DR. A.P.J. ABDUL KALAM TECHNICAL UNIVERSITY, UTTAR PRADESH, LUCKNOW

EVALUATION SCHEME & SYLLABUS

BACHELOR OF PHARMACY

SIXTH SEMESTER

Course Code	Name of the Course	No. of Hours/ week	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
BP601T	Medicinal Chemistry III – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP602T	Pharmacology III – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP603T	Herbal Drug Technology – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP605T	Pharmaceutical Biotechnology– Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP606T	Quality Assurance– Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP607P	Medicinal Chemistry III – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP608P	Pharmacology III – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP609P	Herbal Drug Technology – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP610P	Report on Industrial Training	-	-	-	-	-	100	-	100	2
Total		**36**	**75**	**120**	**18 Hrs**	**195**	**655**	**30 Hrs**	**850**	**32**

SEMESTER VI

BP601T. MEDICINAL CHEMISTRY – III (Theory)

45 Hours

Course Content:

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, Cephalosporin, β-Lactamase inhibitors, Monobactams.

Aminoglycosides: Streptomycin, Neomycin, Kanamycin.

Tetracycline: 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.

Antimalarial: Etiology of malaria.

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

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovaquone.

Unit-III **10 Hours**

Anti-tubercular Agents:

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

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

Urinary tract anti-infective agents:

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

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

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

Unit-IV **08 Hours**

Antifungal agents:

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

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

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

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

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

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

Unit-V **07 Hours**

Introduction to Drug Design

Various approaches used in drug design.

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

Pharmacophore modeling and docking techniques.

Combinatorial Chemistry: Concept and applications of combinatorial Chemistry: Solid phase and solution phase synthesis.

BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Hours/week

I Preparation of drugs and intermediates:

1 Sulphanilamide.
2 7-Hydroxy, 4-methyl coumarin.
3 Chlorobutanol.
4 Triphenyl imidazole.
5 Tolbutamide.
6 Hexamine.

II Assay of drugs:

1 Isonicotinic acid hydrazide.
2 Chloroquine.
3 Metronidazole.
4 Dapsone.
5 Chlorpheniramine maleate.
6 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 (Lipinski's RO5).

Recommended Books (Latest Editions)

- Wilson and Gisvold's Organic Medicinal and Pharmaceutical Chemistry by Block J.H. and Beale J.M., Lippincott Williams and Wilkins.
- Foye's Principles of Medicinal Chemistry by Lemke T.L., Williams D.A., Roche V.F. and Zito S.W., Lippincott Williams and Wilkins.
- Burger's Medicinal Chemistry and Drug Discovery by Abraham D.J., Vol I to IV. John Wiley and Sons Inc., New York.
- Synthesis of Essential Drugs by Vardanyan R.S. and Hruby V.J., Elsevier.
- Medicinal Chemistry: A Biochemical Approach by Nogrady T., Oxford University Press, New York.
- Textbook of Drug Design and Discovery edited by K. Stromgaard, P.V. Larsen and U. Madsen, CRC Press, NY.
- An Introduction to Medicinal Chemistry by Patrick Graham, L., Oxford University Press.
- The Organic Chemistry of Drug Design and Drug Action by Silverman R.B., Elsevier.
- Introduction to Principles of Drug Design by Smith and Williams.
- New Approaches to Drug Development edited by P. Jolles, Library of Congress Cataloging-in-Publication Data, Germany.

- Textbook of Drug Design and Discovery by Larsen P.K., Liljefors T. and Madsen U., Taylor and Francis Inc.

- Martindale's Extra Pharmacopoeia.
- The Organic Chemistry of Drug Design and Drug Action by Richard B. Silverman, Academic Press, USA.
- Elementary Practical Organic Chemistry by Vogel A.I., Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.
- Practical Organic Chemistry by Mann F.G, and Saunders, B.C., Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.
- The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1 to 5.
- The Pharmacopoeia of India, the Controller of Publications, Delhi.

BP602T. PHARMACOLOGY-III (Theory)

45 Hours

Course Content

Unit-I **10 hours**

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 **10 hours**

Chemotherapy: General principles of chemotherapy.

Sulfonamides and Cotrimoxazole.

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

Unit-III **10 hours**

Chemotherapy:

Antitubercular agents.

Antileprotic agents.

Antifungal agents.

Antiviral drugs.

Anthelmintics.

Antimalarial drugs.

Antiamoebic agents.

Unit-IV **08 hours**

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 **07 hours**

Principles of toxicology:

Definition and basic knowledge of acute, sub-acute 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, and organophosphosphorus compound and lead, mercury and arsenic poisoning.

Chronopharmacology:

Definition of rhythm and cycles.

Biological clock and their significance leading to chronotherapy.

