- 11. Preparation of Creams (cold / vanishing cream)
- 12. Evaluation of Glass containers (As per IP)

#### PS511: PHARMACOLOGY - II LAB

#### B. Pharm. III Year I Sem

L	Т	Ρ	С
0	0	4	2

#### List of Experiments:

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

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

#### **RECOMMENDED BOOKS (Latest Editions)**

- 1. A Practical book of Pharmacology by Dr. Ramesh Alluri
- 2. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
- 3. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

### PS512: PHARMACOGNOSY AND PHYTOCHEMISTRY II LAB

#### B. Pharm. III Year I Sem

L	т	Ρ	С
0	0	4	2

#### List of Experiments:

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

#### \*MC500: ENVIRONMENTAL SCIENCES

#### B. Pharm. III Year I Sem

L	Т	Ρ	С
1	0	0	0

**Course Objectives:** 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.

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

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

#### UNIT – I

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

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

#### UNIT – II

#### Ecosystems

Concept of an ecosystem.

Structure and function of an ecosystem.

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

#### UNIT – III

**Biodiversity and Biotic Resources:** Introduction, Definition, genetic, species and ecosystem diversity. Value of biodiversity; consumptive use, productive use, social, ethical, aesthetic and optional values. India as a mega diversity nation, Hot spots of biodiversity. Field visit. Threats to biodiversity: habitat loss, poaching of wildlife, man-wildlife conflicts; conservation of biodiversity: In-Situ and Ex-situ conservation. National Biodiversity act.

#### UNIT – IV

Environmental Pollution: Air pollution; Water pollution; Soil pollution, Noise Pollution

#### UNIT – V

**Environmental Policy, Legislation & EIA:** Environmental Protection act, Legal aspects Air Act- 1981, Water Act, Forest Act, Wild life Act.

**Towards Sustainable Future:** Concept of Sustainable Development, Population and its explosion, Crazy Consumerism, Environmental Education, Urban Sprawl, Human health, Environmental Ethics, Concept of Green Building, Ecological Foot Print, Life Cycle assessment (LCA), Low carbon life style.

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

# PS601: MEDICINAL CHEMISTRY - II

# B. Pharm. III Year II Sem

L	Т	Ρ	С
3	1	0	4

**Course Objectives**: 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.

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

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

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

#### UNIT- I

#### 10 Hours

Antihistaminic agents: Histamine, receptors and their distribution in the human body H<sub>1</sub>-antagonists: Diphenhydramine hydrochloride\*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride\*, Phenidamine tartarate, Promethazine hydrochloride\*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

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

**Gastric Proton pump inhibitors:** Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole **Anti-neoplastic agents:** 

**Alkylatingagents:** 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

Anti-anginal:

**Vasodilators:** Amyl nitrite, Nitroglycerin\*, Pentaerythritol tetranitrate, Isosorbidedinitrite\*, Dipyridamole. **Calcium channel blockers:** Verapamil, Bepridil hydrochloride, Diltiazemhydrochloride, 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, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,\* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

#### UNIT - III

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

#### Antidiabetic agents:

Insulin and its preparations

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

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acarbose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

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

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

**Lidocaine/Anilide derivatives**: Lignocaine, Mepivacaine, Prilocaine, Etidocaine. **Miscellaneous**: Phenacaine, Diperodon, Dibucaine.\*

#### UNIT – V

#### Introduction to Drug Design:

Introduction to molecular modeling tools, molecular representations, file formats, parameters used in QSAR, QSAR methods, Pharmacophore modeling, Docking studies.

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

#### **RECOMMENDED BOOKS (Latest Editions)**

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

#### 10 Hours

#### 07 Hours

#### PS602; PHARMACOLOGY - III

#### B.Pharm. III Year II Sem.

**Course Objectives:** 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.

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

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

#### UNIT- I

#### 1. Pharmacology of drugs acting on Respiratory system

- a. Anti -asthmatic drugs
- b. Drugs used in the management of COPD
- c. Expectorants and antitussives
- d. Nasal decongestants
- e. Respiratory stimulants

#### 2. Pharmacology of drugs acting on the Gastrointestinal Tract

- a. Antiulcer agents.
- b. Drugs for constipation and diarrhoea.
- c. Appetite stimulants and suppressants.
- d. Digestants and carminatives.
- e. Emetics and anti-emetics.

#### UNIT – II

#### Antimicrobial agents

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

#### UNIT – III

#### Chemotherapy

- a. Antitubercular agents
- b. Antifungal agents
- c. Antiviral drugs
- d. Antileprotic agents
- e. Anthelmintics
- f. Antimalarial drugs
- g. Antiamoebic agents
- h. Urinary tract infections and sexually transmitted diseases.

### UNIT – IV

1. Antimalignancy & Immunotherapy

#### 08 hours

# 10 hours

# 10 hours

10 hours

# -

L T P C 3 1 0 4 Types of malignancy. Chemotherapy of cancer.

# 2. Immunopharmacology

- a. Immunostimulants
- b. Immunosuppressant
- c. Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

# UNIT – V

### 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, organ ophosphosphorus compound and lead, mercury and arsenic poisoning.

# **RECOMMENDED BOOKS (Latest Editions)**

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology,
- 2. Churchill Livingstone Elsevier
- 3. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
- 4. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
- 5. Basic Knowledge of Pharmacology BY Roland Seifert, Springer
- 6. 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
- 7. Mycek M. J, Gelnet S. B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
- K. D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
- 9. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R. Craig& Robert,
- 10. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
- 11. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan,
- 12. N. Udupa and P.D. Gupta, Concepts in Chronopharmacology.
- 13. Essentials of Experimental Pharmacology, General Concepts by Sunil Bothra, Pharmamed Press.

#### 07 hours

# PS603: HERBAL DRUG TECHNOLOGY

### B.Pharm. III Year II Sem.

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

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

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

#### UNIT – I

#### 1. Herbs as raw materials

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

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

#### 2. Good Agricultural Practices

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

#### 3. General Introduction to Herbal Industry

Herbal drugs industry: Present scope and future prospects.

A brief account of plant based industries and institutions/ research organizations involved in production and research on medicinal and aromatic plants in India.

#### UNIT – II

### 1. Nutraceuticals

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases, obesity.

Study of following herbs as health food: Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina, Tinospora cordifolia, Linseed.

2. **Herbal-Drug and Herb-Food Interactions:** General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, Ginkobiloba, Ginseng, Garlic, Pepper.

#### UNIT - III

#### 1. Herbal Cosmetics

Principles and preparation of herbal cosmetics formulations- Shampoos, Dyes, face creams, perfumes, tooth pastes and Bleaching agents.

