

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
B. PHARMACY COURSE STRUCTURE AND I & II YEARS SYLLABUS

Effective from Academic Year 2022-23 Admitted Batch

I Year I semester

S. No	Course Code	Subject	L	T	P	Credits
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 [#] / Remedial Mathematics ^{\$}	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

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

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

I Year II semester

S. No	Course Code	Subject	L	T	P	Credits
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

II YEAR I SEMESTER

S. No	Course Code	Course Title	L	T	P	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	T	P	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	T	P	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	PS505 PS506 PS507 PS508	Open Elective - I I. Generic Product Development II. Green Chemistry III. Cell and Molecular Biology IV. Cosmetic science	3	1	0	4
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	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	T	P	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	PS605 PS606 PS607 PS608	Open Elective - II I. Pharmaceutical Quality Assurance II. Pharmaceutical Biotechnology III. Bioinformatics IV. Screening Methods in Pharmacology	3	1	0	4
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	T	P	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	PS705	Open Elective - III i. Pharmaceutical Marketing	3	1	0	4

	PS706 PS707 PS708	ii. Pharmaceutical Regulatory Science iii. Pharmacovigilance 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	T	P	Credits
1	PS801	Biostatistics and Research Methodology	3	1	0	4
2	PS802	Social and Preventive Pharmacy	3	1	0	4
3	PS803	Novel Drug Delivery System	3	1	0	4
4	PS804 PS805 PS806 PS807	Open Elective - IV i. Computer Aided Drug Design ii. Nano Technology iii. Experimental Pharmacology iv. Advanced Instrumentation Techniques	3	1	0	4
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**

L	T	P	C
3	1	0	4

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**10 hours****Introduction to human body**

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

Cellular level of organization

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

Tissue level of organization

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

UNIT – II**10 hours**

Integumentary system Structure and functions of skin

Skeletal system

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

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

Joints

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

UNIT – III**10 hours****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**08 hours****Peripheral nervous system:**

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

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

UNIT – V**07 hours****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. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Taylor. 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 Taylor. 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**

L	T	P	C
3	1	0	4

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**10 Hours****(a) Pharmaceutical analysis-** Definition and scope

- Different techniques of analysis
- Methods of expressing concentration
- Primary and secondary standards.
- Preparation and standardization of various molar and normal solutions-Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, 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****10 Hours**

Acid base titration: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves

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

UNIT – III**10 Hours**

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

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

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

UNIT – IV**08 Hours****Redox titrations:**

- Concepts of oxidation and reduction
 - Types of redox titrations (Principles and applications)
- Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

UNIT – V**07 Hours****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

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. GunduRao, 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

PS103: PHARMACEUTICS**B. Pharm. I Year I Sem**

L	T	P	C
3	1	0	4

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

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

UNIT – I**10 Hours**

Historical background and development of profession of pharmacy: History of profession of Pharmacy in India in relation to pharmacy education, industry, and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and 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**10 Hours**

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

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

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

UNIT – III**08 Hours**

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

Biphasic liquids:

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

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

UNIT – IV**08 Hours**

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

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

UNIT – V**07 Hours**

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

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 GhebreSellassie: 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	T	P	C
3	1	0	4

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**10 Hours****Impurities in pharmaceutical substances:** History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate**General methods of preparation,** assay for the compounds superscripted with **asterisk (*)**, properties and medicinal uses of inorganic compounds belonging to the following classes**UNIT – II****10 Hours****Acids, Bases and Buffers:** Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.**Major extra and intracellular electrolytes:** Functions of 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****10 Hours****Gastrointestinal agents****Acidifiers:** Ammonium chloride* and Dil. HCl**Antacid:** Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture**Cathartics:** Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite**Antimicrobials:** Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations**UNIT – IV****08 Hours****Miscellaneous compounds****Expectorants:** Potassium iodide, Ammonium chloride*.**Emetics:** Copper sulphate*, Sodium potassium tartarate**Haematinics:** Ferrous sulphate*, Ferrous gluconate**Poison and Antidote:** Sodium thiosulphate*, Activated charcoal, Sodium nitrite**Astringents:** Zinc Sulphate, Potash Alum**UNIT – V****07 Hours****Radiopharmaceuticals:** Radio activity, Measurement of radioactivity, Properties of α , β , γ radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I^{131} , Storage conditions, precautions & pharmaceutical application of radioactive substances.**TEXT BOOKS: (Latest Editions)**

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition

4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. Anand&Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian Pharmacopoeia
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. I Year I Sem**

L	T	P	C
2	0	0	2

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**07 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**07 Hours**

Elements of Communication: Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication

Communication Styles: Introduction, The Communication Styles Matrix with example for each - Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

UNIT – III**07 Hours**

Basic Listening Skills: Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations

Effective Written Communication: Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion Required, Shades of Meaning, Formal Communication

Writing Effectively: Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

UNIT – IV**05 Hours**

Interview Skills: Purpose of an interview, Do's and Don'ts of an interview

Giving Presentations: Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

UNIT – V**04 Hours**

Group Discussion: Introduction, Communication skills in group discussion, Do's and Don'ts of group discussion

TEXT BOOKS: (Latest Editions)

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

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

BS106: REMEDIAL BIOLOGY**B. Pharm. I Year I Sem**

L	T	P	C
2	0	0	2

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**07 Hours****Living world:**

- Definition and characters of living organisms
- Diversity in the living world
- Binomial nomenclature
- Five kingdoms of life and basis of classification. Salient features of Monera, Protista, Fungi, Animalia and Plantae, Virus,

Morphology of Flowering plants

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

UNIT – II**07 Hours****Body fluids and circulation**

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

Digestion and Absorption

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

Breathing and respiration

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

UNIT – III**07 Hours****Excretory products and their elimination**

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

Neural control and coordination

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

Chemical coordination and regulation

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

Human reproduction

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

UNIT – IV**05 Hours****Plants and mineral nutrition:**

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

Photosynthesis:

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

UNIT – V**04 Hours****Plant respiration:** Respiration, glycolysis, fermentation (anaerobic).**Plant growth and development**

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

Cell - The unit of life

Structure and functions of cell and cell organelles. Cell division

Tissues

Definition, types of tissues, location and functions.

TEXT BOOKS:

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

REFERENCE BOOKS:

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. I Year I Sem**

L	T	P	C
3	0	0	3

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**06 Hours****Matrices and Determinant:**

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

UNIT- II**06 Hours****Logarithms:**

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

Function:

Real Valued function, Classification of real valued functions

UNIT – III**06 Hours****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 using 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**06 Hours****Integration:**

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

UNIT – V**06 Hours****Differential Equations:**

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

TEXT BOOKS: (Latest Edition)

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

PS108: HUMAN ANATOMY AND PHYSIOLOGY- I Lab**B. Pharm. I Year I Sem**

L	T	P	C
0	0	4	2

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**

L	T	P	C
0	0	4	2

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 Iodometry
- 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. I Year I 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	T	P	C
0	0	4	2

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 Iodide

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	T	P	C
0	0	2	1

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	T	P	C
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**

L	T	P	C
3	1	0	4

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
- Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Unit – I**10 hours****Body fluids and blood**

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

Lymphatic system

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

UNIT – II**10 hours****Cardiovascular system**

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

UNIT – III**06 hours****Digestive system**

Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

Respiratory system

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

UNIT – IV**10 hours****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.

UNIT – V**09 hours****Reproductive system**

Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

Introduction to genetics

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

TEXT BOOKS: (Latest Editions)

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

REFERENCE BOOKS:

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

PS202: PHARMACEUTICAL ORGANIC CHEMISTRY –I**B. Pharm. I Year II Sem**

L	T	P	C
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**07 Hours****Classification, nomenclature and isomerism**

Brief review of structural theory of organic chemistry, hybridization, bond length, bond angle, bond energy; inductive effect, electromeric effect, resonance, hyperconjugation and 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**10 Hours****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, oxymercuration-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

UNIT – III**10 Hours****Alkyl halides***

SN₁ and SN₂ reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations, SN₁ versus SN₂ reactions, Factors affecting SN₁ and SN₂ reactions, 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**10 Hours****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, Clemmensen reduction and Wolff Kishner reduction, Meerwein-Ponndorf Verley reduction, Analysis of aldehydes and ketones: haloform test, 2,4-DNP test, Tollens and Fehling test.

UNIT - V**08 Hours****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

BS203: BIOCHEMISTRY**B. Pharm. I Year II Sem**

L	T	P	C
3	1	0	4

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 shall be able to

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

UNIT – I**10 Hours****Carbohydrate metabolism**

Glycolysis – Pathway, energetics and significance Citric acid cycle- Pathway, energetics and significance

HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency

Glycogen metabolism Pathways and glycogen storage diseases (GSD) Gluconeogenesis- Pathway and its significance

Hormonal regulation of blood glucose level and Diabetes mellitus

Biological oxidation

Electron transport chain (ETC) and its mechanism. Oxidative phosphorylation & its mechanism and substrate level phosphorylation, Inhibitors ETC and oxidative phosphorylation/Uncouplers

UNIT – II**10 Hours****Lipid metabolism**

β-Oxidation of saturated fatty acid (Palmitic acid)

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

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

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

UNIT – III**10 Hours****Amino acid metabolism**

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

Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenylketonuria, Albinism, alcaptonuria, tyrosinemia)

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

Catabolism of heme; hyperbilirubinemia and jaundice

UNIT – IV**08 Hours**

Nucleic acid metabolism and genetic information transfer Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease Organization of mammalian genome

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

Genetic code, Translation or Protein synthesis and inhibitors

UNIT – V**07 Hours****Enzymes**

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

Enzyme inhibitors with examples

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

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

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)

BS204: PATHOPHYSIOLOGY**B. Pharm. I Year II Sem**

L	T	P	C
3	1	0	4

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**10 Hours****Basic principles of Cell injury and Adaptation:**

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

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**10 Hours****Cardiovascular System:**

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

Respiratory system: Asthma, Chronic obstructive airways diseases.

Renal system: Acute and chronic renal failure

UNIT - III**10 Hours****Haematological Diseases:**

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

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

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

Gastrointestinal system: Peptic Ulcer

UNIT – IV**8 Hours**

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

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

Principles of cancer: classification, etiology and pathogenesis of cancer

UNIT – V**7 Hours**

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; 12th 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].
7. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
8. Guyton A, John. E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
9. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
10. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
11. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

CS205: COMPUTER APPLICATIONS IN PHARMACY**B. Pharm. I Year II Sem**

L	T	P	C
3	0	0	3

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**06 hours**

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

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

UNIT –II**06 Hours**

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

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

UNIT – III**06 Hours**

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

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

UNIT – IV**06 hours**

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

UNIT-V**06 hours**

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

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 Wiley and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C. Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N. Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi – 110002
5. Mohiddin S. D. Computer Applications in Pharmaceutical Sciences, Pharma Med Press.

PS206: HUMAN ANATOMY AND PHYSIOLOGY –II LAB**B. Pharm. I Year II Sem**

L	T	P	C
0	0	4	2

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, Jaypee brothers 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**

L	T	P	C
0	0	4	2

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.

BS208: BIOCHEMISTRY LAB**B. Pharm. I Year II Sem**

L	T	P	C
0	0	4	2

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**

L	T	P	C
0	0	2	1

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
B. PHARMACY COURSE STRUCTURE AND I & II YEARS SYLLABUS

Effective from Academic Year 2022-23 Admitted Batch

I Year I semester

S. No	Course Code	Subject	L	T	P	Credits
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 [#] / Remedial Mathematics ^{\$}	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

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

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

I Year II semester

S. No	Course Code	Subject	L	T	P	Credits
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

II YEAR I SEMESTER

S. No	Course Code	Course Title	L	T	P	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	T	P	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	T	P	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	PS505 PS506 PS507 PS508	Open Elective - I I. Generic Product Development II. Green Chemistry III. Cell and Molecular Biology IV. Cosmetic science	3	1	0	4
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	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	T	P	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	PS605 PS606 PS607 PS608	Open Elective - II I. Pharmaceutical Quality Assurance II. Pharmaceutical Biotechnology III. Bioinformatics IV. Screening Methods in Pharmacology	3	1	0	4
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	T	P	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	PS705	Open Elective - III i. Pharmaceutical Marketing	3	1	0	4

PS301: PHARMACEUTICAL ORGANIC CHEMISTRY – II**B. Pharm. II Year I Sem**

L	T	P	C
3	1	0	4

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**10 Hours****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**10 Hours**

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**10 Hours**

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**08 Hours****Polynuclear hydrocarbons:**

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

UNIT – V**07 Hours**

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

RECOMMENDED BOOKS (Latest Editions)

- Organic Chemistry by Morrison and Boyd
- Organic Chemistry by I.L. Finar, Volume-I
- Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
- Pharmaceutical organic Chemistry by V Algarsamy, Pharmamed Press
- Organic Chemistry by P.L. Soni
- Practical Organic Chemistry by Mann and Saunders.
- Vogel's text book of Practical Organic Chemistry
- Advanced Practical organic chemistry by N.K. Vishnoi.
- Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

PS302: PHYSICAL PHARMACEUTICS - I**B. Pharm. II Year I Sem**

L	T	P	C
3	1	0	4

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**10 Hours**

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**10 Hours**

Solubility of drugs: Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, 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**10 Hours**

Micromeritics: 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**08 Hours**

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

UNIT – V**07 Hours**

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

RECOMMENDED BOOKS: (Latest Editions)

1. Physical pharmacy by Alfred Martin
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume 1-3, 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 ManavalanR.
8. Manavalan et. Al, Physical Pharmaceutics, Pharma Med Press

BS303: PHARMACEUTICAL MICROBIOLOGY**B. Pharm. II Year I Sem**

L	T	P	C
3	1	0	4

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**10 Hours**

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

UNIT - II**10 Hours**

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

UNIT – III**10 Hours**

Study of morphology, classification, reproduction/replication and cultivation of Fungi and 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**08 Hours**

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**07 Hours**

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.

RECOMMENDED BOOKS (Latest edition)

1. Rafi MD, Text book of biochemistry for undergraduates, 3rd 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. Pepler: 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**

L	T	P	C
3	1	0	4

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**10 Hours**

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

Size Reduction: Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.

Size Separation: Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.

UNIT – II**10 Hours**

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**10 Hours**

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**08 Hours**

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

RECOMMENDED BOOKS: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson-Latest edition.
3. Unit operation of chemical engineering – McCabe Smith, Latest edition.
4. Pharmaceutical Engineering 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 pharmaceuticals- 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

PS305: PHARMACEUTICAL ORGANIC CHEMISTRY - II LAB**B. Pharm. II Year I Sem**

L	T	P	C
0	0	4	2

I Experiments involving laboratory techniques
Recrystallization
Steam Distillation

II Determination of following oil values (including standardization of reagents)
Acid value
Saponification value
Iodine value

III **Preparation of compounds**

- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
- 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/ Acetanilide by halogenation (Bromination) reaction.
- 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
- Benzoic acid from Benzyl chloride by oxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction
- Cinnamic acid from Benzaldehyde by Perkin reaction
- *p*-Iodo benzoic acid from *p*-amino benzoic acid

RECOMMENDED BOOKS: (Latest Editions)

1. 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**

L	T	P	C
0	0	4	2

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 Iodine in CCl₄ 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

RECOMMENDED BOOKS: (Latest Editions)

1. Experimental pharmaceuticals by Eugene, Parott.
2. Pharmaceutical Calculation, D K Tripathi.
3. Laboratory manual of physical pharmaceuticals, 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**

L	T	P	C
0	0	4	2

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

RECOMMENDED BOOKS (Latest edition)

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**

L	T	P	C
0	0	4	2

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.

