NALLA NARASIMHA REDDY EDUCATION SOCITEY'S GROUP OF INSTITUTIONS
(AUTONOMOUS)
B. PHARMACY III YEAR COURSE STRUCTURE (R21)
Effective from Academic Year 2021 - 22 Admitted Batch

III Year I semester

S. No	Course Code	Subject	L	T	P	Credits
1	21PS501	Medicinal Chemistry - II	3	1	0	4
2	21PS502	Industrial Pharmacy - I	3	1	0	4
3	21PS503	Pharmacology II	3	1	0	4
4	21PS504	Pharmacognosy and Phytochemistry - II	3	1	0	4
5	 21PS505 21PS506 21PS507 21PS508	**Open Elective - I** I. Generic Product Development II. Green Chemistry III. Cell and Molecular Biology IV. Cosmetic science	3	1	0	4
6	21PS509	Industrial Pharmacy - I Lab	0	0	4	2
7	21 PS510	Pharmacology – II Lab	0	0	4	2
8	21 PS511	Pharmacognosy and Phytochemistry – II Lab	0	0	4	2
9	*21 MC500	Environmental Sciences	1	0	0	0
		Total	**16**	**05**	**12**	**26**

III Year II semester

S. No	Course Code	Subject	L	T	P	Credits
1	21PS601	Medicinal Chemistry - III	3	1	0	4
2	21PS602	Pharmacology - III	3	1	0	4
3	21PS603	Herbal Drug Technology	3	1	0	4
4	21PS604	Biopharmaceutics and Pharmacokinetics	3	1	0	4
5	 21PS605 21PS606 21PS607 21PS608	**Open Elective - II** I. Pharmaceutical Quality Assurance II. Pharmaceutical Biotechnology III. Bioinformatics IV. Screening Methods in Pharmacology	3	1	0	4
6	21PS609	Medicinal chemistry - III lab	0	0	4	2
7	21 PS610	Pharmacology - III lab	0	0	4	2
8	21 PS611	Herbal Drug Technology lab	0	0	4	2
9	*21 MC600	Human Values and Professional Ethics	1	0	0	0
		Total	**16**	**05**	**12**	**26**

*MC - Mandatory Course - Satisfactory/ Unsatisfactory.

21PS501: 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, absorbtion, 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 humanbody

H_1–antagonists: Diphenhydramine hydrochloride*,Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizinehydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, LevocetrazineCromolyn sodium

H_2-antagonists: Cimetidine*, Famotidine, Ranitidin.

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

Anti-neoplastic agents:

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

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

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate**Miscellaneous:** Cisplatin, Mitotane.

UNIT – II **10 Hours**

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbid 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, Lorcainide hydrochloride, Amiodarone, Sotalol.

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

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

UNIT - IV **08 Hours**

Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethylstilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

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

UNIT – V **07 Hours**

Antidiabetic agents:

Insulin and its preparations

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

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.
Glucosidase inhibitors: Acarbose, Voglibose.
Local Anesthetics: SAR of Local anesthetics
Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine. **Amino Benzoic acid derivatives**: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine,Tetracaine, Benoxinate.
Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.
Miscellaneous: Phenacaine, Diperodon, Dibucaine.*

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

21PS502: 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:

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

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

UNIT – III **08 Hours**

Capsules:

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

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

c. **Pellets:** Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets, Fluidised bed coater(FBC).

UNIT - IV **10 Hours**

Parenteral Products:

a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity

b. Production procedure, production facilities and controls.

c. Formulation of injections, sterile powders, emulsions, suspensions, large volume parenterals 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, Latestedition
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. Tripati Pharma med press

21PS503: 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 basicconcepts 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 differentdiseases
- Demonstrate isolation of different organs/tissues from the laboratory animals by simulatedexperiments
- 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

1. Introduction to hemodynamic and electrophysiology of heart.
2. Drugs used in congestive heart failure
3. Anti-hypertensive drugs.
4. Anti-anginal drugs.
5. Anti-arrhythmic drugs.
6. 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 autacoids and classification
b. Histamine, 5-HT and their antagonists.
c. Prostaglandins, Thromboxanes and Leukotrienes.
d. Angiotensin, Bradykinin and Substance P.
e. Non-steroidal anti-inflammatory agents
f. Anti-gout drugs

g. Antirheumatic drugs

UNIT - IV **08 hours**

Pharmacology of drugs acting on endocrine system

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

UNIT - V **07 hours**

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. Churchil Livingstone Elsevier
3. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
4. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
5. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., BradleyR.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.