#### 2. Herbal excipients:

Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors.

#### 3. Herbal formulations:

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

4. Introduction to herbal pharmacopeia

# 6 Hours

# 7 Hours

### 10 Hours

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#### UNIT – IV

1. **Evaluation of Drugs** WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.

#### 2. Patenting and Regulatory requirements of natural products:

- a. Introduction to Herbal Pharmacopeia
- b. Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
- c. Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.
- Regulatory Issues Regulations in India (ASU DTAB Ayurvedic Sidda Unani Drugs technical advisory board, ASU DCC - Ayurvedic Sidda Unani drugs Consultative Committee), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

### UNIT – V

### Schedule T– Good Manufacturing Practice for herbal drug industry

Components of GMP (Schedule - T) and its objectives

Infrastructural requirements, working space, storage area, machinery and equipment, standard operating procedures, health and hygiene, documentation and records.

#### **RECOMMENDED BOOKS: (Latest Editions)**

- 1. Textbook of Pharmacognosy by Trease & Evans.
- 2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
- 3. Pharmacognosy by Kokate, Purohit and Gokhale
- 4. Essential of Pharmacognosy by Dr. S.H. Ansari
- 5. Pharmacognosy & Phytochemistry by V.D. Rangari
- 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.
- 8. Herbal drug Technology. By SS Agrawal and M Paridhavi
- 9. Indian Medicinal Plants A compendium of 500 species Vol 1, 11, 111, 1V & V By Arya vaidys sala, Universities Press
- 10. SL Deore, Herbal Drug Technology, Pharma Med Press

# 10 Hours

#### **PS604: BIOPHARMACEUTICS AND PHARMACOKINETICS**

B.Pharm. III	Year II Sem.
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Course Objectives: This subject is designed to impart knowledge and skills necessary for dose
calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving.
Basic theoretical discussions of the principles of Biopharmaceutics and pharmacokinetics are provided
to help the students' to clarify the concepts.

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

- Understand the basic concepts in biopharmaceutics and pharmacokinetics.
- Use plasma data and derive the pharmacokinetic parameters to describe the process of drug absorption, distribution, metabolism and elimination.
- Critically evaluate biopharmaceutic studies involving drug product equivalency
- Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- Detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them

#### UNIT – I

#### Introduction to Biopharmaceutics

**Absorption:** Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from extra-vascular routes(Transmucosal & Transdermal), **Distribution:** Distribution of drugs Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

#### UNIT – II

**Metabolism & Excretion:** Drug metabolism and basic understanding of metabolic pathways. Renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

**Bioavailability and Bioequivalence:** Objectives of bioavailability studies, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, bioequivalence studies.

#### UNIT – III

#### Pharmacokinetics:

Introduction to Pharmacokinetics models, Compartment models, Non-compartment models, physiological models, One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion, extra vascular administrations, calculations of Ka, K<sub>E</sub>. From plasma and urinary excretion data

#### UNIT – IV

**Multicompartment models:** Two compartment open model. IV bolus **Multiple – Dosage Regimens**: Repititive Intravenous injections – One Compartment Open Model

#### UNIT – V

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

10 Hours

10 Hours

#### 10 Hours

# 08 Hours

07 Hours

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

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

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

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

#### UNIT – I

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

#### 2. Total Quality Management (TQM): Definition, elements, philosophies

**3. ICH Guidelines**: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines.

4. Quality by design (QbD): Definition, overview, elements of QbD program

5. ISO 9000 & ISO14000: Overview, Benefits, Elements

6. NABL accreditation: Brief introduction and Principles

#### UNIT – II

**1. Organization and personnel:** Personnel responsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

**2. Equipments and raw materials:** Equipments selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

#### UNIT – III

**Quality Control:** Quality control test for containers (Glass & Plastic) and rubber closures **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

**1. Complaints:** Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

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

#### UNIT – V

**1. 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 and UV-Visible spectrophotometer.

2. Warehousing: Good warehousing practices.

### 07 Hours

# 10 Hours

10 Hours

08 Hours

#### **10 Hours** f Quality

LT P C 3 1 0 4

- 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.
- 3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and related materials Vol I WHO Publications.
- 4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
- 5. How to Practice GMP's P P Sharma.
- 6. ISO 9000 and Total Quality Management Sadhank G Ghosh
- 7. The International Pharmacopoeia Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
- 8. Good laboratory Practices Marcel Deckker Series
- 9. ICH guidelines, ISO 9000 and 14000 guidelines
- 10. Pharmaceutical Quality Assurance by Dr. Sohan Chiltlange
- 11. Chowdary KPR, A Textbook of Pharmaceutical Quality Assurance, Pharma Med Press
- 12. Pharmaceutical Quality Assurance and Management by K. P. Bhusari, Pharma Med Press

#### PS606: PHARMACEUTICAL BIOTECHNOLOGY (Open Elective - II)

#### B.Pharm. III Year II Sem.

#### **Course Objectives:**

- 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 ٠ more.
- It is basically a research-based subject.

Course Outcomes: Upon completion of the subject student shall be able to;

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

#### UNIT – I

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

#### UNIT – II

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

#### UNIT – III

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

### UNIT – IV

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

**08 Hours** 

10 Hours

#### 10 Hours

# 10 Hours

#### LT P C 3 1 0 4

### UNIT – V

#### 07 Hours

- a. Types of mutation/mutants
- b. Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
- c. Large scale production fermenter design and its various controls.
- d. Study of the production of penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,

#### **RECOMMENDED BOOKS (Latest edition):**

- 1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications
- 2. of Recombinant DNA: ASM Press Washington D.C.
- 3. RA Goldshy et. al., Kuby Immunology.
- 4. J. W. Goding: Monoclonal Antibodies.
- 5. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
- 6. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
- 7. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
- 8. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi
- 9. Nagori, Foundations in Pharmaceutical Biotechnology, Rev. Ed. Pharma Med Press
- 10. Pharmaceutical Biotechnology by Ravi Kumar Maddali, Pharma Med Press

#### PS607: BIOINFORMATICS (Open Elective - II)

B.Pharm.	Ш	Year	II	Sem.
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L T P C 3 1 0 4

**Course Objective:** This subject is design to impart fundamental knowledge on the principles of bioinformatics

Course Outcomes: Upon completion of the course the student able to understand

- Foundation of bioinformatics
- Sequence comparisons methods
- Genomic applications
- Proteomic and metabolic applications.