RECOMMENDED BOOKS (Latest edition)

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**

L	T	P	C
3	1	0	4

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**10 Hours****Stereo isomerism**

Optical isomerism – Optical activity, enantiomerism, diastereoisomerism, meso compounds

Elements of symmetry, chiral and achiral molecules, DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers, Reactions of chiral molecules. Racemic modification and resolution of racemic mixture Asymmetric synthesis: partial and absolute

UNIT – II**10 Hours****Geometrical isomerism**

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

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

Stereospecific and stereoselective reactions

UNIT – III**10 Hours****Heterocyclic compounds 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**8 Hours****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**07 Hours****Reactions of synthetic importance**

Metal hydride reduction (NaBH_4 and LiAlH_4), Clemmensen reduction, Birch reduction, Wolff Kishner reduction. Oppenauer-oxidation and Dakin reaction. Beckmanns rearrangement and Schmidt rearrangement, Pinacol-Pinacolone 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

PS402: PHYSICAL PHARMACEUTICS - II**B. Pharm. II Year II Sem**

L	T	P	C
3	1	0	4

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**10 Hours**

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

UNIT - II**10 Hours**

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**10 Hours**

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**08 Hours**

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

UNIT – V**07 Hours**

Colloidal dispersions: Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization & protective action.

RECOMMENDED BOOKS: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceuticals 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. Vidyadhara et al. Physical Pharmaceutics – II, Pharma Med Press

PC403: PHARMACOLOGY - I**B. Pharm. II Year II Sem**

L	T	P	C
3	1	0	4

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**08 hours****1. General Pharmacology**

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

UNIT – II**10 Hours****Adverse Drug Reactions and Drug Interactions**

- Agonists, antagonists (competitive and noncompetitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.
- Adverse drug reactions.
- Drug interactions (pharmacokinetic and pharmacodynamic)
- Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

UNIT – III**10 Hours****2. Pharmacology of peripheral nervous system**

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

UNIT – IV**10 Hours****3. Pharmacology of central nervous system - I**

- Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.
- General anesthetics and pre-anesthetics.
- Sedatives, hypnotics and centrally acting muscle relaxants.
- Anti-epileptics
- Alcohols and disulfiram

UNIT – V**7 Hours****Pharmacology of central nervous system - II**

- a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
- b. Drugs used in Parkinsons disease and Alzheimer's disease.
- c. CNS stimulants and nootropics.
- d. Opioid analgesics and antagonists
- 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 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
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
6. K.D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan
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**

L	T	P	C
3	1	0	4

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

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**10 Hours**

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**10 Hours**

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

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

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**08 Hours**

Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs

Plant Products: Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

Primary metabolites:

General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following

Primary metabolites: **Carbohydrates:** Acacia, Agar, Tragacanth, Honey

Proteins and Enzymes: Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).

Lipids (Waxes, fats, fixed oils): Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax

Marine Drugs:

Novel medicinal agents from marine sources

UNIT - IV**10 Hours**

Pharmacognosy in various systems of medicine:

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

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

RECOMMENDED BOOKS: (Latest Editions)

1. W.C. Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr.SH.Ansari, 11nd 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.**

L	T	P	C
3	1	0	4

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**10 Hours****Drugs and Cosmetics Act, 1940 and its rules 1945:**

Objectives, Definitions, Legal definitions of schedules to the act and rules

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

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

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

UNIT – II**10 Hours****Drugs and Cosmetics Act, 1940 and its rules 1945.**

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**10 Hours**

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**08 Hours**

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

Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, 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)

RECOMMENDED BOOKS: (Latest Edition)

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	T	P	C
0	0	4	2

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

RECOMMENDED BOOKS: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. 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**

L	T	P	C
0	0	4	2

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

PC408: PHARMACOGNOSY AND PHYTOCHEMISTRY – I LAB**B. Pharm. II Year II Sem**

L	T	P	C
0	0	4	2

List of Experiments:

1. Analysis of crude drugs by chemical tests: (i) Tragacanth (ii) Acacia (iii) Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and palisade ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of 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.

RECOMMENDED BOOKS: (Latest Editions)

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

MC400: GENDER SENSITIZATION LAB**B. Pharm. II Year II Sem**

L	T	P	C
1	0	0	0

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 Out Is 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.

Note: 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 Bhugubanda, Duggirala Vasanta, 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%

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
B. PHARMACY III YEAR COURSE STRUCTURE AND SYLLABUS

Effective from Academic Year 2017-18 Admitted Batch

III Year I Semester

S. No.	Course Code	Course Title	L	T	P	Credits
1	PS501	Medicinal Chemistry II	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	PS505 PS506 PS507 PS508	Open Elective - I I. Generic Product Development II. Green Chemistry III. Cell and Molecular Biology IV. Cosmetic science	3	1	0	4
6	PS509	Industrial Pharmacy lab	0	0	4	2
7	PS510	Pharmacology - II lab	0	0	4	2
8	PS511	Pharmacognosy and Phytochemistry - II lab	0	0	4	2
9	*MC500	Environmental sciences	1	0	0	0
		Total	16	05	12	26

III Year II Semester

S. No.	Course Code	Course Title	L	T	P	Credits
1	PS601	Medicinal Chemistry - III	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	PS605 PS606 PS607 PS608	Open Elective - II I. Pharmaceutical Quality Assurance II. Pharmaceutical Biotechnology III. Bioinformatics IV. Screening Methods in Pharmacology	3	1	0	4
6	PS609	Medicinal chemistry - III 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	*MC600	Human Values and Professional Ethics	1	0	0	0
		Total	16	05	12	26

PS501: MEDICINAL CHEMISTRY – II**B.Pharm. III Year I Sem.****L T/P/ C
3 1/0/ 4**

Course Objective: 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, absorption, distribution 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

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

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

UNIT - I**10 Hours**

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

H₁-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine, Cromolyn sodium

H₂-antagonists: Cimetidine*, Famotidine, Ranitidine.

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

Anti-neoplastic agents:

Alkylating agents: Meclorothamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiopeta

Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT – II**10 Hours**

Anti-anginal:

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

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

Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril

hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

UNIT - III**10 Hours**

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

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholestamine and Cholestipol

Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide
Bosentan, Tezosentan.

UNIT - IV**08 Hours****Drugs acting on Endocrine system**

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandrolone, Progestones, Oestriol, Oestradiol, Oestrone, Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

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

UNIT – V**07 Hours****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, Mepylcaine, Cyclomethycaine, Piperocaine.

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

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

Miscellaneous: Phenacaine, Dipreron, Dibucaine.*

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.

PS502: INDUSTRIAL PHARMACY - I**B.Pharm. III Year I Sem.****L T/P/ C
3 1/0/ 4**

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**07 Hours**

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**10 Hours****Tablets:**

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

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

UNIT – III**08 Hours****Capsules:**

- 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.
- 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).

UNIT - IV**10 Hours****Parenteral Products:**

- Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
- Production procedure, production facilities and controls.

- c. Formulation of injections, sterile powders, emulsions, suspensions, large volume parenterals and lyophilized products, Sterilization.
- d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests.

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

UNIT – V

10 Hours

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

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

Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

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
8. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia, 5th edition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.
10. Pharmaceutical Technology 1 &11 BY Gaurav Agarwal CBS Publishers
11. Pharmaceutics Basic principles and Formulations by D.K. Tripathi Pharma med press

PS503: PHARMACOLOGY - II**B.Pharm. III Year I Sem.****L T/P/ C
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**10 hours****Pharmacology of drugs acting on cardio vascular system**

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

UNIT – II**10 hours****1. Pharmacology of drugs acting on cardio vascular system**

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

2. Pharmacology of drugs acting on urinary system

- a. Diuretics
- b. Anti-diuretics.

UNIT - III**10 hours****Autocoids and related drugs**

- a. Introduction to autocoids and classification
- b. Histamine, 5-HT and their antagonists.
- c. Prostaglandins, Thromboxanes and Leukotrienes.
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatory agents
- f. Anti-gout drugs
- g. Antirheumatic drugs

UNIT - IV**08 hours****Pharmacology of drugs acting on endocrine system**

- a. Basic concepts in endocrine pharmacology.

- b. Anterior Pituitary hormones- analogues and their inhibitors.
- c. Thyroid hormones- analogues and their inhibitors.
- d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
- e. Insulin, Oral Hypoglycemic agents and glucagon.
- f. ACTH and corticosteroids.

UNIT - V**07 hours****1. Pharmacology of drugs acting on endocrine system**

- 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. 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. 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.
6. Mycek M. J, Gelnet S. B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
7. K. D. Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
8. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
9. 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.

PS504: PHARMACOGNOSY AND PHYTOCHEMISTRY - II**B.Pharm. III Year I Sem.****L T/P/ C
3 1/0/ 4**

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**7 Hours****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**10 Hours**

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

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

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

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

UNIT - III**10 Hours**

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**10 Hours****Isolation, Identification and analysis of phytoconstituents**

- Terpenoids: Menthol, Citral and Artemisin
- Glycosides: Glycyrrhetic acid and Rutin
- Alkaloids: atropine, Quinine, Reserpine and Caffeine
- Resins: Podophyllotoxin and Curcumin

UNIT - V 8 Hours

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

TEXT BOOKS: (Latest Editions)

1. W. C. Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.

2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr. SH. Ansari, 1st edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H. Pande, Asia Pacific Business press, Inc, New Delhi.
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.

PS505: GENERIC PRODUCT DEVELOPMENT
(Open Elective - I)

B.Pharm. III Year I Sem.

L T/P/ C
3 1/0/ 4

Course Objectives: To learn the generic drug product development process, dosage form design and development, analytical method development and dossier approval process.

Course Outcome: The knowledge of the students is enhanced with the clear information about the generic product development.

UNIT - I

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

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, in-process 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.

PS506: GREEN CHEMISTRY
(Open Elective - I)

B.Pharm. III Year I Sem.

L T/P/ C
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 (Knoevenagel condensation) and bio catalysts (Villegier 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 Warner. Green chemistry: theory and practice. Oxford university Press, 1988
2. Alluwalla V.K, Green chemistry : environmentally benign reactions. 2nd edn, Ane Books Pvt Ltd, New Delhi, 2012
3. Alluwalla V.K, M. Kidwai, New trends in green chemistry. 2nd edn, Anamaya Publishers, New delhi, 2004.

PS507: CELL AND MOLECULAR BIOLOGY
(Open Elective - I)

B.Pharm. III Year I Sem.

L T/P/ C
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

UNIT – I

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
- f. Chemical Foundations – an Introduction and Reactions (Types)

UNIT – II

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

UNIT – III

10 Hours

- a. Proteins: Defined **and** Amino Acids
- b. Protein Structure
- c. Regularities in Protein Pathways
- d. Cellular Processes
- e. Positive Control and significance of Protein Synthesis

UNIT – 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

UNIT – 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, 10th 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 T/P/ C
3 1/0/ 4

Course Objective: This subject deals with cosmetic products, cosmetic excipients, skin care products and their methods of preparation and evaluations.

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, anti-perspirants, deodorants, hair care products etc.
- They also know about the role of herbs in sunscreens.

UNIT – I**10 Hours**

Classification of cosmetic and cosmeceutical products

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

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

UNIT – II**10 Hours****Principles of formulation and building blocks of skin care products:**

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream 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-phenylene diamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT – III**10 Hours**

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-cream and toothpaste.

UNIT – IV**08 Hours**

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi 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

07 Hours

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

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

Antiperspirants and Deodorants- Actives and mechanism of action

REFERENCE BOOKS:

1. Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2. Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
3. Textbook of Cosmetics by Rajesh Kumar Nema, Kmal singh Rathore and BK Dubey
4. Textbook of Cosmetics by M. Vimaladevi

PS509: INDUSTRIAL PHARMACY LAB**B.Pharm. III Year I Sem.****L T/P/ C
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)

Recommended Books: (Latest Editions)

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

PS510: PHARMACOLOGY - II LAB**B.Pharm. III Year I Sem.****L T/P/ C
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_2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD_2 value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

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

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology,
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. 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.
6. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
7. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
8. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
9. 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.

PS511: PHARMACOGNOSY AND PHYTOCHEMISTRY II LAB**B.Pharm. III Year I Sem.****L T/P/ C
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

Recommended Books: (Latest Editions)

1. W. C. Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C. K. Kokate, Purohit, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr. SH. Ansari, 1st edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H. Pande, Asia Pacific Business press, Inc, New Delhi.
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 Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

MC500: ENVIRONMENTAL SCIENCES*B.Pharm. III Year I Sem.****L T/P/ C
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.

Recommended Books (Latest edition):

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. 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

PS601: MEDICINAL CHEMISTRY – III**B.Pharm. III Year II Sem.****L T/P/ C
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****Antibiotics:**

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**10 Hours****Antibiotics:**

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

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

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

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovaquone.

UNIT – III**10 Hours****Anti-tubercular Agents**

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

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

Urinary tract anti-infective agents

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

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

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

UNIT – IV

08 Hours

Antifungal agents:

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

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

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

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

Sulphonamides and Sulfones

Historical development, chemistry, classification and SAR of Sulfonamides:

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

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V

07 Hours

Introduction to Drug Design

Various approaches used in drug design.

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

Pharmacophore modeling and docking techniques.

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 Lednicher, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

PS602; PHARMACOLOGY - III**B.Pharm. III Year II Sem.****L T/P/ C
3 1/0/ 4**

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**10 hours****1. Pharmacology of drugs acting on Respiratory system**

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

2. Pharmacology of drugs acting on the Gastrointestinal Tract

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

UNIT – II**10 hours****Chemotherapy**

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

UNIT – III**10 hours****Chemotherapy**

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

UNIT – IV**08 hours****1. Chemotherapy**

- a. Urinary tract infections and sexually transmitted diseases.
Chemotherapy of malignancy.

2. Immunopharmacology

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

UNIT – V**07 hours****Principles of toxicology**

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

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. 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
6. Mycek M. J, Gelnet S. B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
7. K. D. Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
8. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher 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. N. Udupa and P.D. Gupta, Concepts in Chronopharmacology.

PS603: HERBAL DRUG TECHNOLOGY**B.Pharm. III Year II Sem.****L T/P/ C
3 1/0/ 4**

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:

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

UNIT – I**6 Hours****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. Biodynamic Agriculture

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 involved in work on medicinal and aromatic plants in India.

UNIT – II**7 Hours****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, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.

