

## **SEMESTER V**

## BP501T. MEDICINAL CHEMISTRY – II (Theory)

45 Hours

### 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 (\*).

#### Unit-I

10 Hours

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

**H<sub>1</sub>-antagonist:** Diphenhydramine hydrochloride\*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Triphelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride\*, Phenidamine tartrate, Promethazine hydrochloride\*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine Cromolyn sodium.

**H<sub>2</sub>-antagonists:** Cimetidine\*, Famotidine, Ranitidine.

**Gastric proton-pump inhibitors:** Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole.

**Anti-neoplastic agents:**

**Alkylating agents:** Meclorothamine\*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepea.

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

**Antibiotics:** Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin.

**Plant products:** Etoposide, Vinblastine sulphate, Vincristine sulphate.

**Miscellaneous:** Cisplatin, Mitotane.

#### Unit-II

10 Hours

**Anti-anginal:** Vasodilators: Amyl Nitrite, Nitroglycerin\*, Pentaerythritol tetranitrate, Isosorbide dinitrite\*, Dipyridamole.

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

**Diuretics:** Carbonic Anhydrase Inhibitors: Acetazolamide\*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide\*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop Diuretics: Furosemide\*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride. Osmotic Diuretics: Mannitol.

**Anti-hypertensive Agents:** Timolol, Captopril, Lisinopril, Enalapril, Benazepril

hydrochloride, Quinapril Hydrochloride, Methyldopate Hydrochloride\* Clonidine hydrochloride, Guanethidine Monosulphate, Guanabenz Acetate, Sodium Nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

### **Unit-III**

**10 Hours**

**Anti-arrhythmic Drugs:** Quinidine Sulphate, Procainamide Hydrochloride, Disopyramide Phosphate\*, Phenytoin Sodium, Lidocaine Hydrochloride, Tocainide Hydrochloride, Mexiletine Hydrochloride, Lorcaïnide Hydrochloride, Amiodarone, Sotalol.

**Anti-hyperlipidemic agents:** Clofibrate, Lovastatin, Cholestyramine and Colestipol.

**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, Andralone, Progesterones, Oestriol, Oestradiol, Oestrione, Diethyl Stilbestrol.

**Drugs for erectile dysfunction:** Sildenafil, Tadalafil.

**Oral contraceptives:** Mifepristone, Norgestrel, Levonorgestrel

**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.

Sulfonylureas: 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, Dipiperodon, Dibucaine.

### **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, NY.
- 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., Volume I to IV, John Wiley and Sons Inc., New York.
- Synthesis of Essential Drugs by Vardanyan R.S. and Hruby V.J., Elsevier.
- Introduction to Medicinal Chemistry by Alex Gringauz, Wiley VCH.
- An Introduction to Medicinal Chemistry by Patrick Graham L., Oxford University Press.
- Medicinal Chemistry: A Biochemical Approach by Nogrady T., Oxford University Press, New York.
- The Organic Chemistry of Drug Design and Drug Action by Silverman R.B., Elsevier.
- Introduction to Principles of Drug Design by Smith and Williams, CRC Press, US.
- Medicinal and Pharmaceutical Chemistry by Singh H. and Kapoor V.K., Vallabh Prakashan, Delhi.
- Textbook of Drug Design and Discovery by Larsen P.K., Liljefors T. and Madsen U., Taylor and Francis Inc.
- Martindale's Extra Pharmacopoeia.
- Organic Chemistry by I.L. Finar, Vol. II, Dorling Kindersley (India) Pvt. Ltd., Delhi.
- The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1 to 5.
- The Pharmacopoeia of India, the Controller of Publications, Delhi.
- Elementary Practical Organic Chemistry by Vogel A.I., Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.

## BP502T. INDUSTRIAL PHARMACY I (Theory)

45 Hours

### Course content:

#### Unit-I

07 Hours

**Pre-formulation Studies:** Introduction to pre-formulation, goals and objectives, study of physicochemical characteristics of drug substances.