#### UNIT – I

#### Foundations of bioinformatics

- 1.1 Bioinformatics- a historical perspective
- 1.2 Bioinformatics data- nucleic acid sequence, protein sequence, protein structure, genome variation data, gene expression data, proteomic data, metabolic pathways and networks
- 1.3 Bioinformatics tools and resources- free online tolls, downloadable free tools, software pakags, bioinformatics web portals
- 1.4 Role of internet in Bioinformatics.

#### UNIT - II

#### Sequence comparison methods

2.1 Basics of sequence alignment: Match, mismatch, gaps, scoring an alignment (gap penalties (linear & affine gap penalties), sequence relationships (sequence identity, similarity, homology, orthologs, paralogs & xenologs)

2.2 DNA Vs protein sequence alignment (permissible replacement, similarity score, scoring matrices (PAM & BLOSUM)

2.3 multiple-sequence alignment (MSA): significance of MSA

#### UNIT – III

#### Genomic Applications:

3.1 Bioinformatics for genome sequencing, first and next generation methods of genome sequencing, de-novo and reference based genome sequencing, genome assembly (reads, contigs &scaffolds)
3.2 Transcript- profiling: expression microarrays (gene array& oligo array), transcriptome sequencing and RNA- seg analysis small RNA sequencing and analysis

#### UNIT – IV

4.1 Genome maps an markers: identification of molecular makers (SSR, STS & SNP markers), linkage Vs physical maps, displaying genome annotation using genome browsers

4.2 Medical application of bioinformatics –understanding diseases and identification of disease genes, disease diagnostics, overview of drug discovery, pharmacogenomics.

#### UNIT – V

#### Proteomic and metabolomic applications:

5.1 Protein profiling (2D gels, protein fingerprinting & identification), protein structure analysis

5.2 Protein structure: structure visualization

5.3 Protein: secondary and tertiary structure prediction (homology modelling)

### **RECOMMENDED BOOKS (Latest edition):**

- 1. Bioinformatics by B. G. Gurran, R. J. Walker, S.C. Bhatia. CBS Publishers.
- 2. Bioinformatics: Skills & applications by Rastogi, CBS Publishers
- 3. Bioinformatics: Sequence & genome analysis by mount, CBS Publishers
- 4. Bioinformatics and bioprogramming by CN Chaveli
- 5. Bioinformatics (Basics, alogerthmas and applications by Ruchi singh and Richa Sharma
- 6. Essential Bioinformatics Jinxiong
- 7. Durai Ananda Kumar T. Elementary Pharmacoinformatics, Pharma Med Press
- 8. Khan Imtiyaz Alam, Elementary Bioinformatics, Pharma Med Press

#### PS608: SCREENING METHODS IN PHARMACOLOGY (Open Elective - II)

B.Pharm. III Year II Sem.	LT P C
	3104

**Course Objectives:** The student is going to study about various techniques involved in screening of drugs for various pharmacological activities and guidelines for handling animals

**Course Outcomes:** This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines. The expected outcome are – the students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities and guidelines for regulations involved in screening of new drug molecules on animals.

#### UNIT – I

Care, handling and breeding technique of laboratory animals. Regulations for laboratory animals, CPSCEA guidelines, alternative to animal studies.

#### UNIT – II

Toxiciy test: OECD guidelines, determination of LD<sub>50</sub>, acute, sub-acute and chronic toxicity studies.

#### UNIT – III

Organization of screening for pharmacological activity of new substances with emphasis on the evaluation of antipsychotics, antiepileptics and antidepressants.

#### UNIT – IV

Screening methods for anti-diabetic, antiulcer, CHF and anti-hypertensive drugs.

#### UNIT – V

Screening methods for anti-inflammatory, analgesics and antipyretic drugs.

#### **RECOMMENDED BOOKS (Latest edition):**

- 1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
- 2. Screening methods in Pharmacology by Robert Turner. A.
- 3. Methods in Pharmacology by Arnold Schwartz.
- 4. Pharmacological screening methods and Toxicology by A Srinivasa Rao and N. Bhagya Lakshmi
- 5. Fundamentals of experimental Pharmacology by M.N. Ghosh.
- 6. Experimental Pharmacology for undergraduates by M C Prabhakara.
- 7. Drug discovery and Evaluation by Vogel H.G.
- 8. Experimental Pharmacology by R.K. Goyal.
- 9. Preclinical evaluation of new drugs by S.K. Gupta.
- 10. Pharmacological Screening methods and Toxicology by A. Srinivasa Rao
- 11. Handbook of Experimental Pharmacology, SK. Kulkarni.
- 12. Practical Pharmacology and Clinical Pharmacy, SK. Kulkarni, 3rd Edition.
- 13. Screening Methods in Pharmacology, Robert A. Turner.
- 14. Bodakhe H. Surendra, Guidelines and Screening Methods of Pharmacology, Pharma Med Press

#### PS609: MEDICINAL CHEMISTRY- II LAB

B.Pharm. III Year II Sem.	LTPC
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#### 1. Preparation of drugs and intermediates

- a. Benzocaine
- b. Sulphanilamide
- c. 7-Hydroxy, 4-methyl coumarin
- d. Triphenyl imidazole
- e. Tolbutamide
- f. Phenytoin Sodium
- g. Diphenhydramine HCI
- h. 6-methyl Uracil
- i. Procaine
- j. Promethazine HCI

#### 2. Assay of drugs

- a. Isonicotinic acid hydrazide
- b. Metronidazole
- c. Chlorpheniramine maleate
- d. Quinidine Sulphate
- e. Acetazolamide
- f. Omeprazole
- 3. Preparation of medicinally important compounds or intermediates by Microwave irradiation technique
- 4. Drawing structures and reactions using chem draw®
- Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

### **RECOMMENDED BOOKS (Latest Editions)**

- 1. Indian Pharmacopoeia.
- 2. Text book of practical organic chemistry- A.I. Vogel.
- 3. Durai Ananda Kumar T. Experimental Organic and Medicinal Chemistry Principles & Practice, Pharma Med Press.