21PS504: 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

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

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

Course Outcome: The knowledge of the students is enhanced with the clear information about thegeneric 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 samplesand finished dosage forms.

UNIT - IV

a. Stability studies on active ingredient and finished dosage forms, accelerated stability studies, stability studies at different conditions, determination or 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 andin-vitro tests to ensure bioequivalence of test product.
b. Introduction to electronic Common Technical Document (eCTD), various modules and theimportant 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.

21PS506: 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 andthe 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 andsynthesis.

UNIT - II

In water and solvent less organic reactions

In water reactions: principle and process involved in the Michael reaction and Wartz synthesisSolvent 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 reactionand 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, ionicliquids (Knovenegel ondensatin) and bio catalysts (Villeger reaction)

Solid supported reactions: principles and process Alternative reagents used in green chemistry strategies.

UNIT - V

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

REFERENCE BOOKS

1. Paul T Anastas, John Charles Warmer. Green chemistry: theory and practice. Oxford university Press, 1988
2. Alluwalia V.K,Green chemistry : environmentally benign reactions. 2nd edn,Ane Books Pvt Ltd,New Delhi, 2012
3. Alluwalia V.K, M. Kidwai, New trends in green chemistry. 2nd edn, Anamaya Publishers, Newdelhi, 2004.

21PS507: 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 lifecycle, 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, 10^{th} 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, 4^{th} 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 ofRecombinant DNA: ASM Press Washington D.C.
14. RA Goldshy et. al., Kuby Immunology.

21PS508: 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 productsand their methods of preparation and evaluations.

Course Outcomes:

- Upon completion of the course the student shall be able to know the regulations pertaining tocosmetics 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 1**0 Hours**

Principles of formulation and building blocks of skin care products:
Face wash,
Moisturizing cream, Cold Cream, Vanishing cream their relative skin sensory, advantages anddisadvantages. Application of these products in formulation of cosmecuticals.
Principles of formulation and building blocks of Hair care products:
Conditioning shampoo, Hair conditioners, antidandruff shampoo.Hair oils.
Chemistry and formulation of Para-phylene diamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT – III **10 Hours**

Sun protection, Classification of Sunscreens and SPF.
Role of herbs in cosmetics:
Skin Care: Aloe and turmericHair care: Henna and amla. Oral care: Neem and clove
Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-cream andtoothpaste**.**

UNIT – IV **08 Hours**

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

UNIT – V **07 Hours**

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

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

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes

Cosmetic problemsassociated 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

21PS509: 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.

21PS510: 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 abdominismuscle 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 plotmethod).
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 experimentsby 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. Churchil Livingstone Elsevier
3. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
4. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
5. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., BradleyR.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.

21PS511: 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 phytoconstitutents 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. Sounders & Co., London,2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, NewDelhi.
3. Text book of Pharmacognosy by C. K. Kokate, Purohit, Gokhlae (2007), 37th Edition, NiraliPrakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr. SH. Ansari, IInd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H. Pande, Asia Pacific Business press, Inc, New Delhi.
7. A. N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. 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.

21*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 studiesNatural 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.

Down of Earth, Centre for Science and Environmen

21PS601: 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, Artesunete, Artemether, Atovoquone.

UNIT – III **10 Hours**

Anti-tubercular Agents

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

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

Urinary tract anti-infective agents

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

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

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

UNIT – IV **08 Hours**

Antifungal agents:

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

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

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

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

Sulphonamides and Sulfones

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

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V **07 Hours**

Introduction to Drug Design

Various approaches used in drug design.

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

Pharmacophore modeling and docking techniques.

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

Recommended Books (Latest Editions)

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

21PS602: 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 differentinfectious diseases
- Comprehend the principles of toxicology and treatment of various poisonings and appreciatecorrelation 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 andfluoroquinolins, 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, organ ophosphosphoruscompound 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., BradleyR.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 ModernPharmacology 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.