**Physical properties:** Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism.

**Chemical Properties:** Hydrolysis, oxidation, reduction, racemization, polymerization.

BCS classification of drugs & its significance.

Application of pre-formulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

#### Unit-II

10 Hours

##### Tablets:

Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipment's and tablet tooling.

Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating. Quality control tests: In process and finished product tests.

##### Liquid orals:

Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in Pharmacopoeia.

#### Unit-III

08 Hours

##### Capsules:

**Hard gelatin capsules:** Introduction, Production of hard gelatin capsule shells. Size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

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

**Pellets:** Introduction, formulation requirements, palletization process, and equipment for manufacture of pellets.

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

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

Production procedure, production facilities and controls, aseptic processing.

Formulation of injections, sterile powders, large volume parenteral and lyophilized products.

Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

**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.

## BP506P. INDUSTRIAL PHARMACY I (Practical)

4 Hours/week

1. Preformulation studies of Paracetamol/Aspirin/or any other drug.
2. Preparation and evaluation of Paracetamol tablets.
3. Preparation and evaluation of Aspirin tablets.
4. Coating of tablets- film coating of tables/granules.
5. Preparation and evaluation of Tetracycline capsules.
6. Preparation of Calcium Gluconate injection.
7. Preparation of Ascorbic Acid injection.
8. Quality control test of (as per IP) marketed tablets and capsules.
9. Preparation of Eye drops/ and Eye ointments.
10. Preparation of Creams (cold / vanishing cream).
11. Evaluation of glass containers (as per IP).

### Recommended Books: (Latest Editions)

- Modern Pharmaceutics by Gilbert S. Banker; Christopher T. Rhodes, 4<sup>th</sup> edition; (Volume-121), Marcel Dekker, Inc., NY.
- Pharmaceutical Dosage Forms by Lieberman H.A., Lachman C., Parenteral Medications, Volume 1-3, Marcel Dekker Inc., USA.
- Pharmaceutical Dosage Forms by Lieberman H.A, Lachman C., Tablets, Volume 1-3, Marcel Dekker Inc., USA.
- Pharmaceutical Dosage Forms by Lieberman H.A, Lachman C., Disperse System, Volume 1-3, Marcel Dekker Inc., USA.
- The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS) by Remington.
- 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 & Distributors Pvt. Ltd., New Delhi.
- Pharmaceutics-The Science of Dosage form Design by M.E. Aulton, Churchill Livingstone, Latest edition.
- Introduction to Pharmaceutical Dosage Forms by H.C. Ansel, Lea & Febiger, Philadelphia, 5<sup>th</sup> edition, 2005.
- Drug stability- Principles and Practice by Cartensen & C.J. Rhodes, 3<sup>rd</sup> Edition, Marcel Dekker Series.
- Bentley and Driver's Textbook of Pharmaceutical Chemistry, Oxford University Press, New Delhi.
- J. Swarbrick, J.C. Boylar, 2<sup>nd</sup> ed., Encyclopedia of Practical Technology, Vol. 1-3, 2004. (Updated supplement).

**BP503T. PHARMACOLOGY-II(Theory)****45 Hours****Course Content:****Unit-I****10 Hours****Pharmacology of drugs acting on cardio-vascular system**

Introduction to hemodynamic and electrophysiology of heart Drugs used in congestive heart failure.

Anti-hypertensive drugs.

Anti-anginal drugs.

Anti-arrhythmic drugs.

Anti-hyperlipidemic drugs.

**Unit-II****10 Hours****Pharmacology of drugs acting on cardio vascular system**

Drug used in the therapy of shock.

Hematinics, coagulants and anticoagulants.

Fibrinolytics and anti-platelet drugs.

Plasma volume expanders.

**Pharmacology of drugs acting on urinary system**

Diuretics.

Anti-diuretics.

**Unit-III****10 Hours****Autacoids and related drugs**

Introduction to autacoids and classification of Histamine, 5-HT and their antagonists.

Prostaglandins, Thromboxanes and Leukotrienes.

Angiotensin, Bradykinin and Substance P.

Non-steroidal anti-inflammatory agents.