#### PS610: PHARMACOLOGY - III LAB

#### B.Pharm. III Year II Sem.

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#### List of Experiments:

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

\*Experiments are demonstrated by simulated experiments/videos

#### **RECOMMENDED BOOKS (Latest Editions)**

- 1. A Practical book of Pharmacology by Dr. Ramesh Alluri
- 2. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
- 3. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan,

### PS611: HERBAL DRUG TECHNOLOGY LAB

#### B.Pharm. III Year II Sem.

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#### List of Experiments:

- 1. To perform preliminary phytochemical screening of crude drugs.
- 2. Evaluation of excipients of natural origin
- 3. Incorporation of prepared and standardized extract in cosmetics formulations like creams, lotions, Shampoos and their evaluation.
- 4. Incorporation of prepared and standardized extract in cosmetics formulations like Syrups, Mixtures and tablets and their evaluations as per pharmacopoeial requirements
- 5. Monograph analysis of herbal drugs from recent Pharmacopoeias
- 6. Determination of Aldehyde content
- 7. Determination of phenolic content
- 8. Determination of total alkaloids

#### **RECOMMENDED BOOKS: (Latest Editions)**

- 1. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
- 2. Mandal Vivekananda, Quick Review on Herbal Drug Technology, Pharma Med Press

### PS612: BIOPHARMACEUTICS AND PHARMACOKINETICS LAB

#### B.Pharm. III Year II Sem.

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#### List of Experiments:

- 1. Dissolution experimental study of influence of disintegration
- 2. Drug release from semisolids (Agar diffusion using petri dishes, Salicylic acid release from semisolid dosage form
- 3. Study of permeability of drugs using dialysis tubes/Sac
- 4. Drug permeation across membranes using diffusion cells (franz diffusion cells)
- 5. Calculation of all Pharmacokinetic parameters following the below rate of administration
  - a) IV bolus/Plasma
  - b) IV bolus/Urine
  - c) Extravascular/Plasma
  - d) Extravascular/Urine
  - e) Non compartment Pharmacokinetics Extravascular/Plasma

#### **Reference Books**

1) Experimental approaches to Biopharmaceutics and Pharmacokinetics by Bandari Suresh

2) Biopharmaceutics and Pharmacokinetics lab manual, by Dachinamurthy

#### \*MC600: HUMAN VALUES AND PROFESSIONAL ETHICS

B.Pharm. III Year II Sem.	LTPC
	1000

**Course Objective:** To enable the students to imbibe and internalize the Values and Ethical Behavior in the personal and Professional lives.

**Course Outcome:** The students will understand the importance of Values and Ethics in their personal lives and professional careers. The students will learn the rights and responsibilities as an employee, team member and a global citizen.

#### UNIT - I

**Introduction to Professional Ethics**: Basic Concepts, Governing Ethics, Personal & Professional Ethics, Ethical Dilemmas, Life Skills, Emotional Intelligence, Thoughts of Ethics, Value Education, Dimensions of Ethics, Profession and professionalism, Professional Associations, Professional Risks, Professional Accountabilities, Professional Success, Ethics and Profession.

#### UNIT – II

**Basic Theories:** Basic Ethical Principles, Moral Developments, Deontology, Utilitarianism, Virtue Theory, Rights Theory, Casuist Theory, Moral Absolution, Moral Rationalism, Moral Pluralism, Ethical Egoism, Feminist Consequentialism, Moral Issues, Moral Dilemmas, Moral Autonomy.

#### UNIT – III

**Professional ethics in pharmacy:** general introduction to code of pharmaceutical ethics, objectives, pharmacists in relation to his job, his trade, to his profession and relation to medicinal professions. Pharmacists' oath.

#### UNIT – IV

Work Place Rights & Responsibilities, Ethics in changing domains of Research, Engineers and Managers; Organizational Complaint Procedure, difference of Professional Judgment within the Nuclear Regulatory Commission (NRC), the Hanford Nuclear Reservation.

Ethics in changing domains of research - The US government wide definition of research misconduct, research misconduct distinguished from mistakes and errors, recent history of attention to research misconduct, the emerging emphasis on understanding and fostering responsible conduct, responsible authorship, reviewing & editing.

#### UNIT – V

Global issues in Professional Ethics: Introduction – Current Scenario, Technology Globalization of MNCs, International Trade, World Summits, Issues, Business Ethics and Corporate Governance, Sustainable Development Ecosystem, Energy Concerns, Ozone Deflection, Pollution, Ethics in Manufacturing and Marketing, Media Ethics; War Ethics; Bio Ethics, Intellectual Property Rights.

#### TEXT BOOKS:

- 1. Professional Ethics: R. Subramanian, Oxford University Press, 2015.
- 2. Ethics in Engineering Practice & Research, Caroline Whitbeck, 2e, Cambridge University Press 2015.
- 3. Indian Culture Values and Professional Ethics by P. S. R. Murty, BS Publications

#### **REFERENCE BOOKS:**

- 1. Engineering Ethics, Concepts Cases: Charles E Harris Jr., Michael S Pritchard, Michael J Rabins, 4e , Cengage learning, 2015.
- 2. Business Ethics concepts & Cases: Manuel G Velasquez, 6e, PHI, 2008.
- 3. Forensic Pharmacy by Dr. Kokate
- 4. Forensic Pharmacy by Bhaskar Chaurasia

#### **PS701: INSTRUMENTAL METHODS OF ANALYSIS**

#### B.Pharm. IV Year I Sem.

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

**Course Outcomes:** 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.

#### UNIT – I

#### 1. 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

#### 2. Fluorimetry

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

#### UNIT – II

#### 1. 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, Thermistor, Pyroelectric detector and applications

- 2. Flame Photometry Principle, interferences, instrumentation and applications
- 3. Atomic absorption spectroscopy Principle, interferences, instrumentation and applications
- 4. Nepheloturbidometry Principle, instrumentation and applications

#### UNIT – III

#### Introduction to chromatography

- 1. Adsorption and partition column chromatography- Methodology, advantages, disadvantages and applications.
- 2. **Thin layer chromatography-** Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.
- 3. **Paper chromatography-** Introduction, methodology, development techniques, advantages, disadvantages and applications
- 4. **Electrophoresis** Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

#### UNIT – IV

- 1. **Gas chromatography** Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications
- 2. **High performance liquid chromatography (HPLC)** Introduction, theory, instrumentation, advantages and applications.

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# 10 Hours

10 Hours

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**08 Hours** 

### UNIT – V

07 Hours

- 1. **Ion exchange chromatography** Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications
- 2. Gel chromatography Introduction, theory, instrumentation and applications
- 3. Affinity chromatography Introduction, theory, instrumentation and applications

#### **RECOMMENDED BOOKS (Latest Editions):**

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

# PS702: INDUSTRIAL PHARMACY - II

# B.Pharm. IV Year I Sem.

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**Course Objectives**: This course is designed to impart fundamental knowledge on pharmaceutical product Commercialization from laboratory to market

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

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

#### UNIT – I

**Pilot plant scale up techniques**: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to Platform technology **Plant location, industrial hazards and plant safety:** Plant Layout, utilities and services, Mechanical hazards, Chemical hazards, Fire hazards, explosive hazards and their safety.

**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.

**Material handling systems:** Objectives & applications of Material handling systems, different types of conveyors such as belt, screw and pneumatic conveyors.