21PS603: 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, toothpastes 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 likephytosomes

UNIT – IV **10 Hours**

1. **Evaluation of Drugs** WHO & ICH guidelines for the assessment of herbal drugs Stabilitytesting 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 manufactureof 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, standardoperating 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 vaidyssala , Universities Press

21PS604: 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 providedto 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 drugabsorption, 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 principlesto solve them

UNIT – I **10 Hours**

Introduction to Biopharmaceutics

Absorption: Mechanisms of drug absorption through GIT, factors influencing drug absorption though 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 drugexcretion 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 Ka, KE.

From plasma and urinary excretion data

UNIT – IV **08 Hours**

Multicompartment models: Two compartment open model. IV bolus

Multiple – Dosage Regimens:

a). Repititive Intravenous injections – One Compartment Open Modelb). Repititive Extravascular dosing – One Compartment Open model

UNIT – V **07 Hours**

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity. c. Michaelis-mentonmethod 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 4thedition, Prentice-Hall International edition. USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Fundamentals of Biopharmaceutics and pharmacokinetics by Dr. V. Venkateshwarlu
6. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
7. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS HealthScience 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 andexpanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
13. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.

21PS605: 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 Qualitycontrol, 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 – II **10 Hours**

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

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 wastedisposal.
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 Analyticalmethod 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 VolI 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 Qualityspecification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

21PS606: 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 andfermentation technology makes the subject interesting.
- Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure ofdiseases, new and cheaper pharmaceutical drugs.
- Biotechnology has already produced transgenic crops and animals and the future promiseslot 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**

Study of cloning vectors, restriction endonucleases and DNA ligase.

a. Recombinant DNA technology. Application of genetic engineering in medicine.
b. Application of r DNA technology and genetic engineering in the products:
c. Interferon b) Vaccines- hepatitis- B c) Hormones- Insulin.
d. Brief introduction to PCR
e. Types of immunity- humoral immunity, cellular immunity

UNIT – III **10 Hours**

Structure of Immunoglobulins

a. Structure and Function of MHC
b. Hypersensitivity reactions, Immune stimulation and Immune suppressions.
c. General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins,serum-immune blood derivatives and other products relative to

immunity.

d. Storage conditions and stability of official vaccines
e. 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 andtransposons.
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, sterilizationmethods, 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 ofChemistry.
6. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
7. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
8. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition,Aditya books Ltd., New Delhi

21PS607: 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 ofbioinformatics

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

Bioinformatics- a historical perspective

Bioinformaticss data- nucleic acid sequence, protein sequence, protein structure, genome variationdata, gene expression data, proteomic data, metabolic pathways and networks

Bioinformatics tools and resources- free online tolls, downloadable free tools, software pakags,bioinformatics web portals

Role of internet in Bioinformatics.

UNIT - II
Sequence comparison methods

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)

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

multiple-sequence alignment (MSA): significance of MSA

UNIT - III
Genomic Applications:

Bioinformatics for genome sequencing, first and next generation methods of genome sequencing,de-novo and reference based genome sequencing, genome assembly (reads, contigs &scaffolds)

Transcript- profiling: expression microarrays (gene array& oligo array), transcriptome sequencingand RNA- seq analysis small RNA sequencing and analysis

UNIT - IV

Genome maps an markers: identification of molecular makers (SSR, STS &

SNP markers), linkageVs physical maps, displaying genome annotation using genome browsers

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

UNIT - V

Proteomic and metabolomic applications:

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

Protein structure: structure visualization

Protein: secondary and tertiary structure prediction (homology modelling)

Recommended Books (Latest edition):

1. Bioinformatics by B. G. Gurran, R. J. Walker, S.C. Bhatia. CBS Publishers.
2. Bioinformatics: Skills & applications by Rastogi, CBS Publishers
3. Bioinformatics: Sequence & genome analysis by mount, CBS Publishers
4. Bioinformatics and bioprogramming by CN Chaveli
5. Bioinformatics (Basics, alogerthmas and applications by Ruchi singh and Richa Sharma
6. Essential Bioinformatics Jinxiong

21PS608: 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
Toxiciy test: OECD guidelines, determination of LD_{50}, 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.BhagyaLakshmi
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.

21PS609: 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 irradiationtechnique
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.

