BP103T. PHARMACEUTICS- I (Theory) 45 Hours

Scope: This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

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

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

Course Content:

UNIT – I **10 Hours**

- **Historical background and development of profession of pharmacy**: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career.
- **Dosage forms:** Introduction to dosage forms, classification and definitions
- **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.
- **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

UNIT – II **10 Hours**

- **Pharmaceutical calculations**: Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.
- **Powders:** Definition, classification, advantages and disadvantages,Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.
- **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

UNIT – III **10 Hours**

- **Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.
- **Biphasic liquids:**
  Suspensions: Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.

  Emulsions: Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

UNIT – IV **08 Hours**

- **Suppositories**: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.
- **Pharmaceutical incompatibilities**: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

UNIV – V **07 Hours**

- **Semisolid dosage forms:** Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms

BP109P. PHARMACEUTICS I (Practical)

4 Hours / week

1 . Syrups

a) Syrup IP'66

b) Compound syrup of Ferrous Phosphate BPC'68

2. Elixirs a) Piperazine citrate elixir

b) Paracetamol pediatric elixir

3.Linctus a) Terpin Hydrate Linctus IP'66

b) Iodine Throat Paint (Mandles Paint)

4. Solutions

a) Strong solution of ammonium acetate

b) Cresol with soap solution

c) LugOL'S SOLUTion

5. Suspensions (Any two experiments)

a) Calamine lotion

b) Magnesium Hydroxide mixture

c) Aluminimum Hydroxide gel

6. Emulsions a) Turpentine Liniment

b) Liquid paraffin emulsion

7. Powders and Granules (Any three experiments)

a) ORS powder (WHO)

b) Effervescent granules

c) Dusting powder

d) Divided powders

8. Suppositories (Any two experiments)

a) Glycero gelatin suppository

b) Coca butter suppository

c) Zinc Oxide suppository

8. Semisolids (Any two experiments)

a) Sulphur ointment

b) Non staining-iodine ointment with methyl salicylate

c) Carbopol gel

9. Gargles and Mouthwashes

a) Iodine gargle

b) Chlorhexidine mouthwash

Recommended Books:

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy,Lea& Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory) - 45 Hours

Scope: The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

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

1. to know the techniques in the cultivation and production of crude drugs
2. to know the crude drugs, their uses and chemical nature
3. know the evaluation techniques for the herbal drugs
4. to carry out the microscopic and morphological evaluation of crude drugs

Course Content:

UNIT-I **10 Hours**

Introduction to Pharmacognosy:

(a) Definition, history, scope and development of Pharmacognosy

(b) Sources of Drugs – Plants, Animals, Marine & Tissue culture

(c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs:

Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs

Quality control of Drugs of Natural Origin:

- Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties.
- Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT-II **10 Hours**

Cultivation, Collection, Processing and storage of drugs of natural origin:

- Cultivation and Collection of drugs of natural origin
- Factors influencing cultivation of medicinal plants.
- Plant hormones and their applications.
- Polyploidy, mutation and hybridization with reference to medicinal plants

Conservation of medicinal plants

UNIT-III **07 Hours**

Plant tissue culture:

- Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance.
- Applications of plant tissue culture in pharmacognosy.
- Edible vaccines

UNIT-IV **10 Hours**

Plant description, morphology and anatomy:

Leaves, Roots, Barks, Wood, Flowers, Fruits, Seeds, subterranean organs

Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

UNIT-V **08 Hours**

Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs

Plant Products:

- Fibers - Cotton, Jute, Hemp
- Hallucinogens, Teratogens, Natural allergens

Primary metabolites: General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites:

Carbohydrates: Acacia, Agar, Tragacanth, Honey

Proteins and Enzymes: Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).

Lipids (Waxes, fats, fixed oils): General methods of extraction of lipids.

Castor oil, Chaulmoogra oil, Shark liver oil and Cod liver oil, Wool Fat, Bees Wax

Marine Drugs:

Novel medicinal agents from marine sources a) Cardiovascular agents and b) Anti cancer agents

BP406P. MEDICINAL CHEMISTRY – I (Practical) 4Hrs/week

Synthesis of following medicinally important compounds / drug intermediates with Recrystallization of compound and monitoring reactions with TLC

Preparation of drugs/ intermediates (any six) 10 turns

- 1,3-pyrazole
- 1,3-oxazole
- Benzimidazole
- Benztriazole
- 2,3- diphenyl quinoxaline
- Benzocaine
- Phenytoin
- Phenothiazine
- Barbiturate

Glucosidase inhibitors: Acrabose, Voglibose.