#### UNIT – II

**Technology development and transfer**: WHO guidelines for Technology Transfer: Terminologies, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packing 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), TOT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; Technology of Transfer (TOT) related documentation - confidentiality agreements, licensing, MoUs, legal issues

### UNIT – III

- 1. **Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals
- Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

#### UNIT – IV

**Quality management systems:** Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

# 10 Hours

10 Hours

10 Hours

#### 07 Hours

**Indian Regulatory Requirements:** Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Common Technical Document (CTD), Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

#### **RECOMMENDED BOOKS: (Latest Editions)**

- 1. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php
- 2. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' 2<sup>nd</sup> Edition.
- 3. Regulatory Affairs brought by learning plus, inc. available at http://www.cgmp.com/ra.htm.
- 4. Industrial Pharmacy by Roopa K Khar, S. P Vyas, Farhan J Ahmed, Gaurav K Jain, 4th Edition
- 5. Industrial Pharmacy: A Comprehensive Approach by Tripathi DK, Pharmamed Press

# **PS703: PHARMACY PRACTICE**

B.Pharm. IV Year I Sem.

Course Objectives: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing safe medication and patient counselling.

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

- Know various drug distribution methods in a hospital
- Appreciate the pharmacy stores management and inventory control
- Monitor drug therapy of patient through medication chart review and clinical review
- Know pharmaceutical care services
- do patient counselling in community pharmacy

# UNIT – I

# 1. 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.

# 2. Hospital pharmacy and its organization

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

# 3. 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

# 1. 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.

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

# 3. Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

# UNIT – III

# 1. Drug information services

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

# 2. Patient counselling

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

3. Education and training program in the hospital

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

10 Hours

10 Hours

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### UNIT – IV

#### 1. Clinical Pharmacy

Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.

2. Over the counter (OTC) sales Introduction and sale of over the counter, and Rational use of common over the counter medications.

#### UNIT – V

#### Drug store management and inventory control

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

### **RECOMMENDED BOOKS (Latest Edition):**

- 1. Merchant S. H. and Dr. J. S. Quadry. A textbook of hospital pharmacy, 4<sup>th</sup> ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
- 2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1<sup>st</sup> ed. Chennai: Orient Longman Private Limited; 2004.
- 3. William E. Hassan. Hospital pharmacy, 5th ed. Philadelphia: Lea & Febiger; 1986.
- 4. Tipnis Bajaj. Hospital Pharmacy, 1<sup>st</sup> ed. Maharashtra: Career Publications; 2008.
- 5. Scott LT. Basic skills in interpreting laboratory data, 4<sup>th</sup> ed. American Society of Health System Pharmacists Inc; 2009.
- Parmar N. S. Health Education and Community Pharmacy, 18<sup>th</sup> ed. India: CBS Publishers & Distributers; 2008.
- 7. Balasubramanian, Pharmacy Practice, Pharma Med Press
- 8. Bari B. Sanjay, Pharmacy Practice: Essentials of Hospital, Clinical and Community Pharmacy, Pharma Med Press
- 9. Patient Assessment in Pharmacy, by Yolanda M H
- 10. Patient Communication for Pharmacy: A Case-Study Approach on Theory and Practice, Min Liu, Lakesha M. Butler
- 11. Fundamental Skills for Patient Care in Pharmacy Practice by Colleen Doherty Lauster, Sneha Baxi Srivastava

#### 07 Hours
#### PS704: MEDICINAL CHEMISTRY - III

#### B.Pharm. IV Year I Sem.

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**Course Objectives**: 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.

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

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

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

#### UNIT – I

Antibiotics I:

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

**Beta-Lactam antibiotics:** Penicillin, Cephalosporins, Beta-Lactamase inhibitors, Monobactams **Aminoglycosides:** Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

#### UNIT – II

Antibiotics II:

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

Macrolide: Erythromycin Clarithromycin, Azithromycin.

**Miscellaneous:** Chloramphenicol\*, Clindamycin.

Antimalarials: Etiology of malaria.

**Quinolines:** SAR, Quinine sulphate, Chloroquine\*, Amodiaquine, Primaquine phosphate, Pamaquine\*, Quinacrine hydrochloride, Mefloquine.

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone.

#### UNIT – III

Anti-tubercular Agents

**Synthetic anti tubercular agents:** Isoniazid\*, 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,

#### 10 Hours

10 Hours

Acyclovir\*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.

#### UNIT – IV

#### 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, Mebendazole\*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

#### Sulphonamides and Sulfones

Historical development, chemistry, classification and SAR of Sulfonamides:

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

Folate reductase inhibitors: Trimethoprim\*, Cotrimoxazole.

Sulfones: Dapsone\*.

#### UNIT – V

#### 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.

#### **RECOMMENDED BOOKS (Latest Editions)**

- 1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
- 2. Foye's Principles of Medicinal Chemistry.
- 3. Burger's Medicinal Chemistry, Vol I to IV.
- 4. Introduction to principles of drug design- Smith and Williams.
- 5. Remington's Pharmaceutical Sciences.
- 6. Martindale's extra pharmacopoeia.
- 7. Organic Chemistry by I.L. Finar, Vol. II.
- 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.
- 11. S. P. Vyas and R. K. Khar, Controlled Drug Delivery concepts and advances, Vallabh Prakashan, New Delhi, 1<sup>st</sup> edition 2002.
- 12. Durai Ananda Kumar T. Experimental Organic and Medicinal Chemistry Principles & Practice, Pharma Med Press

#### **08 Hours**

B.Pharm. IV Year I Sem.	LTPC
	3104

**Course Objectives:** The pharmaceutical industry not only needs highly qualified researchers, chemist, 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. Sales & Marketing which grooms the people for taking a challenging role in Sales and Product management.

**Course Outcome:** Provide an understanding of marketing concepts and techniques and the application of the same in the pharmaceutical industry.

#### UNIT – I

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

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

#### UNIT – II

**Product decision:** Meaning, Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

#### UNIT – III

**Promotion:** Meaning and methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

#### UNIT – IV

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

**Professional sales representative (PSR):** Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

#### UNIT – V

**Pricing:** Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).

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

#### **RECOMMENDED BOOKS: (Latest Editions)**

- 1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
- 2. Walker, Boyd and Larreche: Marketing Strategy- Planning and Implementation, Tata McGraw Hill, New Delhi.
- 3. Subba Rao Changanti, Pharmaceutical Marketing in India, Pharma Med Press

### 10 Hours

10 Hours

#### 10 Hours

#### 10 Hours

- 4. Dhruv Grewal and Michael Levy: Marketing, Tata McGraw Hill
- 5. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
- 6. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
- 7. Ramaswamy, U.S & Nanakamari, S: Marketing Management: Global Perspective, Indian Context, Macmillan India, New Delhi.
- 8. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
- 9. Smarta Raja B. Strategic Pharmaceutical Marketing, Pharma Med Press

#### PS706: PHARMACEUTICAL REGULATORY SCIENCE (Open Elective - III)

B.Pharm. IV Year I Sem.	LT	РC
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**Course Objectives:** This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, drug products in regulated countries like US, EU, Japan, Australia and Canada. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products in regulated countries.

