SEMESTER VI

BP601T. MEDICINAL CHEMISTRY – III (Theory)

45 Hours

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

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

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.

Course Content:

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

UNIT – I **10 Hours**

Antibiotics

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

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

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline,Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II **10 Hours**

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity

relationship, Chemical degradation classification 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: Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*

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

Urinary tract anti-infective agents

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

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

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

UNIT – IV **08 Hours**

Antifungal agents:

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

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

Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide,

Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, 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 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.

BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

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

Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV Drawing structures and reactions using chem draw®

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

Recommended Books (Latest Editions)

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.

BP602 T. PHARMACOLOGY-III (Theory)

45 Hours

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

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

understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
comprehend the principles of toxicology and treatment of various poisoningsand appreciate correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I **10hours**

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 **10hours**

Chemotherapy

General principles of chemotherapy.

Sulfonamides and cotrimoxazole.

c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides

UNIT-III **10hours**

Chemotherapy

Antitubercular agents

Antileprotic agents

c. Antifungal agents

d. Antiviral drugs

e.Anthelmintics

f. Antimalarial drugs

g. Antiamoebic agents

UNIT-IV **08hours**

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 **07hours**

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.

BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

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

**Experiments are demonstrated by simulated experiments/videos*

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.

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

Scope: 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

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

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

know the WHO and ICH guidelines for evaluation of herbal drugs

know the herbal cosmetics, natural sweeteners, nutraceuticals

appreciate patenting of herbal drugs, GMP .

Course content:

UNIT-I **6 Hours**

Herbs as raw materials

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

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

Biodynamic Agriculture

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

UNIT-II **05 Hours**

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-III **7 Hours**

Nutraceuticals

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

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

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

UNIT-IV

Herbal Cosmetics

10 Hours

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- V **10 Hours**

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-VI **07 Hours**

General Introduction to Herbal Industry

Herbal drugs industry: Present scope and future prospects.

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

Schedule T – Good Manufacturing Practice of Indian systems of medicine

Components of GMP (Schedule – T) and its objectives

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

BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)

4 hours/ week

To perform preliminary phytochemical screening of crude drugs.

Determination of Ash value

Determination of moisture content of crude drugs

Determination of Extractive values of crude drugs

Determination of the alcohol content of Asava and Arista

Preparation of herbal cosmetics

Preparation and standardization of herbal formulation

Determination of swelling index and foaming index

Monograph analysis of herbal drugs from recent Pharmacopoeias

Analysis of fixed oils

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.

BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

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

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

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

Course Content:

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 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**

Drug Elimination renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

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

UNIT- III **10 Hours**

Pharmacokinetics: Introduction to Pharmacokinetics models, Compartment models,

Non compartment models, physiological models, One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion, extra vascular administrations, calculations of Ka, K_E. 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 Model

b). Repititive Extravascular dosing – One Compartment Open model

UNIT- V **07 Hours**

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity.

c. Michaelis-menton method of estimating parameters, Biotransformation of drugs

Recommended Books: (Latest Editions)

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

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Scope:

Biotechnology has a long promise to revolutionize the biological sciences and technology.

Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting.

Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs.

Biotechnology has already produced transgenic crops and animals and the future promises lot more.

It is basically a research-based subject.

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

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**

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 **10 Hours**

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 products:

Interferon b) Vaccines- hepatitis- B c) Hormones- Insulin.

Brief introduction to PCR

Types of immunity- humoral immunity, cellular immunity

Unit III **10 Hours**

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

Unit IV **08Hours**

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.

Unit V **07 Hours**

Types of mutation/mutants

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,

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

BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

Scope: 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.

Objectives: 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

Course content:

UNIT – I **10 Hours**

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, 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 procedure

UNIT - II **10 Hours**

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

UNIT – III **10 Hours**

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

materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

UNIT – IV **08 Hours**

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 **07 Hours**

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

Warehousing: Good warehousing practice, materials management

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