BP608P. PHARMACOLOGY-III (Practical)

4Hrs/Week

1. Dose calculation in pharmacological experiments.
2. Anti-allergic 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-autoanalyzer.
7. Effect of saline purgative on frog intestine.
8. Insulin hypoglycemic effect in rabbit.
9. Test for pyrogens (rabbit method).
10. Determination of acute oral toxicity (LD50) of a drug from a given data.
11. Determination of acute skin irritation / corrosion of a test substance.
12. Determination of acute eye irritation / corrosion of a test substance.
13. Calculation of pharmacokinetic parameters from a given data.
14. Biostatistics methods in experimental pharmacology (student's t test, ANOVA).
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test).

**Experiments are demonstrated by simulated experiments/videos.*

Recommended Books (Latest Editions)

- Rang and Dale's Pharmacology by Rang H.P., Dale M.M., Ritter J.M., Flower R.J., Churchill Livingstone Elsevier.
- Basic and Clinical Pharmacology by Katzung B.G., Masters S.B., Trevor A.J., Tata McGraw-Hill.
- The Pharmacological Basis of Therapeutics by Goodman and Gilman's, McGraw Hill, USA.
- Applied Therapeutics: The Clinical Use of Drugs by Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A.K., Bradley R.W., The Point Lippincott Williams & Wilkins.
- Lippincott's Illustrated Reviews- Pharmacology by Mycek M.J., Gelnet S.B. and Perper M.M.
- Essentials of Medical Pharmacology by K.D. Tripathi, Jaypee Brothers Medical Publishers (P) Ltd, New Delhi.
- Principles of Pharmacology, Sharma H.L., Sharma K.K., Paras Medical Publisher.
- Modern Pharmacology with Clinical Applications by Charles R. Craig & Robert.
- Fundamentals of Experimental Pharmacology by Ghosh M.N., Hilton & Company, Kolkata,
- Handbook of Experimental Pharmacology by Kulkarni S.K., Vallabh Prakashan,
- Concepts in Chronopharmacology by N. Udupa and P.D. Gupta.

BP603T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

Course content:

Unit-I **10 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.

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 **8 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: Alfa-alfa, 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 **10 Hours**

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 **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-V **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 page, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

P609P. HERBAL DRUG TECHNOLOGY (Practical)

4 Hours/ week

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.

Recommended Books: (Latest Editions)

- Trease and Evans Pharmacognosy by W. C. Evans, 16th edition, W.B. Sounders & Co., London.
- Textbook of Industrial Pharmacognosy by A.N. Kalia, CBS Publishers & Distributers Pvt. Ltd., New Delhi.
- Textbook of Pharmacognosy by Tyler, Brady & Robber, CBS Publishers & Distributers Pvt. Ltd., New Delhi.
- Handbook of Cosmetic Science & Technology by M. Paye, A.D. Barel, H. Maibach, Informa Healthcare, NY.
- Cosmetics Formulation, Manufacture and QA by P.P. Sharma, 4th edition, Vandana Publication Pvt. Ltd.
- Poucher's Perfumes, Cosmetics and Soaps edited by Hilda Bulter, Springer (India) Pvt. Ltd., New Delhi.
- Textbook of Pharmacognosy by C.K. Kokate, Purohit, Gokhale, Nirali Prakashan, New Delhi.
- Essential of Pharmacognosy by Dr. S.H. Ansari, Birla Publications Pvt. Ltd., Delhi.
- Pharmacopeial Standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy).
- Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals by Mukherjee, P.W. Business Horizons Publishers, New Delhi.

BP604T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

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 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 **10 Hours**

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 **10 Hours**

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. Intravenous Injection (Bolus), Intravenous infusion and 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 **08 Hours**

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

Unit-V **07 Hours**

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

Recommended Books: (Latest Editions)

- Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew, B.C.Y.U. 4th edition Prentice-Hall International edition. USA.
- Biopharmaceutics and Pharmacokinetics-A Treatise by D.M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi.
- Handbook of Clinical Pharmacokinetics by Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- Biopharmaceutics by Swarbrick, Lea and Febiger, USA.
- Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, PharmaMed Press, Hyderabad.
- Textbook of Biopharmaceutics and Clinical Pharmacokinetics by Sarfaraz Niazi, PharmaMed Press, Hyderabad.
- Basic Pharmacokinetics by Mohsen A. Hedaya, CRC Press, NY.
- Biopharmaceutics and Pharmacokinetics by V. Ventashewarlu, PharmaMed Press, Hyderabad.
- Clinical Pharmacokinetics, Concepts and Applications by Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.
- Dissolution, Bioavailability and Bioequivalence by Abdou H.M, Mack, Publishing Company, Pennsylvania, 1989.
- Biopharmaceutics and Clinical Pharmacokinetics: An Introduction by Robert F. Notari, 4th edition, Marcel Dekker Inc., New York.