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

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

#### UNIT – I

#### New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

#### UNIT – II

**Regulatory Approval Process:** Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA) in US. Changes to an approved NDA / ANDA.

**Regulatory authorities and agencies:** Overview of regulatory authorities of United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

#### UNIT – III

**Registration of Indian drug product in overseas market:** Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD) research.

#### UNIT – IV

**Clinical trials:** Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials

#### UNIT – V

**Regulatory Concepts:** Basic terminologies, guidance, guidelines, regulations, laws and acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

#### **RECOMMENDED BOOKS (Latest edition):**

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

#### 10 Hours

#### 07 Hours

**08 Hours** 

#### 10 Hours

- 5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
- 6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
- 7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams
- Principles and Practices of Clinical Research, 2<sup>nd</sup> Edition Edited by John I. Gallin and Frederick P. Ognibene
- 9. Drugs: From Discovery to Approval, 2<sup>nd</sup> Edition by Rick N
- 10. Clinical Research: Principles, Practices, Perspective, by Bikash Medhi, Pharmamed Press

#### PS707: PHARMACOVIGILANCE (Open Elective - III)

B.Pharm.	IV	Year I	Sem.
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**Course Objective:** 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.

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

- Why drug safety monitoring is important?
- History and development of pharmacovigilance
- National and international scenario of pharmacovigilance
- International standards for classification of diseases and drugs
- Adverse drug reaction reporting systems and communication in pharmacovigilance
- Data during pre-clinical, clinical and post approval.
- Pharmacovigilance Program of India (PvPI)
- ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning

#### UNIT - I

#### Introduction to Pharmacovigilance:

- a) History and development of Pharmacovigilance
- b) Importance of safety monitoring of Medicine
- c) WHO international drug monitoring programme
- d) Pharmacovigilance Program of India (PvPI)

#### Introduction to adverse drug reactions:

- a) Definitions and classification of ADRs
- b) Detection and reporting
- c) Methods in Causality assessment
- d) Severity and seriousness assessment
- e) Predictability and preventability assessment

#### Basic terminologies used in pharmacovigilance:

- a) Terminologies of adverse medication related events
- b) Regulatory terminologies

#### UNIT – II

#### Drug and disease classification:

- a) Anatomical, therapeutic and chemical classification of drugs
- b) International classification of diseases
- c) Daily defined doses

#### Drug dictionaries and coding in pharmacovigilance:

- a) WHO adverse reaction terminologies
- b) MedDRA and Standardized MedDRA queries
- c) WHO drug dictionary

#### Information resources in pharmacovigilance:

a) Basic drug information resources

#### Establishing pharmacovigilance programme:

- a) Establishing in a hospital
- b) Establishment & operation of drug safety department in industry
- c) Contract Research Organizations (CROs)

#### 10 hours

10 Hours

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#### UNIT – III

#### Vaccine safety surveillance:

- a) Vaccine Pharmacovigilance
- b) Vaccination failure
- c) Adverse events following immunization

#### Pharmacovigilance methods:

- a) Passive surveillance Spontaneous reports and case series
- b) Stimulated reporting
- c) Active surveillance Sentinel sites, drug event monitoring and registries
- d) Comparative observational studies Cross sectional study, case control study and cohort study
- e) Targeted clinical investigations

#### UNIT – IV

# Statistical methods for evaluating medication safety data Safety data generation:

- a) Pre-clinical phase
- b) Clinical phase
- c) Post approval phase

#### ICH Guidelines for Pharmacovigilance:

- a) Organization and objectives of ICH
- b) Expedited reporting
- c) Individual case safety reports
- d) Periodic safety update reports
- e) Post approval expedited reporting
- f) Pharmacovigilance planning
- g) Good clinical practice in pharmacovigilance studies

#### UNIT – V

Pharmacogenomics of adverse drug reactions: Drug safety evaluation in special population

- a) Pediatrics
- b) Pregnancy and lactation
- c) Geriatrics

#### **RECOMMENDED BOOKS (Latest edition):**

- 1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
- 2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
- 3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
- 4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
- 5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
- 6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones& Bartlett Publishers.
- 7. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
- 8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
- 9. National Formulary of India
- 10. Text Book of Medicine by Yashpal Munjal

#### 10 Hours

08 Hours

07 hours

- 11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna, Pharmamed Press.
- 12. A Textbook of Clinical Research and Pharmacovigilance, KPR Chowdary, Pharmamed Press.
- 13. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
- 14. http://www.ich.org/
- 15. http://www.cioms.ch/
- 16. http://cdsco.nic.in/
- 17. http://www.who.int/vaccine\_safety/en/
- 18. http://www.ipc.gov.in/PvPI/pv\_home.html

#### PS708: QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Open Elective - III)

	B.Pharm.	IV	Year I	Sem.
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**Course Objective:** 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.

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

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

#### UNIT – I

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms. WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use

#### UNIT – II

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine. WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.

#### UNIT – III

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

#### UNIT – IV

Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.

#### UNIT – V

Regulatory requirements for herbal medicines.

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

Role of chemical and biological markers in standardization of herbal products

#### **RECOMMENDED BOOKS: (Latest Editions)**

- 1. Pharmacognosy by Trease and Evans
- 2. Pharmacognosy by Kokate, Purohit and Gokhale
- 3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I, Carrier Pub., 2006.
- 4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
- 5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
- 6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
- 7. Shinde M. V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-.

## 10 hours

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#### 08 hours

### 07 hours

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- 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. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
- 10. 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.
- 11. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.
- 12. Deore S L, Quality Control of Herbal Drugs, Pharma Med Press

#### PS709: INSTRUMENTAL METHODS OF ANALYSIS LAB

#### B.Pharm. IV Year I Sem.

#### L T P C 0 0 4 2

#### List of Experiments:

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

#### **RECOMMENDED BOOKS (Latest Editions):**

- 1. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
- 2. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
- 3. Quantitative Analysis of Drugs by D. C. Garrett
- 4. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi

#### PS710: PRACTICE SCHOOL

#### B.Pharm. IV Year I Sem.

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**Course Objectives:** Practice school is an educational innovation seeking to link industry/hospital/ pharmacy experience with university instruction. The student will:

- Meet the rapidly changing needs and challenges of a professional work place.
- Acquire knowledge and skills.
- Bear an economic relevance to the society.