DPP IV inhibitors -Sitagliptin, Teneligliptin

SGLT2 inhibitors – Empagliflozin, Canagliflozin

b) Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives; Meprylcaine, Cyclomethycaine, Piperocaine.

Amino Benzoic acid derivatives: Benzocaine, Procaine, Butacaine, Propoxycaine, Tetracaine.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine

[Tolbutamide, Benzocaine]

Recommended Books (Latest Editions)

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

BP 502 T. Industrial Pharmacy I (Theory) **45 Hours**

Scope:

Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

Objectives:

Upon completion of the course the student shall be able to

1. illustrate various pharmaceutical dosage forms and their manufacturing techniques.
2. describe various factors to be considered in development of pharmaceutical dosage forms
3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

Course content: **3 hours/ week**

UNIT-I **03 Hours**

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

UNIT-II **14 Hours**

Tablets:

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, preformulation and Formulation of tablets, granulation methods, compression and processing problems, Equipments and tablet tooling.

b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.

c. Quality control tests: In process and finished product tests

Liquid orals: Preformulation, 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:

a. 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.

b. 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, pelletization process, equipments for manufacture of pellets

UNIT-IV **10 Hours**

Parenteral Products:

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

b. Production procedure, production facilities and controls, aseptic processing

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

d. 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; preformulation, 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.

Recommended Books: (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz

2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman

3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman

4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition

5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)

6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman

7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition

8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger,Philadelphia, 5thedition, 2005

9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition,Marcel Dekker Series, Vol 107.

BP503.T. PHARMACOLOGY-II (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 different systems of body and in addition, emphasis on the basic concepts of bioassay.

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

1. Understand the mechanism of drug action and its relevance in the treatment of different diseases

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

a) Terpenoids: Menthol, Citral, Artemisin

b) Glycosides: Glycyrhetinic acid & Rutin

c) Alkaloids: Atropine,Quinine,Reserpine,Caffeine

d) Resins: Podophyllotoxin, Curcumin

UNIT-IV **06 Hours**

Industrial production, estimation and utilization of the following phytoconstituents:

Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

UNIT V **12 Hours**

Basics of Phytochemistry

Methods of extraction (Soxhlet, Maceration, Percolation , Supercritical fluid extraction, Microwave assisted extraction, Ultrasound assisted extraction , Solid Phase Extraction)

Application of latest techniques like Spectroscopy, Chromatography and electrophoresis in the isolation, purification and identification of crude drugs

Non-chromatographic separation techniques: Fractional distillation, fractional liberation, sublimation, chemical derivatization, fractional crystallization, centrifugation, Froth floatation technique.

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory) 45 Hours

Scope:

This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India.

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

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.

2. Various Indian pharmaceutical Acts and Laws

3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals

4. The code of ethics during the pharmaceutical practice

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 122 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, CPCSEA 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)

1. Forensic Pharmacy by B. Suresh
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-byM.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9.Bare Acts of the said laws published by Government. Reference books (Theory) 124

BP 506 P. Industrial PharmacyI (Practical) **4 Hours/week**

1. Preformulation studies on paracetamol/asparin/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. Qulaity 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)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger,Philadelphia, 5thedition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition,Marcel Dekker Series, Vol 107.

BP 507 P. PHARMACOLOGY-II (Practical) 4Hrs/Week

Sr. No	Experiment
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

UNIT – VI **03 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, Ferguson principle.

Recommended Books (Latest Editions)

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

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:

1. Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. Comprehend the principles of toxicology and treatment of various poisonings and appreciate correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I **10hr**

Pharmacology of drugs acting on Respiratory system

a. Anti -asthmatic drugs
b. Drugs used in the management of COPD
c. Expectorants and antitussives
d. Nasal decongestants
e. Respiratory stimulants

Pharmacology of drugs acting on the Gastrointestinal Tract

a. Antiulcer agents.
b. Drugs for constipation and diarrhoea.
c. Appetite stimulants and suppressants.
d. Digestants and carminatives.
e. Emetics and anti-emetics.

UNIT-II

Chemotherapy **10hr**

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

UNIT-III

Chemotherapy **10hr**

a. Antitubercular agents
b. Antileprotic agents

c. Antifungal agents
d. Antiviral drugs
a. Anthelmintics
e. Antimalarial drugs
f. Antiamoebic agents

UNIT-IV

Chemotherapy **08hr**

a. Urinary tract infections and sexually transmitted diseases.

b. Chemotherapy of malignancy.