21PS610: 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 inducedulcer 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 Ranktest)

**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, ChurchillLivingstone 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., BradleyR.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 ModernPharmacology 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.

21PS611: 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)

a. Textbook of Pharmacognosy by Trease & Evans.
b. Textbook of Pharmacognosy by Tyler, Brady & Robber.
c. Pharmacognosy by Kokate, Purohit and Gokhale
d. Essential of Pharmacognosy by Dr.S.H.Ansari
e. Pharmacognosy & Phytochemistry by V.D.Rangari
f. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine& Homeopathy)
g. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals.Business Horizons Publishers, New Delhi, India, 2002.

*21MC600: 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 personallives 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, responsibleauthorship, 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:

a. Professional Ethics: R. Subramanian, Oxford University Press, 2015.
b. Ethics in Engineering Practice & Research, Caroline Whitbeck, 2e, Cambridge University Press 2015.REFERENCE BOOKS
c. Engineering Ethics, Concepts Cases: Charles E Harris Jr., Michael S Pritchard, Michael J Rabins, 4e , Cengage learning, 2015.
d. Business Ethics concepts & Cases: Manuel G Velasquez, 6e, PHI, 2008.
e. Forensic Pharmacy by Dr.Kokate
f. Forensic Pharmacy by Bhaskar Chaurasia

NALLA NARASIMHA REDDY EDUCATION SOCIETY'S GROUP OF INSTITUTIONS
(UGC AUTONOMOUS INSTITUTION)
B. PHARMACY IV YEAR COURSE STRUCTURE (R21)
Effective from Academic Year 2021-22 Admitted Batch

IV Year I semester

S. No	Course Code	Subject	L	T	P	Credits
1	21PS701	Instrumental Methods of Analysis	3	1	0	4
2	21PS702	Industrial Pharmacy-II	3	1	0	4
3	21PS703	Pharmacy Practice	3	1	0	4
4	21PS704	Novel Drug Delivery Systems	3	1	0	4
5	 21PS705 21PS706 21PS707 21PS708	**Open Elective - I** I. Pharmaceutical Marketing II. Pharmaceutical Regulatory Science III. Pharmacovigilance IV. Quality Control and Standardization of Herbals	3	1	0	4
6	21PS709	Instrumental Methods of Analysis Lab	0	0	4	2
7	21 PS710	Practice School	0	0	4	2
8	21 PS711	Industrial Training	0	0	2	1
		Total	**15**	**5**	**10**	**25**

IV Year II semester

S. No	Course Code	Subject	L	T	P	Credits
1	21PS801	Biostatistics and Research Methodology	3	1	0	4
2	21PS802	Social and Preventive Pharmacy	3	1	0	4
3	21PS803	Pharmaceutical Jurisprudence	3	0	0	3
4	 21PS804 21PS805 21PS806 21PS807	**Open Elective - II** I. Computer Aided Drug Design II. Nanotechnology III. Experimental Pharmacology IV. Advanced Instrumentation Techniques	3	1	0	4
5	21PS808	Project Work	0	0	6	3
		Total	**12**	**3**	**6**	**18**

21PS701: 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 indrug 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 absorptionspectra, 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, factorsaffecting 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**

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

UNIT – IV **08 Hours**

1. **Gas chromatography** - Introduction, theory, instrumentation, derivatization, temperatureprogramming, 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

21PS702: 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 pharmaceuticalproduct 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 ofPharmaceutical 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 athttp://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 forPrescription 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

21PS703: 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, druginformation, 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**
2. 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.
3. **Hospital pharmacy and its organization**
4. Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.
5. **Community Pharmacy**
6. 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**
2. 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.
3. **Therapeutic drug monitoring**
4. Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.
5. **Community pharmacy management**
6. Financial, materials, staff, and infrastructure requirements.

UNIT – III **10 Hours**

1. **Drug information services**
2. Drug and Poison information centre, Sources of drug information, Computerized services, and storage and retrieval of information.
3. **Patient counseling**
4. Definition of patient counseling; steps involved in patient counseling, and Special cases that requirethe pharmacist
5. **Education and training program in the hospital**
6. 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**
2. 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.
3. **Over the counter (OTC) sales**
4. 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 inventorycontrol: 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 PharmacyPractice- 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 SystemPharmacists Inc; 2009.
6. Parmar N. S. Health Education and Community Pharmacy, 18th ed. India: CBS Publishers &Distributers; 2008.