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

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, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

UNIT - III**10 Hours****1. Herbal Cosmetics**

Principles and preparation of herbal cosmetics formulations- Shampoos, Dyes, face creams, 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 & perfumes.

3. Herbal formulations :

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

UNIT – IV**10 Hours**

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. Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
 - b. Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.
3. **Regulatory Issues** - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT – V**07 Hours**

Schedule T – Good Manufacturing Practice of Indian systems of medicine Components of GMP (Schedule – T) and its objectives

Infrastructural requirements, working space, storage area, machinery and 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
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
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

PS604: BIOPHARMACEUTICS AND PHARMACOKINETICS**B.Pharm. III Year II Sem.****L T/P/ C
3 1/0/ 4**

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**10 Hours****Introduction to Biopharmaceutics**

Absorption: Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution:** 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**10 Hours**

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, in-vitro, in-vivo correlations, bioequivalence studies, methods to enhance the bioavailability.

UNIT – III**10 Hours****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 K_a , K_e . From plasma and urinary excretion data

UNIT – IV**08 Hours**

Multicompartment models: Two compartment open model. IV bolus

Multiple – Dosage Regimens:

- Repetitive Intravenous injections – One Compartment Open Model
- Repetitive Extravascular dosing – One Compartment Open model

UNIT – V**07 Hours**

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

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B. C. YU 4th edition, Prentice-Hall International edition. USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmkar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Fundamentals of Biopharmaceutics and pharmacokinetics by Dr. V. Venkateshwarlu
6. Pharmacokinetics: By Milo Gibaldi 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 Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
13. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.

PS605: BP605T PHARMACEUTICAL QUALITY ASSURANCE
(Open Elective - II)

B.Pharm. III Year II Sem.

L T/P/ C
3 1/0/ 4

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

10 Hours

- 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, ICH stability testing guidelines **Quality by design**
- 4. (QbD):** Definition, overview, elements of QbD program, tools
- 5. ISO 9000 & ISO14000:** Overview, Benefits, Elements, steps for registration
- 6. NABL accreditation:** Principles and procedure

UNIT – II

10 Hours

- 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

10 Hours

- Quality Control:** Quality control test for containers, rubber closures and secondary packing materials.
- Good Laboratory Practices:** General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities.

UNIT – IV

08 Hours

- 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

07 Hours

- 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, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

2. Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

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

PS606: PHARMACEUTICAL BIOTECHNOLOGY
(Open Elective - II)

B.Pharm. III Year II Sem.

L T/P/ C
3 1/0/ 4

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 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

10 Hours

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

UNIT – II

10 Hours

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

Types of immunity- humoral immunity, cellular immunity

UNIT – III

10 Hours

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

UNIT – IV

08 Hours

- a. Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
- b. Genetic organization of Eukaryotes and Prokaryotes
- c. Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.

- d. Introduction to Microbial biotransformation and applications.
- e. Mutation.

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, Degrand, 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

PS607: BIOINFORMATICS
(Open Elective - II)

B.Pharm. III Year II Sem.

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- seq 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, algorithms and applications by Ruchi singh and Richa Sharma
6. Essential Bioinformatics Jinxiong

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

B.Pharm. III Year II Sem.

L T/P/ C
3 1/0/ 4

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

Toxicity test: OECD guidelines, determination of LD₅₀, 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. Handbook of Experimental Pharmacology, SK. Kulkarni.
11. Practical Pharmacology and Clinical Pharmacy, SK. Kulkarni, 3rd Edition.
12. Screening Methods in Pharmacology, Robert A. Turner.

PS609: MEDICINAL CHEMISTRY- III LAB**B.Pharm. III Year II Sem.****L T/P/ C
0 0/4/ 2****1. Preparation of drugs and intermediates**

- a. Sulphanilamide
- b. 7-Hydroxy, 4-methyl coumarin
- c. Chlorobutanol
- d. Triphenyl imidazole
- e. Tolbutamide
- f. Hexamine

2. Assay of drugs

- a. Isonicotinic acid hydrazide
- b. Chloroquine
- c. Metronidazole
- d. Dapsone
- e. Chlorpheniramine maleate
- f. Benzyl penicillin

3. Preparation of medicinally important compounds or intermediates by Microwave irradiation technique**4. Drawing structures and reactions using chem draw®****5. Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)****Recommended Books (Latest Editions)**

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
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.

PS610: PHARMACOLOGY - III LAB**B.Pharm. III Year II Sem.****L T/P/ C
0 0/4/ 2****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. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M. J, Gelnet S. B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
6. K. D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan,
10. N. Udupa and P.D. Gupta, Concepts in Chronopharmacology.

PS611: HERBAL DRUG TECHNOLOGY LAB**B.Pharm. III Year II Sem.****L T/P/ C
0 0/4/ 2****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. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

MC600: HUMAN VALUES AND PROFESSIONAL ETHICS*B.Pharm. III Year II Sem.****L T/P/ C
1 0/0/ 0**

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.

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
B. PHARMACY IV YEAR COURSE STRUCTURE AND SYLLABUS

Effective from Academic Year 2017-18 Admitted Batch

IV Year I Semester

S.No	Course Code	Course Title	L	T	P	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	Novel Drug Delivery Systems	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	2	1
		Total	15	5	10	25

IV Year II Semester

S.No	Course Code	Course Title	L	T	P	Credits
1	PS801	Biostatistics and Research Methodology	3	1	0	4
2	PS802	Social and Preventive Pharmacy	3	1	0	4
3	PS803	Pharmaceutical Jurisprudence	3	0	0	3
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	Project Work	0	0	6	3
		Total	12	3	6	18

PS701: INSTRUMENTAL METHODS OF ANALYSIS

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

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**10 Hours****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**10 Hours****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****10 Hours****Introduction to chromatography****1. Adsorption and partition column chromatography**- Methodology, advantages, disadvantages and applications.**2. Thin layer chromatography**- Introduction, Principle, Methodology, R_f 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****08 Hours****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.

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

PS702: INDUSTRIAL PHARMACY - II

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

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**10 Hours**

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

UNIT – II**10 Hours**

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**10 Hours**

1. **Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals
2. **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**08 Hours**

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

UNIT – V**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. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http://en.wikipedia.org/wiki/Regulatory_Affairs.
2. International Regulatory Affairs Updates, 2005. available at <http://www.iraup.com/about.php>

3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' 2nd Edition.
4. Regulatory Affairs brought by learning plus, inc. available at <http://www.cgmp.com/ra.htm>.
5. Industrial Pharmacy by Roopa K Khar, S. P Vyas, Farhan J Ahmed, Gaurav K Jain, 4th Edition

PS703: PHARMACY PRACTICE

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

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 counseling.

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 counseling in community pharmacy

UNIT – I**10 Hours****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**10 Hours****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**10 Hours****1. Drug information services**

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

2. Patient counseling

Definition of patient counseling; 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.

UNIT – IV**08 Hours****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**07 Hours****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, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. Hospital pharmacy, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. Hospital Pharmacy, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. Basic skills in interpreting laboratory data, 4th ed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N. S. Health Education and Community Pharmacy, 18th ed. India: CBS Publishers & Distributers; 2008.

PS704: NOVEL DRUG DELIVERY SYSTEMS

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

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**10 Hours**

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**10 Hours**

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**10 Hours**

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**08 Hours**

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**07 Hours**

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

Recommended Books: (Latest Editions)

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

PS705: PHARMACEUTICAL MARKETING (Open Elective - III)

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

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**10 Hours**

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

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

UNIT – II**10 Hours**

Product decision: 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**10 Hours**

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**10 Hours**

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

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

UNIT – V**10 Hours**

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

Emerging concepts in marketing: Vertical & Horizontal Marketing; 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. Dhruv Grewal and Michael Levy: Marketing, Tata McGraw Hill

4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Management: Global Perspective, Indian Context, Macmillan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

PS706: PHARMACEUTICAL REGULATORY SCIENCE (Open Elective - III)

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

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**10 Hours****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**10 Hours**

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**10 Hours**

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**08 Hours**

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**07 Hours**

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, 2nd Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.

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

PS707: PHARMACOVIGILANCE (Open Elective - III)

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

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**10 Hours****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**10 hours****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)

UNIT – III

10 Hours

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

08 Hours

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

07 hours

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 Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. <http://www.who.int/dynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297>
13. <http://www.ich.org/>
14. <http://www.cioms.ch/>
15. <http://cdsco.nic.in/>
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

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

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

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**10 hours**

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

UNIT – II**10 hours**

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

UNIT – III**10 hours**

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

UNIT – IV**08 hours**

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

UNIT – V**07 hours**

Regulatory requirements for herbal medicines.
WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias.
Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest Editions)

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

8. 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.

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. 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

PS710: PRACTICE SCHOOL

B.Pharm. IV Year I Sem.

L/T/P/ C
0 /0/4/ 2

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 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, gynecological, pulmonary pediatric 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.

L/T/P/ C
3/1/0/ 4

Course Objectives: To understand the applications of Biostatistics 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**10 Hours**

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples

Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems

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

UNIT – II**10 Hours**

Regression: Curve fitting by the 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**10 Hours**

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

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

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

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

UNIT – IV**8 Hours**

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**7 Hours**

Design and Analysis of experiments:

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

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

Recommended Books (Latest edition):

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

PS802: SOCIAL AND PREVENTIVE PHARMACY

B.Pharm. IV Year II Sem.

L/T/P/ C
3/1/0/ 4

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**10 Hours**

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

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

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

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

UNIT – II**10 Hours**

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

UNIT – III**10 Hours**

National health programs, its objectives, functioning and outcome of the following: HIV and AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

UNIT – IV**08 Hours**

National health intervention programme for mother and child, national family welfare programme, national tobacco 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**07 Hours**

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

Recommended Books (Latest edition):

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

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

PS803: PHARMACEUTICAL JURISPRUDENCE

B.Pharm. IV Year II Sem.

L/T/P/ C
3/0/0/ 3

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**10 Hours****Drugs and Cosmetics Act, 1940 and its rules 1945:**

Objectives, Definitions, Legal definitions of schedules to the act and rules

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

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

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

UNIT – II**10 Hours****Drugs and Cosmetics Act, 1940 and its rules 1945.**

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**10 Hours**

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**08 Hours**

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

Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, 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)

Recommended books: (Latest Edition)

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)

PS804: COMPUTER AIDED DRUG DESIGN (Open Elective - IV)

B.Pharm. IV Year II Sem.

L/T/P/ C
3/1/0/ 4

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 modeling software

UNIT – I**10 Hours**

Introduction to Drug Discovery and Development: Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

UNIT – II**10 Hours**

Quantitative Structure Activity Relationship (QSAR): SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammett's substituent constant and Taft's steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT – III**10 Hours****Molecular Modeling and virtual screening techniques**

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

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

UNIT – IV**08 Hours**

Informatics & Methods in drug design: Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT – V**07 Hours**

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

Recommended Books (Latest Editions):

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Park Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvold's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry" Lea & Febiger.

5. Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

PS805: NANO TECHNOLOGY (Open Elective - IV)

B.Pharm. IV Year II Sem.

L/T/P/ C
3/1/0/ 4

Course Objectives: To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, 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: Nanoplatfroms in Drug Delivery, Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanoscience 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

PS806: EXPERIMENTAL PHARMACOLOGY (Open Elective - IV)

B.Pharm. IV Year II Sem.

L/T/P/ C
3/1/0/ 4

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's '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, 3rd Edition.
12. Screening Methods in Pharmacology, Robert A. Turner.

PS807: ADVANCED INSTRUMENTATION TECHNIQUES (Open Elective - IV)

B.Pharm. IV Year II Sem.

L/T/P/ C
3/1/0/ 4

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**10 Hours****Nuclear Magnetic Resonance spectroscopy**

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

Mass Spectrometry - Principles, Fragmentation, Ionization techniques - Electron impact, chemical ionization, instrumentation and applications.

UNIT - II**10 Hours**

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**10 Hours**

Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC

UNIT – IV**08 Hours**

Radio immune assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

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

UNIT – V**07 Hours**

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

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.PHARMACY (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)
R22 COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2022-23 Admitted Batch

I YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Modern Pharmaceutics-I	3	1	0	4
Professional Core-II	Applied Biopharmaceutics and Pharmacokinetics	3	1	0	4
Professional Elective-I	1. Advanced Physical Pharmaceutics 2. Drug Regulatory affairs 3. Total Quality Management	3	1	0	4
Professional Elective-II	1. Cosmetics and Cosmeceuticals 2. Pharmaceutical Validation 3. Stability of Drugs and Dosage Forms	3	1	0	4
	Research methodology and IPR	2	0	0	2
Laboratory- I	Modern Pharmaceutics – I Lab	0	0	6	3
Laboratory- II	Applied Biopharmaceutics and Pharmacokinetics Lab	0	0	6	3
Audit - I	Audit Course- I	2	0	0	0
	Seminar & Assignment	0	0	4	2
	TOTAL	16	4	16	26

I YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Modern Pharmaceutics - II	3	1	0	4
Professional Core-IV	Advanced Drug Delivery Systems	3	1	0	4
Professional Elective-III	1. Industrial Pharmacy 2. Herbal Cosmetics 3. Pharmaceutical Management	3	1	0	4
Professional Elective-IV	1. Nano based Drug Delivery Systems 2. Nutraceuticals 3. Clinical Research and Pharmacovigilance	3	1	0	4
Laboratory- III	Modern Pharmaceutics – II Lab	0	0	6	3
Laboratory- IV	Advanced Drug Delivery System Lab	0	0	6	3
	Mini Project	2	0	0	2
Audit - II	Audit Course- II	2	0	0	0
	Seminar & Assignment	0	0	4	2
	TOTAL	16	4	16	26

II YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Elective-V	1. Biostatistics 2. Scale up and Technology Transfer 3. Production area, Design and Packaging Development	3	1	0	4
Open Elective	Open Elective	3	1	0	4
	Comprehensive Viva voce	0	0	8	4
	Dissertation Work Review – II	0	0	24	12
	TOTAL	6	2	32	24

II YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Dissertation	Dissertation Work Review - III	0	0	24	12
Dissertation	Dissertation Viva-Voce	0	0	20	10
	TOTAL	0	0	44	22

***For Dissertation Work Review - I, Please refer R22 Academic Regulations.**

Audit Courses I & II:

1. English for Research Paper Writing
2. Disaster Management
3. Sanskrit for Technological Learning
4. Value Education
5. Constitution of India
6. Pedagogy Studies
7. Stress Management by Yoga
8. Personality Development through Life Enlightenment Skills

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICS –I (Professional Core-I)

Course Objectives: Students will know the preformulation studies, methodology, different excipients used in solid dosage forms and their evaluation with references to production technologies. The students also know the optimization techniques and their applications in pharmaceutical industries.

Course Outcome: Students shall explain the preformulation parameters, apply ICH guidelines and evaluate drug, drug excipients compatibility. Students also explain about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques. They also learn and apply the statistical design in different formulations.

