PY-601 . MEDICINAL CHEMISTRY – III (Theory)

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

UNIT – I

Antibiotics
Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes :
β-Lactam antibiotics: Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams
Aminoglycosides: Streptomycin, Neomycin, Kanamycin
Tetracyclines: Tetracycline,Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II

Antibiotics
Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes:
Macrolide: Erythromycin Clarithromycin, Azithromycin.
Miscellaneous: Chloramphenicol*, Clindamycin.
Prodrugs: Basic concepts and application of prodrugs design.
Antimalarials: Etiology of malaria.
Quinolines: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine.
Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.
Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone.

UNIT – III

Anti-tubercular Agents
Synthetic anti tubercular agents: Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*
Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.
Urinary tract anti-infective agents
Quinolones:SAR of quinolones, Nalidixic Acid,Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

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

UNIT – IV

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

Introduction to Drug Design
Various approaches used in drug design.
Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis.
Pharmacophore modeling and docking techniques.
Combinatorial Chemistry: Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.

Recommended Books (Latest Editions)

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

PY 601: MEDICINAL CHEMISTRY- III (Practical)

I Preparation of drugs and intermediates

Sulphanilamide
7-Hydroxy, 4-methyl coumarin
Chlorobutanol
Triphenyl imidazole
Tolbutamide
Hexamine

II Assay of drugs

Isonicotinic acid hydrazide
Chloroquine
Metronidazole
Dapsone
Chlorpheniramine maleate
Benzyl penicillin

III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV Drawing structures and reactions using chem draw®

V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

PY -602 PHARMACOLOGY-III (Theory)

UNIT-I

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

UNIT-II

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

UNIT-III

Chemotherapy
Antitubercular agents
Antileprotic agents
Antifungal agents
Antiviral drugs
Anthelmintics
Antimalarial drugs
Antiamoebic agents

UNIT-IV

Chemotherapy
Urinary tract infections and sexually transmitted diseases.
Chemotherapy of malignancy.
Immunopharmacology
Immunostimulants
Immunosuppressant
Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V

Principles of toxicology
Definition and basic knowledge of acute, subacute and chronic toxicity.
Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity

General principles of treatment of poisoning

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

Chronopharmacology

Definition of rhythm and cycles.

Biological clock and their significance leading to chronotherapy.

Recommended Books (Latest Editions)

Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier

Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill

Goodman and Gilman's, The Pharmacological Basis of Therapeutics

Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins

Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology

K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.

Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,

Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,

Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

PY 602 PHARMACOLOGY-III (Practical)

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

**Experiments are demonstrated by simulated experiments/videos*

PY 603 HERBAL DRUG TECHNOLOGY (Theory)

UNIT-I

Herbs as raw materials
Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation
Source of Herbs
Selection, identification and authentication of herbal materials Processing of herbal raw material
Biodynamic Agriculture
Good agricultural practices in cultivation of medicinal plants including Organic farming.
Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.
Indian Systems of Medicine
Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma.

UNIT-II

Nutraceuticals
General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.
Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina
Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

UNIT-III

Herbal Cosmetics
Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.
Herbal excipients
Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.
Herbal formulations :
Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

UNIT- IV
Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs
Stability testing of herbal drugs.
Patenting and Regulatory requirements of natural products:
Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT - V

General Introduction to Herbal Industry

Herbal drugs industry: Present scope and future prospects.

A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine

Components of GMP (Schedule – T) and its objectives

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

Recommended Books: (Latest Editions)

Textbook of Pharmacognosy by Trease & Evans.

Textbook of Pharmacognosy by Tyler, Brady & Robber.

Pharmacognosy by Kokate, Purohit and Gokhale

Essential of Pharmacognosy by Dr.S.H.Ansari

Pharmacognosy & Phytochemistry by V.D.Rangari

Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)

Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

PY 603 HERBAL DRUG TECHNOLOGY (Practical)

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista
3. Evaluation of excipients of natural origin

4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.

5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.

6. Monograph analysis of herbal drugs from recent Pharmacopoeias

7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids

PY 604 BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

UNIT - I

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** Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II

Elimination: Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, *in-vitro-in-vivo* correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT- III

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations.

Pharmacokinetics parameters - K_E ,t1/2,Vd,AUC,Ka, Clt and CL_R- definitions methods of eliminations, understanding of their significance and application

UNIT- IV

Multicompartment models: Two compartment open model. IV bolus
Kinetics of multiple dosing, steady state drug levels, calculation of loading and mainetnance doses and their significance in clinical settins.

UNIT- V

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

Recommended Books: (Latest Editions)

Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
Biopharmaceutics and Pharmacokinetics; By Robert F Notari

Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall Inernational edition.USA

Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi

Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.

Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.

Biopharmaceutics; By Swarbrick

Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and

Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.

Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.

Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
Remington’s Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

PY 605 PHARMACEUTICAL BIOTECHNOLOGY (Theory)

UNIT- I

Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.

Enzyme Biotechnology- Methods of enzyme immobilization and applications.

Biosensors- Working and applications of biosensors in Pharmaceutical Industries.

Brief introduction to Protein Engineering.

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

Basic principles of genetic engineering.

UNIT- II

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

UNIT- III

Types of immunity- humoral immunity, cellular immunity

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

UNIT-IV

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

UNIT-V

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

Recommended Books (Latest edition):

B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.

RA Goldshy et. al., : Kuby Immunology.
J.W. Goding: Monoclonal Antibodies.
J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.

Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.

S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.

Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

PY 606 PHARMACEUTICAL QUALITY ASSURANCE (Theory)

UNIT – I

Quality Assurance and Quality Management concepts: Definition and concept of Qualitycontrol, Quality assurance and GMP
Total Quality Management (TQM): Definition, elements, philosophies
ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines
Quality by design (QbD): Definition, overview, elements of QbD program, tools
ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration
NABL accreditation : Principles and procedures

UNIT -II

Organization and personnel: Personnel responsibilities, training, hygiene and personal records.
Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.
Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT – III

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

UNIT – IV

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.
Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT – V

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.
Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

Quality Assurance Guide by organization of Pharmaceutical Products of India.
Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
How to Practice GMP's – P P Sharma.

ISO 9000 and Total Quality Management – Sadhank G Ghosh
The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
Good laboratory Practices – Marcel Deckker Series
ICH guidelines, ISO 9000 and 14000 guidelines