**Course Outcome:** Institutionalized linkage between university/college and industry. Student's involvement in real life projects continues internal evaluation and monitoring the faculty help by student to understand the practical issues. After successful completion of 150 hrs, the students will submit the detailed report in the following field.

## Note: Any domains relevant to pharmacy can be given to students. Following domains for for reference

#### Industry oriented PS:

It comprises industry visits and interactions with executives to facilitate the process of learning by observations and discussions duly aided by the check list. It promotes learning by doing in various departments like production quality control and assurance, R&D etc. Taking one issue and working on it for prescribed hours and submit the report.

#### Hospital oriented PS:

The student is asked to visit the hospitals and work on some case studies like cardiovascular, diabetics, gastrointestinal, gynaecological, pulmonary paediatric etc. related cases of some 5 to 6 to be studied and detailed data to be submitted.

#### Retail pharmacy-oriented PS:

The students have to visit different pharmacy shops and collect the data related to the most prescribed medicines in that area, prescription patterns, medical audit etc and submit the report.

#### Election of medicinal plants orientated PS:

The students have to visit medicinal plant gardens and collect some medicinal plants those are useful to various disorders and submit the report in detail about the plants they come across during their study period

**Regulatory affairs:** collect and analyse the regulatory affairs. Some important cases filed by drug control officers to be analysed and reported.

National poison centre: visit the local poison centre and write the relevant matter

**Formulation aspects:** Formulations using any equipments which otherwise are not usually used for regular practicals

#### PS801: BIOSTATISTICS AND RESEARCH METHODOLOGY

#### B.Pharm. IV Year II Sem.

Course Objectives: To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies.

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

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

#### UNIT – I

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation -Pharmaceuticals examples

#### UNIT – II

**Regression:** Curve fitting by the method of least squares, fitting the lines y = a + bx and x = a + by, Multiple regression, standard error of regression-Pharmaceutical Examples.

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) -Pharmaceutical examples

**Parametric test:** t-test (Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference

#### UNIT – III

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

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

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

Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

#### UNIT - IV

Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

#### UNIT – V

**Design and Analysis of experiments:** 

Factorial Design: Definition, 2<sup>2</sup>, 2<sup>3</sup> design. Advantage of factorial design

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

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#### 8 Hours

7 Hours

### 10 Hours

10 Hours

#### **RECOMMENDED BOOKS (Latest edition):**

- 1. Pharmaceutical Statistics Practical and clinical applications, Sanford Bolton, Publisher Marcel Dekker Inc. New York.
- 2. Fundamental of Statistics Himalaya Publishing House- S. C. Guptha
- 3. Design and Analysis of Experiments PHI Learning Private Limited, R. Pannerselvam,
- 4. Design and Analysis of Experiments Wiley Students Edition, Douglas and C. Montgomery
- 5. Bayya Subba Rao, Pharmaceutical Research Methodology and Bio-Statistics: Theory & Practice, Pharma Med Press
- 6. Chowdary KPR, A Textbook of Research Methodologies and Biostatistics for Pharmacy Students, Pharma Med Press

B.Pharm. IV Year II Sem.	LTPC
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**Course Objectives:** 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.

**Course Outcomes:** 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

#### UNIT – I

**Concept of health and disease:** Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

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

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

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

#### UNIT – II

# **Preventive medicine:** General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic

#### UNIT – III

# **National health programs, its objectives, functioning and outcome of the following:** HIV and AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National

filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

#### UNIT – IV

# National health intervention programme for mother and child, national family welfare programme, national tobacco control programme, national malaria prevention program, national programme for the health care for the elderly, social health programme; role of \*who in indian national program

#### UNIT – V

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

#### **RECOMMENDED BOOKS (Latest edition):**

- 1. Short Textbook of Preventive and Social Medicine, Prabhakara G N, 2<sup>nd</sup> Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
- 2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4<sup>th</sup> Edition, 2013, ISBN: 9789350901878, JAYPEE Publications

### 07 Hours

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### 10 Hours

# 10 Hours

10 Hours

- 3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6<sup>th</sup> Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
- 4. Essentials of Community Medicine A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2<sup>nd</sup> Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
- 5. Park Textbook of Preventive and Social Medicine, K Park, 21<sup>st</sup> Edition, 2011, ISBN-14: 9788190128285, Banarsidas Bhanot Publishers.
- 6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad
- 7. K. Ravi Shankar, Social and Preventive Pharmacy, Pharma Med Press.

### **PS803: NOVEL DRUG DELIVERY SYSTEMS**

### B.Pharm. IV Year II Sem.

Course Objectives: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Course Outcomes: Upon completion of the course student shall be able:

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

#### UNIT – I

- 1. 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
- 2. Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

#### UNIT – II

- 1. Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications
- 2. Mucosal Drug Delivery system: Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems
- 3. Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump

#### UNIT – III

- 1. Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches
- 2. Gastroretentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS - Floating, high-density systems, inflatable and gastroadhesive systems and their applications
- 3. Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

#### UNIT - IV

Nanotechnology and its Concepts: Concepts and approaches for targeted drug delivery systems, advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

#### UNIT – V

- 1. Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome -Preliminary study, ocular formulations and ocuserts
- 2. Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

10 Hours

### 08 Hours

07 Hours

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#### **RECOMMENDED BOOKS: (Latest Editions)**

- 1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
- 2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
- 3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
- N. K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, 1<sup>st</sup> edition 1997 (reprint in 2001).
- 5. Tripathi Dulal Krishna, Novel Drug Delivery Systems, Pharma Med Press

#### PS804: COMPUTER AIDED DRUG DESIGN (Open Elective - IV)

B.Pharm. IV Year II Sem.

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

Course Outcomes: 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 modelling software

#### UNIT - I

#### Introduction to Drug Discovery and Development: Stages of drug discovery and development Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

#### UNIT – II

Quantitative Structure Activity Relationship (QSAR): SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

#### UNIT - III

#### Molecular Modeling and virtual screening techniques

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

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

#### UNIT – IV

Informatics & Methods in drug design: Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

#### UNIT – V

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

#### **RECOMMENDED BOOKS (Latest Editions):**

- 1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
- Martin YC. "Quantitative Drug Design" Dekker, New York.
- 3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
- 4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.