UNIT I

Preformulation studies: Goals of Preformulation, preformulation parameters, Polymorphs and Amorphous forms, selection of drugs- solubility, partition coefficient, salt forms, humidity, solid state properties, Particle Size Analysis (Laser Diffraction and Dynamic Light Scattering) drug-excipient compatibility, flow properties, format and content of reports of preformulation, preformulation stability studies as per ICH.

UNIT II

Formulation development of solid dosage forms – I: New materials, excipient science - diluents, disintegrants, superdisintegrants, etc, evaluation of functional properties of excipient, co-processed materials, methods of preparation and evaluation.

UNIT III

Formulation development of solid dosage forms– II: Coating, coating machines, coating techniques in tablet technology for product development, computerization, inprocess control of tablets, formulation development and manufacture of powder dosage forms for internal use.

Microencapsulation- types, methodology, problems encountered.

UNIT IV

Formulation development of soft and hard gelatin capsules: Introduction, production and methods of manufacture, filling equipment and filling operations, formulations, finishing, special techniques, advances in capsule manufacture, machines, processing and control including pharmaceutical aspects, physical stability and packaging.

UNIT V

Optimization techniques in pharmaceutical formulation and processing: Introduction, optimization parameters, statistical design, response surface method, contour diagrams, factorial design, partial factorial design, simplex methods, mixture designs, Plackett Burman method, Box Benken method, applications in pharmaceutical formulation.

TEXT BOOKS

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman and Schwartz.
3. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
4. Pharmaceutical Dosage forms – Disperse systems (Vol I, II and III) by Avis, Lieberman and Lachman.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.

6. Pharmaceutical statistics by Bolton

REFERENCE BOOKS:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
4. Generic Drug Product Development by Leon Shargel and Isadore Kanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.
6. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi – 2013

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS (Professional Core – II)

Course Objectives: The student shall know about bioavailability, bioequivalence and factor affecting bioavailability. They also know the pharmacokinetic parameter like drug disposition, absorption, non-linear and time dependant pharmacokinetics. They also know about the drug interactions & problems associated in pharmacokinetic parameters calculations.

Course Outcomes: students will be able to tell factors affecting the bioavailability and stability of dosage form; they also know the bioequivalence studies and protocols for bioequivalent studies. They also know the parameters for the disposition, absorption and Michaelis-Menton constants for non-linear kinetics.

UNIT I

- a. Biological and metabolic factors affecting bioavailability, complexation, dissolution - techniques of enhancing dissolution.
- b. Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals, liquid orals and topical dosage forms.
- c. **Bioavailability:** Importance, dose dependency, AUC, rate and extent, assessment, blood and urine samples, single dose and multiple dose studies, *Invitro- Invivo* Correlation analysis and Levels of Correlations.
- d. **Bioequivalence:** Importance equivalency concepts, biowaivers, study designs, protocol, transformation of data, Statistical Criteria as per the Regulations.

UNIT II

Pharmacokinetics – Drug Disposition: compartment models: One, two and non-compartmental approaches to pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

- a. Distribution: Apparent volume of distribution and its determination, factors affecting.
- b. Metabolism: Metabolic rate constant, Factors affecting Metabolism
- c. Elimination: Over all apparent elimination rate constant, and half life.
All the above under the following conditions:
 1. Intravenous infusion
 2. Multiple dose injections
- d. Non-invasive methods of estimating pharmacokinetics parameters with emphasis on salivary and urinary samples.
- e. Concept of clearance: organ, total clearance, hepatic clearance, lung clearance and renal clearance.

UNIT III

Pharmacokinetics – Absorption: Rate constants – Zero order, first order, Models of experimental study of absorption (in silico, in vitro, in situ and in vivo) – Absorption half lives, method of residuals, Wagner – Nelson method, Loo - Reigleman method, Analysis of kinetics from urine samples. Pharmacokinetic parameters determination pertaining to: Multiple dosage oral administration.

UNIT IV

Non-linear pharmacokinetics: Concepts of linear and non-linear pharmacokinetics, Michaelis-Menton kinetics characteristics. Basic kinetic parameters, possible causes of non-induction, non-linear binding, and non-linearity of pharmacological responses.

Clinical Pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics. kinetics in GI disease, malabsorption syndrome, liver, cardiac, renal and pulmonary disease states.

UNIT V

Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug) chemically induced dependency.

Drug Interactions: Kinetics of drug interaction, study of drug-drug interaction mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence.

❖ Numerical problems associated with all units, if any.

TEXT BOOKS

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and Pharmacokinetics
3. Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, Vallabh Prakashan.2010.
4. Basic biopharmaceutics, Sunil S. Jambhekar and Philip J Brean.
5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by NiaziSarfaraz, Pharmamed Press

REFERENCE BOOKS

1. Bio-Pharmaceutics and Pharmacokinetics by V. Venkateshwarlu.
2. Pharmacokinetics, Biopharmaceutics and Clinical pharmacy by Robert E. Notari.
3. Biopharmaceutics and Clinical Pharmacokinetics - An Introduction by Robert E. Notari.
4. Drug drug interactions, scientific and regulatory perspectives by Albert P. G

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

ADVANCED PHYSICAL PHARMACEUTICS (Professional Elective – I)

Course Objectives: the students shall know about particle science, polymer science and its use in pharmaceutical dosage forms. They also know the compression and consolidation parameters for powders and granules. Students also know about the rheology, disperse systems, dissolution and solubility parameters for dosage forms.

Course Outcomes: The students will know particle size analysis method, solid dispersion, physics of tablets, polymer classification and its applications, student will also know the stability calculations, shelf life calculations and accelerated stability studies. They also know the rheology, absorption related to liquids and semi-solid dosage forms. They also know the factors affecting the dissolution and solubility in related to invitro/invivo correlations.

UNIT I

Polymer science: Classification, properties and characterization of polymers, phase separation, polymers in solid state, preparation of polymer solution, application of polymers in pharmaceutical formulations. Mechanism of biodegradation of biodegradable polymers including controlled drug delivery systems, Mucoadhesive, Hydrodynamically balanced and Transdermal Systems.

UNIT II

Physics of tablet compression: Basic principles of interactions, compression and consolidation, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, Measurement of compression with strain gauges, compression pressure-QA parameters.

UNIT III

Kinetics and drug stability: Stability calculations, rate equations, complex order kinetics, Factors influencing stability, strategy of stability testing, method of stabilization, method of accelerated stability testing in dosage forms, temperature and humidity control, physical stability testing of pharmaceutical products. Photodecomposition, Method, solid state decomposition.

UNIT IV

Viscoelasticity: Theoretical consideration, instrumentation, rheological properties of disperse systems and semisolids. Oscillatory testing, Creep measurement.

Characterization of API and excipients: Differential Scanning Calorimetry: Principle, thermal transitions, advantages, disadvantages, instrumentation, applications and interpretations

X Ray Diffraction methods: Origin of x-rays, principle, advantages, disadvantages, instrumentation, applications and interpretations.

UNIT V

Dissolution and solubility: Solubility and solubilization of nonelectrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid-state manipulation, Mechanisms of Drug release - dissolution, diffusion (Matrix and Reservoir) and swelling controlled (Peppas Model) and dissolution equipment.

TEXT BOOKS:

1. Physical Pharmacy, 4th Edition by Alfred Martin.
2. Theory and Practice of Tablets – Lachman, Vol. 4.
3. Pharmaceutical Dosage forms – Disperse systems Vol. I & II.

4. Cartenson "Drug Stability, Marcel Decker Solid state properties, Marcel Dekker.
5. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi – 2013.

REFERENCE BOOKS:

1. Dispersive systems I, II, and III.
2. Robinson. Controlled Drug Delivery Systems.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

DRUG REGULATORY AFFAIRS (Professional Elective-I)

Course Objectives: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

Course Outcomes:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authorization application (MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

UNIT I

Drug Regulatory Aspects (India)

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC & BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

UNIT II

Good Manufacturing Practices (GMP)

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety (HVAC, Water Systems, Stores Management, Effluent etc.)
5. Quality Assurance and Quality Control – Basic understanding for in-built quality.

UNIT III

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT IV

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.
 Quality, safety and legislation for cosmetic products and herbal products.

UNIT V

Governing Regulatory Bodies across the globe.

Country Authority Submission

- a. U.S Food & Drug Administration USDMF
- b. Canada Therapeutic Product Directorate DMF
- c. Europe
 - 1) European Medicines Agency (EMA/ National Authorities) EDMF
 - 2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.

3) MHRA – Medicines and Health Care Products Regulatory Agency

- d. Product Filing
- e. Responding Regulatory Deficiencies
- f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

TEXT AND REFERENCE BOOKS

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Text Book of Forensic Pharmacy by C K Kokate, Pharmamed Press
6. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

TOTAL QUALITY MANAGEMENT (Professional Elective - I)

Course Objectives: Total quality management constitutes very useful chapter like –good manufacturing practices, GLP, GCP, ICH etc. Which increases the knowledge of students in various quality control & regulatory aspects.

Course Outcomes: Total quality management helps the students to learn the established regulatory guidelines in GMP, GCP, GLP, USFDA, WHO, ISO etc to become a perfect budding pharmacist. It is very useful to students to acquire vast knowledge regarding the quality control aspects of different regulatory bodies as per their requirements throughout the world.

UNIT - I

Concepts and Philosophy of TQM, GLP, GMP (orange guide).

UNIT – II

Drug regulatory and accrediting agencies of the world (USFDA, TGA, ICH, WHO, ISO etc.)

UNIT - III

Good manufacturing practices: Organization and personnel, responsibilities, training, hygiene. Premises: Location, design, plant layout, construction, maintenance and sanitation, environmental control, utilities and services like gas, water, maintenance of sterile areas, control of contamination. Equipments: Selection, purchase specifications, maintenance, clean-in-place, sterilize-in-place, methods (TP and STP). Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls on raw materials and finished dosage forms. Manufacture of and controls on dosage forms: Manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities. In process quality controls on various dosage forms; sterile and non–sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc., Packaging and labelling control, line clearance, reconciliation of labels, cartons and other packaging materials. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls instruments, reagents, sampling plans, standard test procedures, protocols, non-clinical testing, controls on animal house. Data generation and storage, quality control documents, retention samples, records and audits of quality control facilities. Finished products release, quality review, quality audits, batch release document.

UNIT - IV

Regulatory Considerations for Pre-clinical and Clinical Evaluation: Pre-clinical requirements currently in use. Regulatory requirements of single dose and repeat dose toxicity studies. Study of specific toxicities such as mutagenicity, carcinogenicity and teratogenicity. Animal pharmacokinetics and toxicokinetics. Regulatory requirements of clinical evaluation, pharmacokinetics in man genetic polymorphism. Design and interpretation of clinical trials. Quality assurance standards as per ISO.

UNIT - V

Globalization of drug industry, present status and scope of pharmaceutical industry in India. WHO and NABL certification, ICH guidelines for manufacturing and quality assurance of drug formulation.

TEXT AND REFERENCE BOOKS:

1. Guidelines for Developing National Drug Policies; WHO Publications, 1998.

2. Quality Assurance of Pharmaceuticals—A Compendium of Guidelines and Related Materials, Vol.–1; WHO Publications.
3. A Guide to Total Quality Management by Kaushik Maitra and Sedhan K. Ghosh.
4. GMP by Mehra.
5. How to Practice GMP by P.P. Sharma.
6. ISO 9000 and Total Quality Management by Sadhan K. Ghosh.
7. Good Manufacturing Practices for Pharmaceuticals-A Plan for Total Quality Control by Sidney H. Willing & James R Stoker. (Drugs & Pharm. Sciences) Vol. 78; Marcel Dekker Inc.
8. OPPI-Quality Assurance, USP.
9. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
10. Quality assurance and quality management in pharmaceutical industry by Y. Anjaneyulu and marayya
11. Total Quality Management, An integrated Approach by D. R. Kiran, BS Publications
12. Total Quality Management, 3rd edition by Joel E. Ross. CRC press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

COSMETICS AND COSMECEUTICALS (Professional Elective - II)

Course Objectives: Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Course Outcomes: Upon completion of the subject student shall able to know Regulatory biological aspects of cosmetics, excipients used for various formulations, designing of cosmeceuticals and herbal products

UNIT I

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

UNIT II

Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

UNIT III

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT IV

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

UNIT V

Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCE BOOKS:

1. Harry's Cosmeticology. 8th edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, P. P. Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O. Barel, M. Paye and H.I. Maibach. 3rd edition
5. Cosmeceuticals by Y Madhusudan Rao, Pharmamed Press
6. Cosmetics for the Skin: Physiological and Pharmaceutical Approach by A. K. Mohiuddin, Pharmamed Press.
7. Cosmetic and Toiletries recent suppliers' catalogue.
8. CTFA directory.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

PHARMACEUTICAL VALIDATION (Professional Elective - II)

Course Objective: The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

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

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments

UNIT I

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status -Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipments.

UNIT II

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC

Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT III

Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus.

Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

UNIT IV

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place (CIP).

UNIT V

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

- Validate the manufacturing facilities

REFERENCE BOOKS:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).

5. Michael Levin, Pharmaceutical Process Scale-Up, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Pharmaceutical Facilities: Design, Layouts and Validation, 2nd Ed, Potdar, Pharmamed Press.
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective - II)

Course Objectives: These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation.

Course Outcomes: The students should describe the evaluation of stability of solutions, solids and formulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

UNIT - I

Drug decomposition mechanisms:

1. Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of Pharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

UNIT - II

Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of solid-state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

Physical stability testing of dosage forms:

1. Solids – tablets, capsules, powder and granules
2. Disperse systems
3. Microbial decomposition
4. Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT - III

Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Factors affecting extraction of drugs.

UNIT - IV

General method of analysis to determine the quality of raw materials used in cosmetic industry. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

UNIT - V

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.

Stability studies: Concept of stability studies.

- a) cGMP & ICH guidelines for Accelerated stability Testing.
- b) Interaction of containers & closure Compatibility Testing.