Immunopharmacology

a. Immunostimulants
b. Immunosuppressant

Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V

Principles of toxicology **07hr**

a. Definition and basic knowledge of acute, subacute and chronic toxicity.
b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
c. General principles of treatment of poisoning
d. Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning.

Chronopharmacology

a. Definition of rhythm and cycles.
b. Biological clock and their significance leading to chronotherapy.

Recommended Books (Latest Editions)

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

2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata McGraw-Hill
3. Goodman and Gilman‟s, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A.K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point LippincottWilliams &Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott‟s Illustrated Reviews-Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers MedicalPublishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

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:

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .

Course content:

UNIT-I **11 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

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy

b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma.

Pharmacognosy in various systems of medicine:

Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine.

UNIT-II **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

Study of Omega-3-polyunsaturated fatty acids, Dietary fibers, Carotenoids, proanthocyanidins, and Resveratrol

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

Market overview, ,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:

Market overview , Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal formulations :

Market overview, Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

UNIT- IV **12 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:

a) Definition of the terms: Patent, IPR, Farmers right, Breeder‟s right, Bioprospecting and Biopiracy

b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

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

Other issues related to export of natural products (such as CITES Certificate, DGFT Notification, Negative list of herbs, TRAFFIC)

UNIT-V **05Hours**

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.

S**chedule T – GoodManufacturing 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 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory) 45 Hours

Scope: This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical dosage form development.

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

- Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
- Use plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- Understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- Understand the concept of dissolution and application of in vitro in vivo correlation in drug product development.

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, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II 10 Hours

6. S.B. Primrose: Molecular Biotechnology (Second Edition) BlackwellScientific Publication.

7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentationtechnology, 2nd edition, Aditya books Ltd., NewDelhi.

BP 606T PHARMACEUTICAL QUALITY ASSURANCE (Theory) 45 Hours

Scope:

This course deals with the various aspects of quality control and qualityassurance aspects of pharmaceutical industries. It deals with the important aspects likecGMP, QC tests, documentation, quality certifications and regulatory affairs.

Objectives:

Upon completion of the course student shall be able to:

1. Understand the cGMP aspects in a pharmaceutical industry
2. Appreciate the importance of documentation
3. Understand the scope of quality certifications applicable to pharmaceutical industries
4. 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, Introduction to Regulatory agencies like CDSCO, USFDA, WHO, PIC/S.

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: Brief overview of QSEM, ICH stability testing guidelines

Quality by design (QbD): Definition, Overview, Elements of QbD program

ISO 9000 & ISO14000: Overview, Benefits and Elements

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 of Packaging material: Quality control test for containers, rubber closures and secondary packing materials.

Good Laboratory Practices &Role of CPCSEA

UNIT – IV **08 Hours**

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling andwaste disposal.

Document maintenance in pharmaceutical industry in brief: Batch Formula Record, Master Formula Record, SOP, distribution records.

UNIT – V **07 Hours**

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, type of validation.

General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, SandyWeinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Relatedmaterials Vol IWHO Publications.
4. A guide to Total QualityManagement- Kushik Maitra and Sedhan K Ghosh

FINAL YEAR B. PHARM SEMESTER – VII

BP701T	INSTRUMENTAL METHODS OF ANALYSIS (Theory)	45 Hours

Scope:

This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs.This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives:

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

1. Upon completion of the course the student shall be ableto
2. Illustrate the interaction of matter with electromagnetic radiations and justify its applications in drug analysis
3. Classifythechromatographicseparationmethodsandchooseappropriatetechniquefor analysis of drugs.
4. Design methods for performing quantitative & qualitative analysis of drugs using various analytical instruments.