Antigout drugs, Anti rheumatic drugs.

**Unit-IV****08 Hours****Pharmacology of drugs acting on endocrine system**

Basic concepts in endocrine pharmacology.

Anterior Pituitary hormones- analogues and their inhibitors.

Thyroid hormones- analogues and their inhibitors.

Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin D.

Insulin, Oral Hypoglycemic agents and glucagon. ACTH and corticosteroids.

**Unit-V****07 Hours****Pharmacology of drugs acting on endocrine system**

Androgens and Anabolic steroids. Estrogens, progesterone and oral contraceptives. Drugs acting on the uterus.

**Bioassay**

Principles and applications of bioassay. Types of bioassay.

Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT.

## BP507P. PHARMACOLOGY-II(Practical)

4Hours/Week

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog *rectus abdominis* muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog *rectus abdominis* muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three-point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four-point bioassay.
11. Determination of PA<sub>2</sub> value of prazosin using rat anococcygeus muscle (by Schild plot method).
12. Determination of PD<sub>2</sub> value using guinea pig ileum.
13. Effect of spasmogens and spasmolytic using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

*Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by software and 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., 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, New Delhi.
- Principles of Pharmacology by Sharma H. L., Sharma K. K., Paras medical publisher.
- Modern Pharmacology with Clinical Applications by Charles R. Craig & Robert, Lippincott Williams & Wilkins, USA.
- Fundamentals of Experimental Pharmacology by Ghosh M.N., Hilton & Company.
- Handbook of Experimental Pharmacology by Kulkarni S.K., Vallabh Prakashan.

**BP504T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)**

**45Hours**

**Course Content:**

**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**

**14 Hours**

General introduction, composition, chemistry & chemical classes, bio -sources, 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.

**Tannins:** Catechu, Pterocarpus.

**Resins:** Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony.

**Glycosides:** Senna, Aloes, Bitter Almond.

**Iridoids, Other terpenoids & Naphthaquinones:** Gentian, Artemisia, Taxus, carotenoids.

**Unit-III**

**06 Hours**

Isolation, Identification and Analysis of Phytoconstituents.

Terpenoids: Menthol, Citral, Artemisin.

Glycosides: Glycyrrhetic acid & Rutin.

Alkaloids: Atropine, Quinine, Reserpine, Caffeine

Resins: Podophyllotoxin, Curcumin.

**Unit-IV**

**10 Hours**

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

**Unit-V**

**8 Hours**

**Basics of Phytochemistry**

Modern methods of extraction, application of latest techniques like Spectroscopy, Chromatography and electrophoresis in the isolation, purification and identification of crude drugs.

## **BP508P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)**

**4 Hours/Week**

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander.
2. Exercise involving isolation & detection of active principles:
  - a. Caffeine - from tea dust.
  - b. Diosgenin from Dioscorea.
  - c. Atropine from Belladonna.
  - d. Sennosides from Senna.
3. Separation of sugars by Paper chromatography.
4. TLC of herbal extract.
5. Distillation of volatile oils and detection of phytoconstituents by TLC.
6. Analysis of crude drugs by chemical tests:
  - (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh.

### **Recommended Books: (Latest Editions)**

- Trease and Evans Pharmacognosy by W.C. Evans, 16th edition, W.B. Saunders & Co., London.
- Pharmacognosy and Phytochemistry by Mohammad Ali, CBS Publishers and Distribution.
- Textbook of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.
- Herbal Drug Industry by R.D. Choudhary, 1<sup>st</sup> Ed, Eastern Publisher, New Delhi.
- Essentials of Pharmacognosy by Dr. S.H. Ansari, 2<sup>nd</sup> Ed, Birla publications, New Delhi.
- Herbal Cosmetics by H. Panda, Asia Pacific Business Press, Inc., New Delhi.
- Textbook of Industrial Pharmacognosy by A.N. Kalia, CBS Publishers, New Delhi.
- Plant Cell Biotechnology by R. Endress, Springer-Verlag, Berlin, 1994.
- Pharmacognosy & Pharmacobiotechnology by James Bobbers, Marilyn KS, VE Tylor.
- The Formulation and Preparation of Cosmetic, Fragrances and Flavors by Louis Appell, Micelle Press.
- The Science and Practice of Pharmacy, 20<sup>th</sup> edition Pharmaceutical Science (RPS) by Remington.
- Textbook of Biotechnology by Vyas and Dixit, CBS Publishers & Distributers Pvt. Ltd., New Delhi.
- Biosynthesis of Natural Products by Manitto P., Ellis Horwood Limited.