REFERENCE BOOKS:

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnsen – 2004.
2. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition. 3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogel's Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
3. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
4. J. B. Wilkinson and R. J. Moore, Herry's Cosmeticology; Longman Scientific and Technical Publishers, Singapore.
5. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
6. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
8. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
9. Drug stability: Principles and practices by Jens T. Carstensen
10. Stability Testing of Drug Products by W. Grimm.
11. Stability of Drugs and Dosage Forms by Yoshioka and Stella.,BSP Books

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

RESEARCH METHODOLOGY AND IPR

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes: At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

UNIT - I:

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

UNIT - II:

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT - III:

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT - IV:

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT-V:

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

TEXT BOOKS:

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"
3. Pharmaceutical Research Methodology and BioStatistics, B Subba Rao, Pharmamed Press
4. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press

REFERENCE BOOKS:

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
5. Asimov, "Introduction to Design", Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in New Technological Age", 2016.
7. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICS – I LAB (Laboratory - I)

List of Experiments:

1. To carry out the preformulation studies of solid dosage forms.
2. To study the effect of compressional force on tablet disintegration time
3. To study the micromeritic properties of powders and granules
4. To study the effect of particle size on dissolution of capsules.
5. To study the effect of binders on dissolution of tablets
6. To study enteric coated tablets dissolution in relevant pH.
7. Accelerated stability testing of different tablets
8. Determination of first order, second order rate constants by acid and alkaline hydrolysis
9. Preparation and evaluation of beta cyclodextrin complexes of new drugs
10. Preparation of paracetamol tablets and comparison with marketed products
11. Design of experiments (DOE) in the optimization of an immediate release tablets.
12. Calculation of shelf life using accelerated stability data,

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS LAB (Laboratory- II)

List of Experiments:

1. Analysis of dissolution by various data-kinetic modelling.
2. Calibration curve of different API's by UV/HPLC/HPTLC
3. Dissolution of immediate release, sustained release and delayed release.
4. Evaluation of drug-protein binding analysis
5. Assignment of numerical problems, one compartment and two compartment disposition, method of residuals, AUC and evaluation of pharmacokinetic parameters.
6. Calculation of K_a (absorption rate constant) absorption curve- Wagner nelson method , Loo-Riegel method.
7. Calculation of pharmacokinetics parameters of one compartment oral data and two compartment IV data.
8. Construction of IVIVC from the data
9. Calculation of Urinary Pharmacokinetics
10. Calculation of Bioavailability and Bioequivalence Studies
11. Permeation studies of Franz diffusion cell
12. Drug Release from semisolids by Agargel method or Franz diffusion cell.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICS - II (Professional Core - III)

Course Objective: The students shall understand about the pilot plant and their scale up techniques for manufacturing of tablets capsules, suspensions, emulsions and semisolids. The students also learn the filling of capsules, compression machines, sterilizers for formulation of parenterals and also understand the properties of propellants, DPI, MDI and their quality control. The students also understand about the cosmetics and nutraceuticals.

Course Outcomes: students will understand the planning of pilot plant techniques used for all pharmaceutical dosage forms such as tablets, capsules, parenterals, aerosols, cosmetics and nutraceuticals.

UNIT I

Pilot plant scale-up techniques used in pharmaceutical manufacturing

a. Pilot plant: Technology transfer from R&D to pilot plant to pilot scale considerations of steps involved with manufacture, layout design, facility, equipment selection of tablets, capsules, suspensions, emulsions & semisolids.

b. Scale up: Importance, Scale up process-size reduction, mixing, blending, granulation, compression, coating involved in tablets, capsules & liquid-liquid mixing.

UNIT II

Formulation development of parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilization methods (Moist heat, dry heat, filtration, radiation, gaseous sterilization), product layout.

UNIT III

Pharmaceutical Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosols formulation, manufacture and quality control.

UNIT IV

a. Cosmetics: Formulation approaches, preparation & method of manufacturing labelling & Q.C. of anti-ageing products, sun screen lotion and fairness creams.

b. Nutraceuticals:

1. Introduction, source, manufacture and analysis of glucosamine & cartinine.
2. Monographs: General and specific properties of glucosamine & cartinine.
3. A brief overview of role of nutraceuticals in cancer prevention & cardio vascular disorders.

UNIT V

Aseptic processing operation

a. Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

b. Air handling systems: Study of AHUs, humidity & temperature control.

TEXT BOOKS:

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
3. Remington's Science and Practice of Pharmacy by A. Gennaro.

4. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr.
5. Nicholas G. Popovich, Howard C. Ansel.
6. Pharmaceutical Dosage forms - Parenterals (Vol I, II and III) by Avis, Lieberman and Lachman.
7. Scale up techniques – Pharmaceutical process by Michael Levin, Marcel Dekker

REFERENCE BOOKS:

1. Bentley's Text Book of Pharmaceutics by EA Rawlins.
2. Generic Drug Product Development by Leon Shargel.
3. Dispensing for Pharmaceutical Students by SJ Carter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
5. Nutraceuticals, 2nd edition by Brian lock wood.
6. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

ADVANCED DRUG DELIVERY SYSTEMS (Professional Core - IV)

Course Objectives: The students shall apply the pharmacokinetic and pharmacodynamic principles in the design of CDDS. They also apply the design, evaluation and applications related to oral, parenteral, transdermal, implants, bioadhesives and targeted drug delivery systems.

Course Outcomes: Students will select the drugs for CDDS design of the formulation fabrication of systems of above drug delivery systems with relevant applications.

UNIT I

Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems

- a. Controlled release oral drug delivery systems
- b. Parenteral controlled release drug delivery systems

UNIT II

Design, fabrication, evaluation and applications of the following

- a. Implantable Therapeutic systems
- b. Transdermal delivery systems
- c. Ocular and Intrauterine delivery systems
- d. Vaccine delivery: Delivery systems used to promote uptake, absorption enhancers, oral immunization, controlled release microparticles for vaccine development

UNIT III

Biochemical and molecular biology approaches for drug delivery using following technologies

- a. Bioadhesive drug delivery systems
- b. Nasal drug delivery systems
- c. Drug delivery to Colon

UNIT IV

Biochemical and molecular biology approaches to control drug delivery of

- a. Liposomes
- b. Niosomes
- c. Microspheres
- d. Nanoparticles
- e. Resealed erythrocytes

UNIT - V

Drug targeting to particular organs

- a. Delivery to lungs
- b. Delivery to the brain and problems involved
- c. Drug targeting in neoplasms

TEXT BOOKS:

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel Drug Delivery Systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.

5. Advances in Drug Delivery, 4 Vol. set, Rao Madhusudan Y, Pharmamed Press
6. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
7. Oral Drug Delivery Technology, 2nded, by Aukunuru Jithan

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

INDUSTRIAL PHARMACY (Professional Elective - III)

Course Objectives: The students shall learn the theory of unit operations, machinery, materials of constructions, qualification of equipments and its utility. The students shall also understand about the objectives and principles of GMP, TQM and effluent analysis and specifications. They also understand the regulatory basis for the validation of analytical methods related to solids, sterile and liquid dosage forms

Course Outcome: The students will explain the machinery involved in milling, mixing, filtration, drying and packing material constructions used in the production of pharmaceutical materials. They also learn salient features of GMP, TQM applicable in industry. They also understand the effluent treatments and prevent the pollution. They also should evaluate the validation of analytical methods and processes

UNIT I

Pharmaceutical unit operations: A detailed study involving machinery and theory of Pharmaceutical unit operations like milling, mixing, filtration, granulation, drying and blending.

UNIT II

- a. Materials of construction of pharmaceutical equipment and packaging materials: Study of the principles, production techniques in the large scale production of tablets, capsules, suspensions, liquid pharmaceuticals, ophthalmic products and sterile products.
- b. Qualification of equipment (IQ, OQ, PQ)

UNIT III

Production management: Production organization, objectives and policies of good manufacturing practices, layout of buildings, services, equipments and their maintenance, material management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Total Quality Management (TQM)

UNIT IV

Effluent Testing and Treatment: Effluent analysis, specifications and preventive measures water of pollution, solid pollution, air pollution and sound pollution.

UNIT V

Validation: Regulatory basis, validation process for solid dosage forms, sterile products, and liquid dosage forms.

TEXT BOOKS:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Good Manufacturing Practice for Pharmaceuticals by Sidney H. Willig.
3. Pharmaceutical Process validation by Robert A. Nash, Alfred H. Wachter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
5. Pharmaceutical production management, C.V.S. Subrahmanyam, Vallabh Prakash.
6. Industrial Pharmacy: A Comprehensive Approach, D K Tripathi, Pharmamed Press.

REFERENCE BOOKS:

1. Unit operations of Chemical Engineering by Warren L. McCabe, Julian C. Smith, Peter Harriott.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Bentley's Text book of Pharmaceutics by EA Rawlins.
4. CGMP, H.P.P. Sharma

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

HERBAL COSMETICS (Professional Elective - III)

Course Objective: The topics helps the students to get exposed to processes involved in the manufacturing of herbal cosmetics including the skin and hair care herbal products preparation and their evaluation.

Course Outcome: Students will learn about the raw materials used in herbal cosmetics and get exposed to various preparations of herbal cosmetics.

UNIT - I

Introduction: Herbal/ natural cosmetics, Classification & Economic aspects.

Regulatory Provisions relation to manufacture of cosmetics: -

License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.

UNIT - II

- a) Commonly used herbal cosmetics raw materials –water, preservatives, surfactants, oils /waxes, colors, and some functional herbs
- b) Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Molding, Packing.
- c) General principles of quality control of herbal cosmetics

UNIT - III

Skin care Products: Physiology and chemistry of skin, Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Creams, Lotions, Lipsticks, Face packs. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT - IV

Hair care Products: Hair structure and its chemistry

Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Hair dyes, Creams, Oils and Shampoos. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT - V

Herbs in cosmetics:

A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as Acacia concinna pods, Aloe Vera, Almond oil, Neem, Citrus aurantium peels, Henna, Turmeric, Liquorices, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

REFERENCE BOOKS:

1. Cosmetics- Formulation, Manufacturing and Quality control –P.P. Sharma
2. Herbal Cosmetics Hand Book- H. Panda
3. Herbal Cosmetics by P.K Chattopadhyay
4. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

PHARMACEUTICAL MANAGEMENT (Professional Elective - III)

Course Objective: The topics which are present in the pharmaceutical management are very much useful to the students in personality development become a perfect pharma professional.

Course Outcomes:

- These topics are useful for the students to know how to manage a pharma industry and its various departments viz QA, QC, RA, Production etc.
- Along with this it aids the students to develop leadership qualities, communication & interpersonal skills, decisions making, motivation, organization & various managerial functions & professional skills required for a dynamic professional.
- Management helps to understand the concept of managerial control, its levels & role, importance in pharma industry

UNIT I

Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling—a preliminary idea of concepts, processes and techniques.

UNIT II

Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, accounting, auditing, and budgetary control. Entrepreneurship development.

UNIT III

Understanding organizations: Meaning, process, types of organization structures and departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labsetc.

UNIT IV

Professional Managers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.

Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.

UNIT V

Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

TEXT AND REFERENCE BOOKS:

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo.
3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.

4. Modern Management by Hempran David R.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi
8. Organization Structure, Process and out comes Vth Edition Richard. H. Hall
9. Principles and Methods of Pharmacy Management 3rd Edition Harry A. Smith.
10. Management "Global Perspective Heinz Weihrich, Harold Koontz by Tata McGraw Hill".
11. Personnel Management and Industrial Relations by P. C. Tripathi.
12. Pharmaceutical Industrial Management by G. Vidya Sagar, Pharmamed Press.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

NANO BASED DRUG DELIVERY SYSTEMS (Professional Elective - IV)

Course Objective - To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, 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 and classification of nanomaterials
- d. Role of size and size distribution of nanoparticles properties.
- e. Marketed formulations based on nanotechnology and science behind them

UNIT - II – Synthesis of Nanomaterials

Physical, chemical and biological Methods

Methods for synthesis of

- Gold nanoparticles
- Magnetic nanoparticles
- Polymeric nanoparticles
- Self – assembly structures such as liposomes, Niosomes, transferosomes, micelles, aquasomes and nanoemulsions

UNIT - III - Biomedical applications of Nanotechnology

- a. Nanotechnology products used for in vitro diagnostics
- b. Improvements to medical or molecular imaging using nanotechnology
- c. Targeted nanomaterials for diagnostic and therapeutic purpose

UNIT - IV

Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

UNIT - V

Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

TEXT AND REFERENCE BOOKS:

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: Nanoplatfroms in Drug Delivery, Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanoscience 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. Kulkarni, Springer (2007)

5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press (2004)
6. Nano-Carrier Systems Theories, Methods & Applications, Amit K. Goyal, Goutam Rath, Pharmamed Press.
7. Nano chemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)
8. Nanocomposite science and technology, pulickel M. Ajayan, Linda S. Schadler, paul V. Braun, Wiley - VCH Verlag, Weiheim (2003)
9. Nanoscale materials in chemistry, Edited by Kenneth J. Klabunde, John Wiley & Sons, 2009
10. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
11. Introduction to Nano Science and Technologies, AnkaneyuluYerramilli, BS Publications. 2016

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

NUTRACEUTICALS (Professional Elective - IV)

Course Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations.

Course Outcomes: Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals

UNIT I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.

b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:

Spirulina, Soya bean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

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

- a) Carotenoids- α and β -Carotene, Lycopene, Xanthophylls, lutein
- b) Sulfides: Diallylsulfides, Allyltrisulfide.
- c) Polyphenolics: Resveratrol
- d) Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones
- e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lactobacillum
- f) Phytoestrogens: Isoflavones, daidzein, Geestrogen, lignans
- g) Tocopherols

UNIT III

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

b. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.

b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α -Lipoic acid, melatonin

Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

REFERENCE BOOKS:

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

CLINICAL RESEARCH AND PHARMACOVIGILANCE (Professional Elective - IV)

Course Objectives: This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post market surveillance.

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

- explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in pharmacovigilance

UNIT I

Regulatory Perspectives of Clinical Trials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

UNIT II

Clinical Trials: Types and Design:

Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

UNIT III

Clinical Trial Documentation:

Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

UNIT IV

Basic aspects, terminologies and establishment of pharmacovigilance:

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring Program, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and National Programs related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

UNIT V**Methods, ADR reporting and tools used in pharmacovigilance:**

International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

REFERENCE BOOKS:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary, Pharmamed Press.
7. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Textbook of Pharmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
10. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICS – II LAB (Laboratory- III)

List of Experiments:

1. Scale up calculations from R&D to pilot plant for the following unit operations
 - a) Wet granulations using RMG/PLM
 - b) Blending & Lubrications
 - c) Film coating
2. Preparation of Injectables, Ampoules & Vials
3. Preparation of Ophthalmic products, Eye drops and Eye ointments
4. Preparation of Dry powder Inhalations
5. Formulation Development and Demonstration of function of DPI of marketed products
6. Formulation of Aerosol Demonstration of marketed products

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

ADVANCED DRUG DELIVERY SYSTEMS LAB (Laboratory- IV)

List of Experiments:

1. Study on diffusion of drugs through various polymeric membranes (2 experiments)
2. Formulation and Evaluation of sustained release Oral Matrix Tablet (2 experiments)
3. Formulation and Evaluation of sustained release Oral Reservoir System (2 experiments)
4. Formulation and Evaluation of Microspheres / Microencapsules (2 experiments)
5. Study of in-vitro Dissolution of various SR products in market (2 experiments)
6. Formulation and Evaluation of Transdermal Films (2 experiments)
7. Formulation and Evaluation of Mucoadhesive System (2 experiments)
8. Preparation and Evaluation of Enteric Coated Pellets / Tablets (2 experiments)
9. Preparation and Evaluation of Liposomes, Niosomes and Nanoparticles

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)

BIOSTATISTICS (Professional Elective - V)

Course Objectives: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data.

Course Outcomes: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data.

UNIT I

Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement and presentation, formation of table and charts.

UNIT II

Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.

Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III

Measures of Correlation and Regression

Probability rules: Binomial, Poisson and Normal distribution.