21PS704: 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 drugdelivery 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 Noveldrug 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 implantsand 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, developmentof 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 InterscincePublication, 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, VallabhPrakashan, New Delhi, 1st edition 2002.

21PS705: 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 applicationof 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 thePSR.

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) andNPPA (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 McGrawHill, 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, IndianContext, 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.

21PS706: 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 regulatedcountries.

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, clinicalstudies, 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, EuropeanUnion, 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, Orangebook, 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, 5thedition, 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 /editedby 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
9. P. Ognibene
10. Drugs: From Discovery to Approval, 2nd Edition by Rick N

21PS707: 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 dataSafety data generation:

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

ICH Guidelines for Pharmacovigilance:

Organization and objectives of ICH

a) Expedited reporting
b) Individual case safety reports
c) Periodic safety update reports
d) Post approval expedited reporting
e) Pharmacovigilance planning
f) 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.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
13. http://www.ich.org/
14. http://www.cioms.ch/
15. http://cdsco.nic.in/
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

21PS708: 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 opportunityfor 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 foruse

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

Comparisonof 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 herbaldrugs. 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.

21PS709: 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 organiccompounds
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

21PS710: 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 willsubmit the detailed report in the following field.

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

Industry oriented PS:

It comprises industry visits and interactions with executives to facilitate the process of learning by observations and discussions duly aided by the check list. It promotes learning by doing in various departments like production quality control and assurance, R&D etc. Taking one issue and working onit 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 bestudied 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 drugcontrol 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 forregular practicals

21PS801: 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 Biostatics in Pharmacy. This subject deals withdescriptive statistics, Graphics, Correlation, Regression, ANOVA, Introduction to Design ofExperiments, 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 - Pharmaceuticalsexamples

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, FriedmanTest

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, Designingclinical 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'sto 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, OptimizationTechniques

Recommended Books (Latest edition):

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

21PS802: 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 pharmaceuticalproblems 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 thesick.

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 thehealth 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 RabindraNath, 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, HiremathDhananjaya 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

21PS803: 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 drugsfor 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 andcosmetics, 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 EthicsCommittee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisitionof 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 ofscheduled formulations, National List of Essential Medicines (NLEM)

UNIT – V **07 Hours**

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

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

Medical Termination of pregnancy actRight 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)

21PS804: 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 designprocess 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, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT – III **10 Hours**

Molecular Modeling and virtual screening techniques

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

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

UNIT – IV **08 Hours**

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

21PS805: 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 formsand 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

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UNIT - II

Synthesis of Nanomaterials

a. Methods for synthesis of:
b. Gold nanoparticles
c. Magnetic nanoparticles
d. Polymeric nanoparticles
e. 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 andlocalized drug delivery systems.

UNIT - V

Characterization, drug release and stability studies of nanomaterials

Recommended Books (Latest Editions):

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body,Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery, Jose
3. L. Arias, CRC press
4. Nano: The Essentials: Understanding Nanosicence and Nanotechnology, T. Pradeep, TataMcGraw-Hill Publishing Company Limited, New Delhi, 2008.
5. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P.J. Thomas and G.U.Kulakarni, Springer (2007)
6. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao,Imperial College Press (2004)
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, Ankaneyulu Yerramilli, BS Publications. 2016

21PS806: 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 theassays

UNIT - I

Laboratory Animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia

UNIT - II

Preclinical screening models: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups

UNIT - III

Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics and skeletal muscle relaxants.

UNIT - IV

Preclinical screening models for diuretics, anticoagulants and anticancer activities

UNIT - V

Research methodology and Bio-statistics, Selection of research topic, review of literature, research hypothesis and study design, Interpretation using Student’t’ test and One-way ANOVA. Graphical representation of data.

Recommended Books (Latest Editions):

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
2. Screening methods in Pharmacology by Robert Turner. A.
3. Methods in Pharmacology by Arnold Schwartz.
4. Pharmacological screening methods and Toxicology by A Srinivasa Rao and N. BhagyaLakshmi
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.

21PS807: 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, FlamePhotometer, HPLC and GC

UNIT – IV **08 Hours**

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

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