**BP505T. PHARMACEUTICAL JURISPRUDENCE (Theory)**

**45 Hours**

**Course Content:**

**Unit-I** **10 Hours**

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

Objectives, Definitions, Legal definitions of schedules to the Act and Rules.

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

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

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

**Unit-II** **10 Hours**

**Drugs and Cosmetics Act, 1940 and its rules 1945**

Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA)  
Sale of Drugs – Wholesale, Retail sale and restricted license. Offences and penalties.

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules– Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, licensing authorities, controlling authorities, Drugs Inspectors.

**Unit-III** **10 Hours**

**Pharmacy Act-1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties.

**Medicinal and Toilet Preparation Act-1955:** Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.

**Narcotic Drugs and Psychotropic substances Act-1985 and Rules:** Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties.

**Unit-IV****08 Hours**

**Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.

**Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSE guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.

**National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM).

**Unit-V****07 Hours**

**Pharmaceutical Legislations** - A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee.

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

**Medical Termination of Pregnancy Act**

**Right to Information Act**

**Introduction to Intellectual Property Rights (IPR)**

**Recommended books: (Latest Edition)**

- Forensic Pharmacy by B. Suresh, Birla Publication Pvt. Ltd., Delhi.
- Textbook of Forensic Pharmacy by B.M. Mittal, Vallabh Prakashan, Delhi.
- Handbook of Drug Law by M.L. Mehra, the University Book Agency, Lucknow.
- A Textbook of Forensic Pharmacy by N.K. Jain, Vallabh Prakashan, Delhi.
- Drugs and Cosmetics Act/Rules, Govt. of India publications.
- Medicinal and Toilet Preparations Act 1955, Govt. of India Publications.
- Narcotic Drugs and Psychotropic Substances Act, Govt. of India Publications.
- Drugs and Magic Remedies Act, Govt. of India Publication.
- Bare Acts of the Laws.
- Intellectual Property Rights in Pharmaceutical Industry: Theory and Practice by B. Subba Rao and P.V. Appaji, PharmaMed Press, Hyderabad.

### **BP509P. HOSPITAL TRAINING-I**

Training of students at a hospital establishment for a minimum duration of 45 days. The hospital training shall include: First aid (wound dressing, artificial respiration etc.), different routes of injection, study of patient observation charts, prescriptions and dispensing, simple diagnostic reports, etc.

**May be performed at the end of the 4<sup>th</sup> semester.**

## **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.

**$\beta$ -Lactam antibiotics:** Penicillin, Cephalosporin,  $\beta$ -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 fluoroquinolones, 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 organophosphorus 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. Saunders & 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, 4<sup>th</sup> 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.
- Pharmacopoeial 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 through 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 –  $K_E$ ,  $t_{1/2}$ ,  $V_d$ , AUC,  $K_a$ ,  $Cl_t$  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. Brahmkar 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, 4<sup>th</sup> 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., 2<sup>nd</sup> 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, 2<sup>nd</sup> 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 & Distributors Pvt. Ltd., New Delhi.
- N.K. Jain, Pharmaceutical Product Development, CBS Publishers & Distributors Pvt. Ltd., New Delhi.
- Production and Operation Management by S.N. Chary, 3<sup>rd</sup> 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, 4<sup>th</sup> edition; (vol-121), Marcel Dekker, Inc., NY.
- Pharmaceutical Facilities: Design by Manohar. A. Potdar, Layout and Validation, 2<sup>nd</sup> 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 5<sup>th</sup> semester.**