Course Content:

UNIT - I **UV Visible spectroscopy** Introduction to spectroscopy, Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations. Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode. Applications - Spectrophotometric titrations, Single component and multi component Analysis **Fluorimetry** Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications	**10 Hours**

UNIT –II **FTIR spectroscopy** Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector, FTIR instrument, sample handling attachments –DRS and ATR and applications **Flame Photometry** Principle, interferences, instrumentation and applications **Atomic absorption spectroscopy** Principle, interferences, instrumentation and Applications **Nepheloturbidimetry** Introduction	**10 Hours**
UNIT –III **Introduction to chromatography -** **Adsorption and partition column chromatography:** Methodology, advantages, disadvantages and applications. **Paper chromatography:** Introduction, methodology, development techniques, advantages, disadvantages and applications **Thin layer chromatography:** Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications. **HPTLC:** Introduction, Instrumentation and applications	**10 Hours**
UNIT –IV **Theory of Chromatography** Plate theory, Rate theory, System suitability parameters **Gas chromatography** Introduction, theory, instrumentation, temperatureprogramming,advantages, disadvantages andapplications **High performance liquid chromatography (HPLC)** Introduction, theory, instrumentation, advantages and applications.	**08 Hours**

UNIT –V **Ion exchange chromatography-** Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications **Gel chromatography-** Introduction, theory, instrumentation and applications Affinity chromatography- Introduction	**07 Hours**
Recommended Books (Latest Editions): 1. Instrumental Methods of Chemical Analysis by B.K Sharma 2. Organic spectroscopy by Y.RSharma 3. Text book of Pharmaceutical Analysis by Kenneth A.Connors 4. Vogel's Text book of Quantitative Chemical Analysis by A.I.Vogel 5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B.Stenlake 6. Organic Chemistry by I. L.Finar 7. Organic spectroscopy by WilliamKemp 8. Quantitative Analysis of Drugs by D. C.Garrett 9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D.Sethi 10. Spectrophotometric identification of Organic Compounds bySilverstein.	

BP703T	PHARMACY PRACTICE (Theory)	45 Hours

Scope:

In the changing scenario of pharmacy practice in India,for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy,students will be learning various skills such and dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counseling for improved patient care in the community setup.

Objectives:

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

1. Know various drug distribution methods in a hospital
2. Appreciate the pharmacy stores management and inventory control
3. Monitor drug therapy of patient through medication chart review and clinical review.
4. Obtain medication history interview and counsel the patients
5. Identify drug related problems
6. Detect and assess adverse drug reactions
7. Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. Know pharmaceutical care services
9. Do patient counseling in community pharmacy;
10. Appreciate the concept of rational drug therapy.

Course Content:

UNIT-I **Hospital and it's organization** Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions. **Hospital pharmacy and its organization** Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists. **Adverse drug reaction** Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions ,spontaneous case reports and record linkage	**10 Hours**

studies,and Adverse drug reaction reporting and management.	
Community Pharmacy Organization and structure of retail and wholesale drug store, types and design, Legal requirementsforestablishmentandmaintenanceofadrugstore,Dispensingofproprietary products, maintenance of records of retail and wholesale drugstore.	
UNIT-II **Drug distribution system in a hospital** Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, dispensing of drugs to ambulatory patients ,and Dispensing of controlled drugs. **Hospital formulary** Definition,contents of hospital formulary ,Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary. **Therapeutic drug monitoring** Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring. **Medication adherence** Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence. **Patient medication history interview** Need for the patient medication history interview, medication interview forms. **Community pharmacy management** Financial, materials, staff, and infrastructure requirements.	**10 Hours**
UNIT-III **Pharmacy and therapeutic committee** Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation. **Drug information services** Drug and Poison information centre, Sources ofdrug information, Computerized services, and storage and retrieval of information. **Patient counseling** Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist **Education and training program in the hospital** Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education. **Prescribed medication order and communication skills** Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.	**10 Hours**

UNIT-IV **Budget preparation and implementation Budget preparation and implementation Clinical Pharmacy** Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist ,Drug therapy monitoring-medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern. **Over the counter (OTC) sales** Introduction and sale of over the counter, and Rational use of common over the counter medications.	**08 Hours**
UNIT-V **Drug store management and inventory control** Organization of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure. **Investigational use of drugs** Description,principals involved, classification, control, identification, role of hospital pharmacist, advisory committee. **Interpretation of Clinical Laboratory Tests** Blood chemistry, hematology, and urinalysis	**07 Hours**
Recommended Books (Latest Edition): 1. Merchant S.H. and Dr. J. S. Quadry. A textbook of hospital pharmacy, 4th ed. Ahmadabad: B.S. Shah Prakakshan;2001. 2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1st ed. Chennai: Orient Longman Private Limited;2004. 3. William E. Hassan. Hospital pharmacy, 5th ed. Philadelphia: Lea &Febiger;1986. 4. Tipnis Bajaj. Hospital Pharmacy, 1st ed. Maharashtra: Career Publications;2008. 5. Scott LT. Basic skills in interpreting laboratory data, 4thed. American Society of Health System Pharmacists Inc;2009. 6. Parmar N.S. Health Education and Community Pharmacy, 18th ed. India:	

CBS Publishers & Distributers;2008.