UNIT IV

Experimental designing, planning of an experiment, replication and randomization.

Analysis of Variance (ANOVA): 1-way, 2- Way

UNIT V

Hypothesis testing: Student 't' test, Chi square test,

Non- Parametric Tests: Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

REFERENCE BOOKS:

1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
4. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
5. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
6. A Textbook of Research Methodologies and Biostatistics for Pharmacy Students, KPR Chowdary, Pharmamed Press.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)
SCALE UP AND TECHNOLOGY TRANSFER (Professional Elective - V)

Course Objectives: This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Course Outcomes: On completion of this course it is expected that students will be able to;

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards

UNIT I

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenteral and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenteral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

UNIT II

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vendor qualification.

UNIT III

Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.

UNIT IV

Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

UNIT V

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

REFERENCE BOOKS:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T. Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L. Lachman, H.A. Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiley.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.\
10. Pharmaceutical Process Scale-up 2nd Ed. Levin Michael, CRC press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)
PRODUCTION AREA DESIGN & PACKAGING DEVELOPMENT
(Professional Elective - V)

Course Objectives: The student shall learn about Industrial area design, Current good manufacturing practices. They also learn about packaging components, polymers and metals used in packaging. They also understand about the storage conditions of different formulations and their stability evaluations.

Course Outcomes: At the end of the semester student will get an idea about Industrial area design and packaging of different formulations and its stability conditions.

UNIT I

Production Area Design: Selection of plant location, Design of plant for bulk drugs and formulations (Solids, Semisolids, Injectables, Nutraceuticals etc.), General utilities such as purified water, portable water, water for injection, Air handling units-Relative humidity and Temperature control, Material and personnel movement. Warehouse handling-API, Excipients, packaging materials and solvents.

UNIT II

Current Good Manufacturing Practices: GMP design for buildings & facilities. GMP layout design. Clean room classifications. Segregation & cross contamination control. HVAC (heating, ventilation & air-conditioning) systems. Clean room environment control. Documentation and record keeping: Specifications and testing procedures, Specifications for finished products, Master Formulae, Packaging instructions. Batch processing records, Standard operating procedures.

UNIT III

Pharmaceutical packaging and Design: Introduction, Packaging system, Components of packaging, Symbols used on packages and labels. Package development and Design research. Packaging materials- Polymers and Plasters, Glass, Metal and Blister and strip packaging.

UNIT IV

Stability of Packaging: Introduction, Legislation, Regulation, Pharmaceutical Stability Testing in Climatic Cabinets, Pharmaceutical Stability Testing Conditions, Photo-Stability Testing, Review of Pharmaceutical Product Stability, Packaging and the ICH Guidelines.

UNIT V

Packaging of Solids, Semisolids, Parenterals, Ophthalmic and Aerosols: Introduction, Packaging of Solid and semisolids, Packaging of Sterile Pharmaceuticals, Packaging Components, Inspection of Filled Injectable Products, Storage and Labelling, Packaging of Ophthalmics, Selection of Packaging Materials, Packaging of Aerosols.

REFERENCE BOOKS:

1. Leon Lachman; Lieberman Herbert A.; Kanig, Joseph L. The theory and Practice of Industrial Pharmacy.
2. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
3. Aulton's Pharmaceutics: The design and Manufacture of Medicine
4. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis.
5. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester, New
6. Pharmaceutical Facilities: Design, Layouts and Validation, Potdar, Pharmamed Press
7. Wilmer A. Jenkins, Kenton R. Osborn. Packaging drugs and pharmaceuticals.
8. Remington: The Science and Practice of Pharmacy. 8. Michael E. Aulton, Kevin Tylor
9. Pharmaceutical Packaging Technology, UK jain, Pharmamed Press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)

Prerequisite: None

Course objectives: Students will be able to:

- Understand that how to improve your writing skills and level of readability
- Learn about what to write in each section
- Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission

UNIT-I:

Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

UNIT-II:

Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts. Introduction

UNIT-III:

Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

UNIT-IV:

key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature,

UNIT-V:

skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions. useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

TEXT BOOKS/ REFERENCES:

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman's book.
4. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

DISASTER MANAGEMENT (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- critically understand the strengths and weaknesses of disaster management approaches,
- planning and programming in different countries, particularly their home country or the countries they work in

UNIT-I:

Introduction:

Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.

Disaster Prone Areas in India:

Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

UNIT-II:

Repercussions of Disasters and Hazards:

Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT-III:

Disaster Preparedness and Management:

Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT-IV:

Risk Assessment Disaster Risk:

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT-V:

Disaster Mitigation:

Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

TEXT BOOKS/ REFERENCES:

1. R. Nishith, Singh AK, "Disaster Management in India: Perspectives, issues and strategies "New Royal book Company.
2. Sahni, Pardeep Et. Al. (Eds.), " Disaster Mitigation Experiences and Reflections", Prentice Hall of India, New Delhi.
3. Goel S. L., Disaster Administration and Management Text and Case Studies", Deep &Deep Publication Pvt. Ltd., New Delhi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature

Course Outcomes: Students will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science & technology can be understood
- Being a logical language will help to develop logic in students

UNIT-I:

Alphabets in Sanskrit,

UNIT-II:

Past/Present/Future Tense, Simple Sentences

UNIT-III:

Order, Introduction of roots,

UNIT-IV:

Technical information about Sanskrit Literature

UNIT-V:

Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

TEXT BOOKS/ REFERENCES:

1. "Abhyaspustakam" – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. "Teach Yourself Sanskrit" Prathama Deeksha-Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. "India's Glorious Scientific Tradition" Suresh Soni, Ocean books (P) Ltd., New Delhi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

VALUE EDUCATION (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

Course outcomes: Students will be able to

- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

UNIT-I:

Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

UNIT-II:

Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

UNIT-III:

Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity and discipline, Punctuality, Love and Kindness.

UNIT-IV:

Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

UNIT-V:

Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively

TEXT BOOKS/ REFERENCES:

1. Chakroborty, S.K. "Values and Ethics for organizations Theory and practice", Oxford University Press, New Delhi

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

CONSTITUTION OF INDIA (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals' constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

Course Outcomes: Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

UNIT-I:

History of Making of the Indian Constitution: History Drafting Committee, (Composition & Working), **Philosophy of the Indian Constitution:** Preamble, Salient Features.

UNIT-II:

Contours of Constitutional Rights & Duties: Fundamental Rights Right to Equality, Right to Freedom, Right against Exploitation, Right to Freedom of Religion, Cultural and Educational Rights, Right to Constitutional Remedies, Directive Principles of State Policy, Fundamental Duties.

UNIT-III:

Organs of Governance: Parliament, Composition, Qualifications and Disqualifications, Powers and Functions, Executive, President, Governor, Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualification, Powers and Functions.

UNIT-IV:

Local Administration: District's Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. Pachayati raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy (Different departments), Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

UNIT-V:

Election Commission: Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

TEXT BOOKS/ REFERENCES:

1. The Constitution of India, 1950 (Bare Act), Government Publication.
2. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
3. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

PEDAGOGY STUDIES (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Review existing evidence on the review topic to inform programme design and policy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes: Students will be able to understand:

- What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

UNIT-I:

Introduction and Methodology: Aims and rationale, Policy background, Conceptual framework and terminology Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions. Overview of methodology and Searching.

UNIT-II:

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT-III:

Evidence on the effectiveness of pedagogical practices, Methodology for the indepth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT-IV:

Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class sizes

UNIT-V:

Research gaps and future directions: Research design, Contexts, Pedagogy, Teacher education, Curriculum and assessment, Dissemination and research impact.

TEXT BOOKS/ REFERENCES:

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
3. Akyeampong K (2003) Teacher training in Ghana - does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.

4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? *International Journal Educational Development*, 33 (3): 272–282.
5. Alexander RJ (2001) *Culture and pedagogy: International comparisons in primary education*. Oxford and Boston: Blackwell.
6. Chavan M (2003) *Read India: A mass scale, rapid, 'learning to read' campaign*.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

STRESS MANAGEMENT BY YOGA (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To achieve overall health of body and mind
- To overcome stress

Course Outcomes: Students will be able to:

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

UNIT-I:

Definitions of Eight parts of yog. (Ashtanga)

UNIT-II:

Yam and Niyam.

UNIT-III:

Do's and Don't's in life.

- i) Ahinsa, satya, astheya, bramhacharya and aparigraha
- ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

UNIT-IV:

Asan and Pranayam

UNIT-V:

- i) Various yog poses and their benefits for mind & body
- ii) Regularization of breathing techniques and its effects-Types of pranayam

TEXT BOOKS/ REFERENCES:

1. 'Yogic Asanas for Group Training-Part-I': Janardan Swami Yogabhyasi Mandal, Nagpur
2. "Rajayoga or conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS
(Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes: Students will be able to

- Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life
- The person who has studied Geeta will lead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

UNIT-I:

Neetisatakam-Holistic development of personality

- Verses- 19,20,21,22 (wisdom)
- Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)

UNIT-II:

Neetisatakam-Holistic development of personality

- Verses- 52,53,59 (don't's)
- Verses- 71,73,75,78 (do's)

UNIT-III:

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

UNIT-IV:

Statements of basic knowledge.

- Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

UNIT-V:

- Chapter2-Verses 17, Chapter 3-Verses 36,37,42,
- Chapter 4-Verses 18, 38,39
- Chapter18 – Verses 37,38,63

TEXT BOOKS/ REFERENCES:

1. "Srimad Bhagavad Gita" by Swami Swarupananda Advaita Ashram (Publication Department), Kolkata.
2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P. Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.PHARMACY (PHARMACEUTICAL ANALYSIS)
R22 COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2022-23 Admitted Batch

I YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Modern Pharmaceutical Analytical Techniques	3	1	0	4
Professional Core-II	Pharmaceutical Food Analysis	3	1	0	4
Professional Elective-I	1. Advanced Pharmaceutical Analysis 2. Drug Regulatory Affairs 3. Phytochemistry	3	1	0	4
Professional Elective-II	1. Pharmaceutical Validation 2. Cosmetics and Cosmeceuticals 3. Stability of Drugs and Dosage forms	3	1	0	4
	Research Methodology & IPR	2	0	0	2
Laboratory-I	Modern Pharmaceutical Analytical Techniques lab	0	0	6	3
Laboratory-II	Pharmaceutical food Analysis Lab	0	0	6	3
Audit - II	Audit course- I	2	0	0	0
	Seminar & Assignment	0	0	4	2
	TOTAL	16	4	16	26

I YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Advanced Instrumental Analysis - I	3	1	0	4
Professional Core-IV	Pharmaceutical Quality Control & Quality Assurance	3	1	0	4
Professional Elective-III	1. Modern Bio-analytical Techniques 2. Herbal Cosmetics 3. Pharmacoepidemiology & Pharmacoeconomics	3	1	0	4
Professional Elective-IV	1. Advanced Instrumental Analysis - II 2. Nutraceuticals 3. Clinical Research and Pharmacovigilance	3	1	0	4
Laboratory- III	Advanced Instrumental Analysis I Lab	0	0	6	3
Laboratory- IV	Pharmaceutical Quality Control & Quality Assurance Lab	0	0	6	3
	Mini project	2	0	0	2
Audit - II	Audit Course - II	2	0	0	0
	Seminar & Assignment	0	0	4	2
	Total	16	4	16	26

II YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Elective-V	1. Biostatistics 2. Scale up and Technology Transfer 3. Production Area Design and Packaging Development	3	1	0	4
Open Elective	Open Elective	3	1	0	4
Dissertation	Comprehensive Viva Voce	0	0	8	4
	Dissertation Work Review - II	0	0	24	12
	Total	6	2	32	24

II YEAR II SEMESTER

Course Code	Course Title	L	T	P	Credits
Dissertation	Dissertation Work Review - III	0	0	24	12
Dissertation	Dissertation Viva-Voce	0	0	20	10
	Total	0	0	44	22

***For Dissertation Work Review - I, Please refer R22 Academic Regulations.**

Audit Courses I&II:

1. English for Research Paper Writing
2. Disaster Management
3. Sanskrit for Technological Learning
4. Value Education
5. Constitution of India
6. Pedagogy Studies
7. Stress Management by Yoga
8. Personality Development through Life Enlightenment Skills

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Professional Core - I)

Course Objective: The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, Mass, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

Course Outcome: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.

UNIT I

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation

- a. **Column Chromatography:** Adsorption and partition, theory, preparation, procedure and methods of detection
- b. **Thin Layer Chromatography:** Theory, preparation, procedures, detection of compounds
- c. **Paper Chromatography:** Theory, different techniques employed, filter papers used, qualitative and quantitative detection

UNIT II

- a. **Gas chromatography:** Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, derivatization.
- b. **HPLC:** Basic parameters, Principles and instrumentation, solvents and columns used, Operational modes, detection and applications of HPLC
- c. **HPTLC:** Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III

- a. **UV-Visible spectroscopy:** Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy
- b. **IR spectroscopy:** Basic principles -Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

UNIT IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, **interpretation of spectra** and applications for identification and structure determination.

UNIT V

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect (NOE), ¹³CNMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy.

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
5. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
6. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
7. Organic Chemistry by I. L. Finar
8. Organic spectroscopy by William Kemp
9. Quantitative Analysis of Drugs by D. C. Garrett
10. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
11. Spectrophotometric identification of Organic Compounds by Silverstein
12. HPTLC by P.D. Seth
13. Indian Pharmacopoeia 2007
14. High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
15. Introduction to instrumental analysis by Robert. D. Braun

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
PHARMACEUTICAL FOOD ANALYSIS (Professional Core – II)

Course Objective: This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Course Outcome: At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- Pharmaceuticals (API & Dosage forms)
- And also student shall have the knowledge on food regulations and legislations

UNIT I

- a. **Carbohydrates:** Classification and properties of food carbohydrates, General methods of analysis of food carbohydrates
- b. **Proteins:** Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids

UNIT II

Probiotics: Definition, history, importance, mode of action, identification advantages and disadvantages of probiotics. Applications of Probiotics

UNIT III

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils.

UNIT IV

Vitamins: Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series

UNIT V

- a. **General Analytical methods** for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.
- b. **Analysis of fermentation products** like wine, spirits, beer and vinegar.

TEXT BOOKS:

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International
6. 18th edition, 2005. Theory and Practice of Industrial Pharmacy by Lieberman and Lachman

REFERENCES:

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. Food Chemistry and Nutrition: A Comprehensive Treatise, Sumathi S, Pharmamed Press.
3. David Pearson, The Chemical Analysis of Foods, 7th edn, Churchill Livingstone, Edinburgh.
4. Nielsen S. Introduction to chemical analysis of foods. Jones & Bartlett Publishers, Boston, 1974
5. Indian Pharmacopoeia 2012

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
ADVANCED PHARMACEUTICAL ANALYSIS (Professional Elective - I)

Course Objective: The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to different categories are discussed in detail. The applications of the important reagents like MBTH, FC, PDAB etc. in the determination of the pharmaceuticals are also discussed.