BP605T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Course content:

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 production of:

i) Interferon
ii) Vaccines- hepatitis- B
iii) Hormones-Insulin.

Brief introduction to PCR.

Unit-III **10 Hours**

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 infections, 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 Substitutes.

Unit-IV **08 Hours**

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 **07 Hours**

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 Substitutes.

Recommended Books (Latest edition):

- Molecular Biotechnology: Principles and Applications of Recombinant DNA by B.R. Glick and J.J. Pasternak, ASM Press Washington D.C.
- Kuby Immunology by R.A. Goldsby *et. al.*, W.H. Freeman and Company, NY.
- Biotechnology by U. Satyanarayan, Books and allied Pvt. Ltd., Kolkata.
- Industrial Microbiology by L.E. Casida Jr., New Age International Pub., New Delhi.
- Crueger's Biotechnology- A textbook of Industrial Microbiology by Crueger and Aneja, Medtech, New Delhi.
- Monoclonal Antibodies by J.W. Goding, Academic Press.
- Molecular Biology and Biotechnology by J.M. Walker and E.B. Gingold, Royal Society of Chemistry.
- Immobilized Enzymes by Zaborsky, CRC Press, Ohio.
- Molecular Biotechnology by S.B. Primrose, Blackwell Scientific Publication.
- Principles of Fermentation Technology by Stanbury F.P., Whitakar A., and Hall J.S., 2nd ed., Aditya books Ltd., New Delhi.
- Pharmaceutical Biotechnology: Concepts and Applications by G. Walsh, Wiley and Sons Pvt. Ltd., USA.
- Pharmaceutical Biotechnology: Biochemistry and Biotechnology by G. Walsh, Wiley and Sons Pvt. Ltd., USA.

BP606T. PHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

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 procedures.

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: Equipment 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 Guidelines and Related Materials, Volume-I, WHO Publications.
- A Guide to Total Quality Management by Kushik Maitra and Sedhan K. Ghosh.
- How to Practice GMPs by P.P. Sharma, Vandana Publications Pvt. Ltd., Delhi.
- How to Practice GLP by P.P. Sharma, Vandana Publications Pvt. Ltd., Delhi.
- ISO 9000 and Total Quality Management by Sadhank G. Ghosh, Oxford Publishing House, UK.
- The International Pharmacopoeia – Volume I, II, III, IV- General Methods of Analysis and Quality Specification for Pharmaceutical Substances, Excipients and Dosage forms.
- Good Laboratory Practices by Marcel Dekker Series.
- ICH guidelines, ISO 9000 and 14000 guidelines.
- Quality Control of Packaging Materials in the Pharmaceutical Industry by Kenneth and Harburn, Marcel Dekker, Inc., NY.
- cGMP (Current Good Manufacturing Practices) for Pharmaceuticals, Manohar A. Potdar, PharmaMed Press, Hyderabad.
- Lachman/Lieberman's Theory and Practice of Industrial Pharmacy by Roop K. Khar, S.P. Vyas, F.J. Ahmad and G.K. Jain, CBS Publishers & Distributers Pvt. Ltd., New Delhi.
- N.K. Jain, Pharmaceutical Product Development, CBS Publishers & Distributers Pvt. Ltd., New Delhi.
- Production and Operation Management by S.N. Chary, 3rd edition, Tata McGraw-Hill Education
- Concepts of Quality Management in Pharmaceutical Industry by Manohar A. Potdar, PharmaMed press, Hyderabad.
- Quality Assurance and Quality Management in Pharmaceutical Industry by Y. Anjaneyulu; R. Marayya, PharmaMed press.
- Pharmaceutical Quality Assurance and Quality management by Bhusari K.P; Shivhare U.D; Goupale D.C., PharmaMed press, Hyderabad.
- Modern Pharmaceutics by Gilbert S. Banker; Christopher T. Rhodes, 4th edition; (vol-121), Marcel Dekker, Inc., NY.
- Pharmaceutical Facilities: Design by Manohar. A. Potdar, Layout and Validation, 2nd edition; PharmaMed press, Hyderabad.
- Pharmaceutical Packaging Technology by V.K. Jain, D.C. Goupale, S. Nayak, PharmaMed press, Hyderabad.
- Quality Control & Total Quality Management by P.L. Jain, Tata McGraw Hill, New Delhi.

BP610P. REPORT ON INDUSTRIAL TRAINING

Training of students at an industrial establishment or an approved research laboratory. The industrial training shall include: in case of industry- different sections and subsections of the industry, an idea about the functioning of the industry, product range of the industry and various approvals of the industry; in case of research laboratory- different departments of the laboratory, an idea about the interdisciplinary coordination, contribution of the laboratory to the society and various approvals of the laboratory. A proper report of the same shall be submitted by the students, which shall be subsequently evaluated to assess the impact of the visit.

May be performed at the end of the 5th semester.