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### JNTUH

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- 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.
- 9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.
- 10. Durai Ananda Kumar T. Current Concepts in Drug Design. Pharma Med Press

#### PS805: NANO TECHNOLOGY (Open Elective - IV)

B.Pharm. IV Year II Sem.	LΤ	Ρ	С
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**Course Objectives:** To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nano pharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

**Course Outcomes:** The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

#### UNIT – I

#### Introduction to Nanotechnology

- a. Definition of nanotechnology
- b. History of nanotechnology
- c. Unique properties of nanomaterials
- d. Classification of nanomaterials

#### UNIT – II

#### Synthesis of Nanomaterials

Methods for synthesis of:

- a. Gold nanoparticles
- b. Magnetic nanoparticles
- c. Polymeric nanoparticles
- d. Self assembly structures such as liposomes, Niosomes, micelles, aquasomes and nanoemulsions

#### UNIT – III

#### **Biomedical applications of Nanotechnology**

- a. Nanotechnology products used for in vitro diagnostics
  - b. Applications in imaging and targeting.

#### UNIT – IV

Design of nanomaterials for drug delivery, pulmonary, nasal drug delivery, cardiovascular diseases and localized drug delivery systems.

#### UNIT – V

Characterization, drug release and stability studies of nanomaterials

#### **RECOMMENDED BOOKS (Latest Editions):**

- 1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body, Eiki Igarashi, CRC press. 2015
- 2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery, Jose L. Arias, CRC press
- 3. Nano: The Essentials: Understanding Nanosicence and Nanotechnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
- 4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P.J. Thomas and G.U. Kulakarni, Springer (2007)
- 5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press (2004)

- 6. Nano chemistry: A Classical Approach to Nanomaterials Royal Society for Chemistry, Cambridge, UK (2005)
- 7. Nanocomposite science and technology, pulickel M. Ajayan, Linda S. Schadler, paul V. Braun, Wiley-VCH Verlag, Weiheim (2003)
- 8. Nanoscale materials in chemistry, Edited by Kenneth J. Klabunde, John Wiley & Sons, 2009
- 9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
- 10. Introduction to Nano Science and Technologies, Ankaneyulu Yerramilli, BS Publications. 2016
- 11. Anjaneyulu Y. Introduction to Nano-Science and Technologies, Pharma Med Press.

#### PS806: EXPERIMENTAL PHARMACOLOGY (Open Elective - IV)

B.Pharm. IV Year II Sem.	LTPC
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**Course Objectives:** This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines.

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

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals and newer screening methods used in the drug discovery
- Understand the Research methodology to be followed Bio-statistical data interpretation of the assays

#### UNIT – I

**Laboratory Animals:** Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia

#### UNIT – II

**Preclinical screening models**: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups

#### UNIT - III

**Preclinical screening models:** for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics and skeletal muscle relaxants.

#### UNIT - IV

Preclinical screening models for diuretics, anticoagulants and anticancer activities

#### UNIT – V

Research methodology and Bio-statistics, Selection of research topic, review of literature, research hypothesis and study design, Interpretation using Student't' test and One-way ANOVA. Graphical representation of data.

#### **RECOMMENDED BOOKS (Latest Editions):**

- 1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
- 2. Screening methods in Pharmacology by Robert Turner. A.
- 3. Methods in Pharmacology by Arnold Schwartz.
- 4. Pharmacological screening methods and Toxicology by A Srinivasa Rao and N. Bhagya Lakshmi
- 5. Fundamentals of experimental Pharmacology by M. N. Ghosh.
- 6. Experimental Pharmacology for undergraduates by M C Prabhakara.
- 7. Drug discovery and Evaluation by Vogel H. G.
- 8. Experimental Pharmacology by R. K. Goyal.
- 9. Preclinical evaluation of new drugs by S.K. Gupta.
- 10. Handbook of Experimental Pharmacology, S K. Kulkarni.
- 11. Practical Pharmacology and Clinical Pharmacy, S K. Kulkarni, 3<sup>rd</sup> Edition.
- 12. Screening Methods in Pharmacology, Robert A. Turner.
- 13. Guidelines and Screening Methods of Pharmacology, Surendra H. Bodakhe, Pharmamed Press.

#### PS807: ADVANCED INSTRUMENTATION TECHNIQUES (Open Elective - IV)

**Course Objectives:** 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.

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

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

#### UNIT – I

#### Nuclear Magnetic Resonance spectroscopy

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

**Mass Spectrometry** - Principles, Fragmentation, Ionization techniques - Electron impact, chemical ionization, instrumentation and applications.

#### UNIT - II

Thermal Methods of Analysis: Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction and applications.

#### UNIT - III

### Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC

#### UNIT – IV

**Radio immune assay:** Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

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

#### UNIT – V

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

#### **RECOMMENDED BOOKS (Latest Editions):**

- 1. Instrumental Methods of Chemical Analysis by B. K Sharma
- 2. Organic spectroscopy by Y. R Sharma
- 3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
- 4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
- 5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
- 6. Organic Chemistry by I. L. Finar

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### 10 Hours

#### 10 Hours

10 Hours

#### 08 Hours

- 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
- 11. Liptak, Analytical Instrumentation, T&F

#### PS808: NOVEL DRUG DELIVERY SYSTEMS LAB

#### B.Pharm. IV Year II Sem.

- 1. Study on diffusion of drugs through various polymeric membranes
- 2. Study on polymeric properties
- 3. Preparation and Evaluation of Microencapsules by different methods
- 4. Preparation and Evaluation of Mucosal Drug Delivery Systems
- 5. Preparation and Evaluation of Transdermal Drug Delivery Systems
- 6. Preparation and Evaluation of Gastroretentive Drug Delivery Systems
- 7. Preparation and Evaluation of Buccal Drug Delivery Systems
- 8. Preparation and Evaluation of Osmotic Drug Delivery Systems
- 9. Preparation and Evaluation of Liposomes, Niosomes and Nanoparticles

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#### **PROJECT WORK**

The student should select a project work from the following areas and should work in respective industries/departments to complete project. The project work done has to be presented as a report. The student should present the findings of the project work in the college for final evaluation.

- 1. Formulation Development
- 2. Analytical Development
- 3. Chemical synthesis/Natural products
- 4. Pharmacological / toxicological screening
- 5. Pharmacovigilance
- 6. Herbal drugs, formulations and Analysis
- 7. Regulatory Affairs
- 8. Bioavailability, Bioequivalence, clinical students
- 9. Intellectual property management
- 10. Hospital Pharmacy
- 11. Community Pharmacy
- 12. Any project work related to Pharmacy profession

#### **Reference Books**

1) Tripathi Dulal Krishna, Novel Drug Delivery Systems, Pharma Med Press