Course Outcome: The quantitative determination of various organic compounds is clearly understood. The spectral analysis, dissolution parameters and microbial assays are also learned.

UNIT I

Principles and procedures involved in the determination of the official compounds in IP with the following analytical techniques

- | | |
|------------------------|--------------------------|
| A. Non-aqueous | C. Complexometric |
| B. Oxidation-reduction | D. Diazotization methods |
| E. Neutralization | F. Acid – Base |

UNIT II

A detailed study of the principles and procedures involved in the quantitative determination of the following organic functional groups

- | | |
|----------------|-------------------------|
| A. Amines | C. Carbonyl compounds |
| B. Esters | D. Hydroxy and carboxyl |
| E. Amino Acids | |

UNIT III

- a. **Reference Standards:** Types, preparation methods and uses.
- b. Principles and procedures involved in using the following reagents in the determination of pharmaceutical dosage forms official in IP
 - a. MBTH (3-methyl-2-benzothiazolone hydrazone)
 - b. F.C. Reagent (Folin-Ciocalteu)
 - c. PDAB (*para*-Dimethyl Amino Benzaldehyde)
 - d. 2, 3, 5 - *tri*Phenyltetrazolium salt
 - e. 2,6 *di* -ChloroquinoneChlorimide
 - f. *N* - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent)
 - g. Carr – Price Reagent
 - h. 2,4 - DNP

UNIT IV

- a. **Analysis of Excipients:** Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), loss on drying, ash content, conductivity.
- b. **Excipients of interest:** Disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

UNIT V

- a. **Dissolution Tests:** Types of Dissolution apparatus, dissolution test requirements for immediate release, delayed release, extended release dosage forms, coated, uncoated, enteric coated, gelatin capsules etc.
- b. **Microbiological assays and Biological tests:** Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

TEXT BOOKS:

1. Pharmaceutical Chemistry by Becket and Stanlake
2. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3. Instrumental Methods of Chemical Analysis By B.K. Sharma
4. A Text Book of Pharmaceutical Analysis by Kennenth A. Connors
5. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
6. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
7. Fundamentals of Analytical Chemistry, DK Sarkar, Pharmamed Press

REFERENCES:

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
3. Indian Pharmacopoeia 2010
4. Journals (Indian Drugs, IJPS etc.)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
DRUG REGULATORY AFFAIRS (Professional Elective - I)

Course Objective: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

Course Outcome:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authorization application (MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

UNIT I

Drug Regulatory Aspects (India)

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC & BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

UNIT II

Good Manufacturing Practices (GMP)

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety (HVAC, Water Systems, Stores Management, Effluent etc.)
5. Quality Assurance and Quality Control – Basic understanding for in-built quality.

UNIT III

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT IV

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.
Quality, safety and legislation for cosmetic products and herbal products.

UNIT V

Governing Regulatory Bodies across the globe.

Country Authority Submission

- a. U.S Food & Drug Administration USDMF
- b. Canada Therapeutic Product Directorate DMF
- c. Europe
 - 1) European Medicines Agency (EMA/ National Authorities) EDMF
 - 2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.
 - 3) MHRA – Medicines and Health Care Products Regulatory Agency

- d. Product Filing
- e. Responding Regulatory Deficiencies
- f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

TEXT AND REFERENCE BOOKS:

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
PHYTOCHEMISTRY (Professional Elective - I)

Course Objective: Helps the students to get exposed to natural product drug discovery and to perform quantitative and qualitative evaluation of herbal extracts. To understand the chemistry of important phytoconstituents of different categories.

Course Outcome: On the basis of chemistry data of phytoconstituents students will acquire knowledge on various types of phytoconstituents present in the plants.

UNIT I

Biosynthetic pathways and Radio tracing techniques: containing drugs:

- a) Methods of Biogenetic Investigations, detailed study of isotropic tracer techniques.
- b) Study of Biosynthetic pathways of following phyto-pharmaceuticals: Atropine, Morphine, Cardiac glycosides and Flavonoids.

UNIT II

Drug discovery and development: Approaches to discovery and development of natural products as potential new drugs. Sourcing and archiving Natural products for discovery, evaluating natural products for therapeutic properties, Identifying the biologically active Natural products, the lead structure selection process and Optimization with suitable examples from the following source: artemesin, andrographolides.

UNIT III

- a) Extraction/Isolation methods for specific Phytochemical groups, Choice of solvents and Interfering compounds for general Isolation and purification of desired phytoconstituents.
- b) Recent sophisticated extraction techniques like: Super critical fluid extraction and Ultra-sonic extraction. Separation of phytoconstituents by Vacuum and Flash column chromatography.

UNIT IV

Sources, Chemical structure, Identification tests, mechanism of action SAR, uses of the following phyto-pharmaceuticals:

- a) Atropine, caffeine, Morphine and brief account on its derivatives and analogues
- b) Camptothecin, Digoxin
- c) Taxol, Podophyllotoxin

UNIT V

- a. Natural colorants: Biological Source, colouring principles, chemical nature and usage of the following Annatto, Cochineal, Caramel, Henna, Indigo, Madder, Saffron, Turmeric
- b. Flavours and Perfumes: Sandal wood oil, Orange oil, Lemon oil, Palmarosa oil, Geranium oil.

REFERENCES:

1. Phytochemical methods of chemical analysis by Harbone
2. Modern methods of plant analysis- peach & M. V. Tracey Vol. 1 to VII
3. Pharmacognosy & Phytochemistry of medical plants by Jean Brunton
4. Thin layer chromatography by Stahl
5. Chemistry of natural products by Atur Rahman
6. Comprehensive Medicinal Chemistry, Vol 1-6, Elsevier Publication
7. Medicinal Chemistry Drug Discovery by Donald J, Abrahm,
8. Plant drug analysis by Wagner
9. Clarke's isolation & identification of drugs by AC Mottal

10. Chromatography of Alkaloids by Varpoorte Swendson
11. Jenkins Quantitative pharmaceutical chemistry by AN Kenwell
12. Standardization of botanicals by V. Rajpal Vol 1 & 2
13. Pharmacognosy and Phytochemistry: A Comprehensive Approach, S L Deore, Pharmamed Press
14. Medicinal chemistry and drug discovery by Burger's
15. Foye's Principles of medicinal chemistry.
16. Pharmacognosy and phytochemistry by Biren seth
17. Herbal Perfumes and cosmetics by Panda
18. Herbal Drug Technology by SS Agarwal
19. Pharmacognosy and Phytochemistry by VD Rangari.
20. Textbook of Pharmacognosy by G. E. Trease, W. C. Evans, ELBS

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
PHARMACEUTICAL VALIDATION (Professional Elective - III)

Course Objective: The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

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

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments

UNIT I

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status -Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipments.

UNIT II

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC

Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT III

Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus.

Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

UNIT IV

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place (CIP).

UNIT V

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

- Validate the manufacturing facilities

REFERENCES:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Pharmaceutical Facilities: Design, Layouts and Validation, Potdar, Pharmamed Press

6. Michael Levin, Pharmaceutical Process Scale-Up, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
COSMETICS AND COSMECEUTICALS (Professional Elective - II)

Course Objectives: Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Course Outcomes: Upon completion of the subject student shall able to know Regulatory biological aspects of cosmetics, excipients used for various formulations, designing of cosmeceuticals and herbal products

UNIT I

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

UNIT II

Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

UNIT III

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars. **Perfumes;** Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. **Controversial ingredients:** Parabens, formaldehyde liberators, dioxane.

UNIT IV

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

UNIT V

Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

1. Harry's Cosmeticology. 8th edition.

2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, P. P. Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmeceuticals by Y Madhusudan Rao, Pharmamed Press
6. Cosmetic and Toiletries recent suppliers' catalogue.
7. CTFA directory.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective –II)

Course Objective: These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation.

Course Outcome: The students should describe the evaluation of stability of solutions, solids and formulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

UNIT I

Drug decomposition mechanisms:

1. Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of Pharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

UNIT II

Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of solid-state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

Physical stability testing of dosage forms:

1. Solids – tablets, capsules, powder and granules
2. Disperse systems
3. Microbial decomposition
4. Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT III

Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Factors affecting extraction of drugs.

UNIT IV

General method of analysis to determine the quality of raw materials used in cosmetic industry. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

UNIT V

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.

Stability studies: Concept of stability studies.

- a) cGMP& ICH guidelines for Accelerated stability Testing.
- b) Interaction of containers & closure Compatibility Testing.

REFERENCES:

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnsen – 2004.
2. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition. 3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogel's Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
3. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
4. J. B. Wilkinson and R. J. Moore, Herry's Cosmeticology; Longman Scientific and Technical Publishers, Singapore.
5. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
6. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
8. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
9. Drug stability: Principles and practices by Jens T. Carstensen
10. Stability Testing of Drug Products by W. Grimm. 12. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
RESEARCH METHODOLOGY AND IPR

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes: At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

UNIT I

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

UNIT II

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT III

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT IV

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT V

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

TEXT BOOKS:

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students"

2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction".
3. Pharmaceutical Research Methodology and Biostatistics, B Subba Rao, Pharmamed Press.
4. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press.

REFERENCES:

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
5. Asimov, "Introduction to Design", Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in New
7. Technological Age", 2016.
8. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB (Laboratory – I)

LIST OF EXPERIMENTS:

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
5. Separation and calculation of R_f values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Calibration of glasswares
7. Calibration of pH meter
8. Calibration of UV-Visible spectrophotometer
9. Calibration of FTIR spectrophotometer
10. Calibration of HPLC instrument

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
PHARMACEUTICAL FOOD ANALYSIS LAB (Laboratory –II)

LIST OF EXPERIMENTS:

1. Determination of total reducing sugar
2. Determination of proteins
3. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
4. Determination of fat content and rancidity in food products
5. Analysis of natural and synthetic colors & food additives in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Assay of any two Analgesic & Antipyretic drugs (API & dosage forms) official in IP
9. Assay of any two Antihistamines (API & dosage forms) official in IP
10. Assay of any two Diuretics (API & dosage forms) official in IP
11. Microbiological assay of any two Antibiotics official in IP

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
ADVANCED INSTRUMENTAL ANALYSIS – I (Professional Core - III)

Course Objectives: This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Course Outcome: By the completion of topics the students will come out with the thorough knowledge of various spectral aspects of X-Ray, IR, SEM, ORD etc which help them in further projects works and also industrial opportunities.

UNIT I

X-Ray diffraction methods: Origin of X-rays, basic aspects of crystals, X-ray crystallography, miller indices, rotating crystal techniques, single crystal diffraction, powder diffraction, structural elucidation and applications.

UNIT II

- a. **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.
- b. **Super critical fluid chromatography:** Principles, instrumentation, pharmaceutical applications.

UNIT III

Capillary Electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE,

UNIT IV

- a. **DSC:** Principle, thermal transitions, instrumentation (Heat flux and power- compensation designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, Sources of errors) and their influence, advantages and disadvantages, pharmaceutical applications.
- b. **DTA:** Principle, instrumentation, advantage and disadvantage, pharmaceutical application, derivative differential thermal analysis (DDTA).
- c. **TGA:** Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical application.

UNIT V

Scanning electron microscope (SEM): Principles, Instrumentation and applications.

Optical Rotatory Dispersion (ORD), Circular Dichroism, Cotton effect, Octane rule and applications.

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth 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. HPTLC by P.D. Seth

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE
(Professional Core – IV)

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, GLP and regulatory affairs.

Course Outcome: The study of this subject builds the confidence in the minds on the students to develop and formulate high quality pharmaceutical products.

UNIT I

- a. **Impurity and stability studies:** Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines.
- b. **Impurities in new drug products:** Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products
- c. **Impurities in residual solvents:** General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents.

UNIT II

- a. Concepts of Quality Assurance, Total Quality Management, Philosophy of GMP and cGMP
- b. Guidelines for Quality Assurance of Human Blood Products and large volume parenterals.

UNIT III

- a. Organization and personnel, responsibilities, training hygiene
- b. **Premises:** Location, design, plan Layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.
- c. **Equipments:** Selection, purchase specifications, maintenance, clean in place, sterilize in place – Raw – materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

UNIT IV

- a. Packaging and labeling controls, line clearance and other packaging materials.
- b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage.

UNIT V

Manufacture and controls on dosage forms

- a. Manufacturing documents, Master Formula, Batch Formula, Records, Standard Operating Procedures,
- b. In process quality control on various dosage forms sterile and biological products, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

TEXT BOOKS:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition General Methods of Analysis Quality Specifications for Pharmaceutical Substances, Excipients, Dosage Forms.
2. Quality Assurance of Pharmaceuticals. A Compendium of Guidelines and Related Material Vol. 1 and Vol. 2, WHO 2007)
3. GMP by Mehra

4. Pharmaceutical Process Validation by Berry and Nash
5. How to Practice GMP's – P.P. Sharma

REFERENCES:

1. Basic Tests for Pharmaceutical Substances - WHO (1991)
2. The Drugs and Cosmetic Act 1940 by Vijay Malik
3. Q.A. Manual by D.H. Shah
4. Pharmaceutical Quality Assurance and Management, K. P. Bhusari, Pharmamed Press
5. SOP Guidelines by D.H. Shah
6. Quality Assurance Guide by OPPI
7. Good Manufacturing-Practices for Pharmaceuticals, by Graham Bunn and Joseph 6th Ed. D. Nally (Dec 26, 2006)
8. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
MODERN BIO-ANALYTICAL TECHNIQUES (Professional Core - IV)

Course Objectives: This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

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

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies

UNIT I

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novel sample preparation approach.

UNIT II

Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

UNIT III

Bioanalysis and bioanalytical method validation:

- a. Types of body fluids, requirement of analysis, matrix effects, non-biological analytical samples.
- b. Bioanalytical method validation: USFDA and EMEA guidelines. Acceptance criteria in comparison to non-biological samples.

UNIT IV

Pre-Formulation: A consideration of following characteristics of medicinal agents in their dosage form:

Physical characteristics-Particle size, polymorphism, crystal form, solubility, Interfacial tension, Salt formation, wetting of solids, flow characteristics, compressibility and Partition coefficient.

Chemical Characteristics-Degradation: Hydrolytic, oxidative, reductive and photolytic, Drug – Excipient compatibility studies.

UNIT V

- a. **Automation and computer-aided analysis, LIMS:** The concept of auto samplers and high throughput analysis, computer-controlled instrumentation and networked laboratory. Peculiarities of laboratory information management systems (LIMS).
- b. **Drug Product Performance, In Vivo:** Purpose of Bioavailability Studies, Bioavailability and Bioequivalence Studies.

REFERENCES:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, New York. 1995.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.

4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercey. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, New York, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jersey, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines
11. Palmer

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
HERBAL COSMETICS (Professional Elective - III)

Course Objective: The topics helps the students to get exposed to processes involved in the manufacturing of herbal cosmetics including the skin and hair care herbal products preparation and their evaluation.

Course Outcome: Students will learn about the raw materials used in herbal cosmetics and get exposed tovarious preparations of herbal cosmetics.

UNIT I

Introduction: Herbal/ natural cosmetics, Classification & Economic aspects.

Regulatory Provisions relation to manufacture of cosmetics: -

License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.

UNIT II

- a) Commonly used herbal cosmetics raw materials –water, preservatives, surfactants, oils /waxes, colors, and some functional herbs
- b) Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Molding, Packing.
- c) General principles of quality control of herbal cosmetics

UNIT III

Skin care Products: Physiology and chemistry of skin, Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Creams, Lotions, Lipsticks, Face packs. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT IV

Hair care Products: Hair structure and its chemistry

Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Hair dyes, Creams, Oils and Shampoos. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT V

Herbs in cosmetics:

A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as Acacia concinna pods, Aloe Vera, Almond oil, Neem, Citrus aurantium peels, Henna, Turmeric, Liquorices, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

REFERENCES:

1. Cosmetics- Formulation, Manufacturing and Quality control –P. P. Sharma
2. Herbal Cosmetics Hand Book- H. Panda
3. Herbal Cosmetics by P.K Chattopadhyay
4. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm. I Year II Sem (Pharmaceutical Analysis)
PHARMACOEPIDEMOLOGY & PHARMACOECONOMICS (Professional Elective - III)

Course Objective: This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

UNIT I

Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT II

Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta-analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT III

Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost-Effective Ratio, Average Cost-Effective Ratio. Person Time, Willingness to Pay, Time Trade Off and Discounting.

UNIT IV

Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

UNIT V

Definition, Steps involved, Applications, Advantages and disadvantages of the following:

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in Pharmacoeconomic analysis, Applications of Pharmacoeconomics.

REFERENCES:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwe rLippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modeling for Health Economic Evaluation, Oxford University Press, London.
4. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.
5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programs Oxford University Press, London.
6. George E Mackinnon III. Understanding health outcomes and Pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
10. Relevant review articles from recent medical and pharmaceutical literature
11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Sem – II (PHARMACEUTICAL ANALYSIS)
ADVANCED INSTRUMENTAL ANALYSIS – II (Professional Elective - IV)

Course Objectives: This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Course Outcome: By the completion of topics the students will come out with the thorough knowledge of various electrochemical methods, fluorimetry, AAS, RIA, ELISA etc. which help them in further projects works and also industrial opportunities

UNIT I

Polarography – Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications.

Amperometry - Principles, instrumentation and applications including amperometric titrations.

UNIT II

- a. **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.
- b. **Conductometry**– Introduction, Conductivity cell, Conductometric titrations, applications

UNIT III

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

UNIT IV

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT V

- a. **Radio chemical methods including RIA:** Radio Active Isotopes, tagging of compounds, Labeled Reagents, Isotope dilution Analysis, Scintillation counter, RIA.
- b. **ELISA:** Principle, types and application of ELISA

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth 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. HPTLC by P.D. Seth

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
NUTRACEUTICALS (Professional Elective - IV)

Course Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations

Course Outcome: Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals

UNIT I

- a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.
- b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:
Spirulina, Soya bean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

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

- a. Carotenoids- α and β -Carotene, Lycopene, Xanthophylls, lutein
- b. Sulfides: Diallylsulfides, Allyltrisulfide.
- c. Polyphenolics: Resveratrol
- d. Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones
- e. Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum
- f. Phytoestrogens, Isoflavones, daidzein, Geeststin, lignans
- g. Tocopherols

UNIT III

- a. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
- b. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV

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

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

REFERENCES:

1. Dietetics by Sri Lakshmi

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
CLINICAL RESEARCH AND PHARMACOVIGILANCE (Professional Elective - IV)

Course Objective: This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post market surveillance.

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

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in pharmacovigilance

UNIT I

Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

UNIT II

Clinical Trials: Types and Design: Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

UNIT III

Clinical Trial Documentation: Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

UNIT IV

Basic aspects, terminologies and establishment of pharmacovigilance: History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and Nationalprogrammesrelatedtopharmacovigilance.RolesandresponsibilitiesinPharmacovigilance.

UNIT V

Methods, ADR reporting and tools used in pharmacovigilance: International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, targeted clinical investigations and Vaccine safety surveillance.

Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, ArisG Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

REFERENCES:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary, Pharmamed Press
7. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Textbook of Pharmacovigilance: Concept and Practice. G. P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
10. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
ADVANCED INSTRUMENTAL ANALYSIS-I LAB (Laboratory –III)

LIST OF EXPERIMENTS:

1. Determination of chlorides and sulphates by Nephelo -Tubmidimetry
2. Determination of compounds of sodium, potassium and calcium by Flame photometry.
3. Estimation of riboflavin/quinine sulphate by flourimetry
4. Assay of official compounds by potentiometric titrations **(Any 2)**
5. Assay of official compounds by conductimetric titrations **(Any 2)**
6. Demonstration on ELISA
7. Quenching of fluorescence
8. Perform phosphate interference on absorption of calcium

(Note: Minimum of two experiments covering each of the above-mentioned topics)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE LAB

LIST OF EXPERIMENTS:

1. QC tests for tablets (minimum 2 experiments)
2. QC tests for capsules (minimum 2 experiments)
3. QC tests for oral liquids monophasic (minimum 2 experiments)
4. QC tests for oral liquids biphasic (minimum 2 experiments)
5. Forced degradation studies of some drugs.
6. Interpretation of spectras by IR, NMR and MASS
7. Assay of drug formulations using UV-Spectrophotometer (Any four)
8. Demonstration of functional groups of the given samples by IR Spectrophotometer.
9. Physicochemical tests for water
10. Solubility studies of weakly acidic and weakly basic drugs.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Analysis)
BIostatISTICS (Professional Elective - V)

Course Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data.

Course Outcome: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data

UNIT I

Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement and presentation, formation of table and charts.

UNIT II

Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.

Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III

Measures of Correlation and Regression

Probability rules: Binomial, Poisson and Normal distribution.

UNIT IV

Experimental designing, planning of an experiment, replication and randomization.

Analysis of Variance (ANOVA): 1-way, 2-Way

UNIT V

Hypothesis testing: Student 't' test, Chi square test,

Non- Parametric Tests: Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

REFERENCES:

1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
4. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
5. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Analysis)
SCALE UP AND TECHNOLOGY TRANSFER (Professional Elective - V)

Course Objective: This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Course Outcome: On completion of this course it is expected that students will be able to;

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

UNIT I

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenteral and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenteral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

UNIT II

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vendor qualification.

UNIT III

Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.

UNIT IV

Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

UNIT V

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

REFERENCES:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T. Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L. Lachman, H.A. Lieberman, Varghese Publ Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.
10. Pharmaceutical Process Scale-up 2nd Ed. Levin Michael, CRC press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Analysis)
PRODUCTION AREA DESIGN & PACKAGING DEVELOPMENT (Professional Elective - V)

Course Objectives: The student shall learn about Industrial area design, Current good manufacturing practices. They also learn about packaging components, polymers and metals used in packaging. They also understand about the storage conditions of different formulations and their stability evaluations.

Course Outcome: At the end of the semester student will get an idea about Industrial area design and packaging of different formulations and its stability conditions.

UNIT I

Production Area Design: Selection of plant location, Design of plant for bulk drugs and formulations (Solids, Semisolids, Injectables, Nutraceuticals etc.), General utilities such as purified water, portable water, water for injection, Air handling units-Relative humidity and Temperature control, Material and personnel movement. Warehouse handling-API, Excipients, packaging materials and solvents.

UNIT II

Current Good Manufacturing Practices: GMP design for buildings & facilities. GMP layout design. Clean room classifications. Segregation & cross contamination control. HVAC (heating, ventilation & air-conditioning) systems. Clean room environment control. Documentation and record keeping: Specifications and testing procedures, Specifications for finished products, Master Formulae, Packaging instructions. Batch processing records, Standard operating procedures.

UNIT III

Pharmaceutical packaging and Design: Introduction, Packaging system, Components of packaging, Symbols used on packages and labels. Package development and Design research. Packaging materials- Polymers and Plasters, Glass, Metal and Blister and strip packaging.

UNIT IV

Stability of Packaging: Introduction, Legislation, Regulation, Pharmaceutical Stability Testing in Climatic Cabinets, Pharmaceutical Stability Testing Conditions, Photo-Stability Testing, Review of Pharmaceutical Product Stability, Packaging and the ICH Guidelines.

UNIT V

Packaging of Solids, Semisolids, Parenterals, Ophthalmic and Aerosols: Introduction, Packaging of Solid and semisolids, Packaging of Sterile Pharmaceuticals, Packaging Components, Inspection of Filled Injectable Products, Storage and Labelling, Packaging of Ophthalmics, Selection of Packaging Materials, Packaging of Aerosols.

REFERENCES:

1. Lachman; Lieberman Herbert A.; Kanig, The theory and Practice of Industrial Pharmacy.
2. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
3. Aulton's Pharmaceutics: The design and Manufacture of Medicine
4. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis.
5. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester
6. Pharmaceutical Facilities: Design, Layouts and Validation, Potdar, Pharmamed Press
7. Wilmer A. Jenkins, Kenton R. Osborn. Packaging drugs and pharmaceuticals.
8. Remington: The Science and Practice of Pharmacy. 8. Michael E. Aulton, Kevin Tylor
9. Pharmaceutical Packaging Technology, UK jain, Pharmamed Press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)

Prerequisite: None

Course objectives: Students will be able to:

- Understand that how to improve your writing skills and level of readability
- Learn about what to write in each section
- Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission

UNIT-I:

Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

UNIT-II:

Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts. Introduction

UNIT-III:

Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

UNIT-IV:

key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature,

UNIT-V:

skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions. useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

TEXT BOOKS/ REFERENCES:

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman's book.
4. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

DISASTER MANAGEMENT (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- critically understand the strengths and weaknesses of disaster management approaches,
- planning and programming in different countries, particularly their home country or the countries they work in

UNIT-I:

Introduction:

Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.

Disaster Prone Areas in India:

Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

UNIT-II:

Repercussions of Disasters and Hazards:

Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT-III:

Disaster Preparedness and Management:

Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT-IV:

Risk Assessment Disaster Risk:

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT-V:

Disaster Mitigation:

Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

TEXT BOOKS/ REFERENCES:

1. R. Nishith, Singh AK, "Disaster Management in India: Perspectives, issues and strategies "New Royal book Company.
2. Sahni, Pardeep Et. Al. (Eds.), " Disaster Mitigation Experiences and Reflections", Prentice Hall of India, New Delhi.
3. Goel S. L., Disaster Administration and Management Text and Case Studies", Deep &Deep Publication Pvt. Ltd., New Delhi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature

Course Outcomes: Students will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science & technology can be understood
- Being a logical language will help to develop logic in students

UNIT-I:

Alphabets in Sanskrit,

UNIT-II:

Past/Present/Future Tense, Simple Sentences

UNIT-III:

Order, Introduction of roots,

UNIT-IV:

Technical information about Sanskrit Literature

UNIT-V:

Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

TEXT BOOKS/ REFERENCES:

1. "Abhyaspustakam" – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. "Teach Yourself Sanskrit" Prathama Deeksha - Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. "India's Glorious Scientific Tradition" Suresh Soni, Ocean books (P) Ltd., New Delhi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

VALUE EDUCATION (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

Course outcomes: Students will be able to

- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

UNIT-I:

Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

UNIT-II:

Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

UNIT-III:

Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity and discipline, Punctuality, Love and Kindness.

UNIT-IV:

Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

UNIT-V:

Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively

TEXT BOOKS/ REFERENCES:

1. Chakroborty, S.K. "Values and Ethics for organizations Theory and practice", Oxford University Press, New Delhi

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CONSTITUTION OF INDIA (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals' constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

Course Outcomes: Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

UNIT-I:

History of Making of the Indian Constitution: History Drafting Committee, (Composition & Working), **Philosophy of the Indian Constitution:** Preamble, Salient Features.

UNIT-II:

Contours of Constitutional Rights & Duties: Fundamental Rights Right to Equality, Right to Freedom, Right against Exploitation, Right to Freedom of Religion, Cultural and Educational Rights, Right to Constitutional Remedies, Directive Principles of State Policy, Fundamental Duties.

UNIT-III:

Organs of Governance: Parliament, Composition, Qualifications and Disqualifications, Powers and Functions, Executive, President, Governor, Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualification, Powers and Functions.

UNIT-IV:

Local Administration: District's Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. Pachayat raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy (Different departments), Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

UNIT-V:

Election Commission: Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

TEXT BOOKS/ REFERENCES:

1. The Constitution of India, 1950 (Bare Act), Government Publication.
2. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
3. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

PEDAGOGY STUDIES (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Review existing evidence on the review topic to inform programme design and policy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes: Students will be able to understand:

- What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

UNIT-I:

Introduction and Methodology: Aims and rationale, Policy background, Conceptual framework and terminology Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions. Overview of methodology and Searching.

UNIT-II:

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT-III:

Evidence on the effectiveness of pedagogical practices, Methodology for the in depth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT-IV:

Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class sizes

UNIT-V:

Research gaps and future directions: Research design, Contexts, Pedagogy, Teacher education, Curriculum and assessment, Dissemination and research impact.

TEXT BOOKS/ REFERENCES:

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
3. Akyeampong K (2003) Teacher training in Ghana - does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.

4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? *International Journal Educational Development*, 33 (3): 272–282.
5. Alexander RJ (2001) *Culture and pedagogy: International comparisons in primary education*. Oxford and Boston: Blackwell.
6. Chavan M (2003) Read India: A mass scale, rapid, 'learning to read' campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

STRESS MANAGEMENT BY YOGA (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To achieve overall health of body and mind
- To overcome stress

Course Outcomes: Students will be able to:

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

UNIT-I:

Definitions of Eight parts of yog. (Ashtanga)

UNIT-II:

Yam and Niyam.

UNIT-III:

Do's and Don't's in life.

- i) Ahinsa, satya, astheya, bramhacharya and aparigraha
- ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

UNIT-IV:

Asan and Pranayam

UNIT-V:

- i) Various yog poses and their benefits for mind & body
- ii) Regularization of breathing techniques and its effects-Types of pranayam

TEXT BOOKS/ REFERENCES:

1. 'Yogic Asanas for Group Training-Part-I': Janardan Swami Yogabhyasi Mandal, Nagpur
2. "Rajayoga or conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS
(Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes: Students will be able to

- Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life
- The person who has studied Geeta will lead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

UNIT-I:

Neetisatakam-Holistic development of personality

- Verses- 19,20,21,22 (wisdom)
- Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)

UNIT-II:

Neetisatakam-Holistic development of personality

- Verses- 52,53,59 (don't's)
- Verses- 71,73,75,78 (do's)

UNIT-III:

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

UNIT-IV:

Statements of basic knowledge.

- Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

UNIT-V:

- Chapter2-Verses 17, Chapter 3-Verses 36,37,42,
- Chapter 4-Verses 18, 38,39
- Chapter18 – Verses 37,38,63

TEXT BOOKS/ REFERENCES:

1. "Srimad Bhagavad Gita" by Swami SwarupanandaAdvaita Ashram (Publication Department), Kolkata.
2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P.Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.