Journals:

1. Therapeutic drug monitoring. ISSN:0163-4356
2. Journal of pharmacy practice. ISSN:0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900(online)
4. Pharmacy times (Monthly magazine)

SEMESTER – VIII

BP801T	BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)	45 Hours

Scope:

To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel**.**

Objectives:

Upon completion of the course the student shall be able to

1. Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
2. Know the various statistical techniques to solve statistical problems
3. Appreciate statistical techniques in solving the problems**.**

Course content:

UNIT-I **Introduction:** Statistics, Biostatistics, Frequency distribution **Measures of central tendency**: Mean, Median, Mode- Pharmaceutical examples **Measures of dispersion**: Dispersion, Range, standard deviation, Pharmaceutical problems **Correlation**: Definition,KarlPearson'scoefficientofcorrelation,Multiplecorrelation-Pharmaceuticals examples	**10 Hours**
UNIT-II **Regression:** Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical Examples **Probability:** Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution,properties–problems,Sample,Population,largesample,smallsample,Null hypothesis,alternativehypothesis,sampling,essenceofsampling,typesofsampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples **Parametric test**: t-test(Sample, Pooled or Unpaired and Paired),ANOVA,(Oneway and Two way),Least Significance difference	**10 Hours**

UNIT-III **Non Parametric tests:** Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test **Introduction to Research:** Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism **Graphs:** Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph **Designing the methodology:** Sample size determination and Power of a study, Report writing and presentation ofdata, Protocol,Cohortsstudies, Observational studies,Experimental studies,Designingclinical trial, various phases.	**10 Hours**
UNIT-IV Blocking and confounding system for Two-level factorials **Regression modeling:** Hypothesis testing in Simple and Multiple regression nmodels **Introduction to Practical components of Industrial and Clinical Trials Problems**: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach	**08 Hours**
UNIT-V **Design and Analysis of experiments:** **Factorial Design:** Definition, 2^2, 2^3 design. Advantage of factorial design **Response Surface methodology**: Central composite design, Historical design, Optimization Techniques	**07 Hours**
Recommended Books (Latest edition): 1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork. 2. Fundamental of Statistics – Himalaya Publishing House-S.C.Guptha 3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam, 4. Design and Analysis of Experiments – Wiley Students Edition, Douglas andC.Montgomery	

REGULATORY AFFAIRS
(MPH 104T)

SCOPE

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

OBJECTIVES

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

THEORY **60 Hrs**

1. a) Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch– Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in–vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in -vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. **12 Hrs**

   b) Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs. **12 Hrs**

2. CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH – Guidelines of ICH–Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. **12 Hrs**

3. Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). **12 Hrs**

4. Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA – new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. **12 Hrs**

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga–basics

PHARMACEUTICAL QUALITY ASSURANCE (MQA)

QUALITY MANAGEMENT SYSTEMS (MQA 102T)	60 Hrs

Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the Pharmaceutical industries.

Objectives

Upon completion of the course the student shall be able to

- The importance of quality
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

COURSE CONTENT

UNIT-I • **Introduction to Quality: Evolution of Quality** • **Definition of Introduction to Quality**: Evolution of Quality, Definition of Quality, Dimensions of Quality • **Quality as a Strategic Decision**: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behaviour, concept of internal and external customers. Case studies. • **Cost of Quality**: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, preventing cost of quality.	**08 Hrs**
UNIT-II • **Pharmaceutical quality Management**: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management-ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.	**16 Hrs**
UNIT-III • **Six System Inspection model** : Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labelling system. Concept of self inspection. • **Quality systems**: Change Management / Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), • **Complaints** - evaluation and handling, Investigation and determination	**12 Hrs**

of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.	
UNIT-IV • **Drug Stability**: ICH guidelines for stability testing of drug substances and drug products. • Study of ICH Q8, Quality by Design and Process development report • **Quality risk management**: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.	**12 Hrs**
UNIT-V • **Statistical Process control (SPC)**: Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.	**08 Hrs**
UNIT-VI • **Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking**: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.	**04 Hrs**

REFERENCES

1. Al Endres, Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, Wiley, 2000.
2. Jiju Antony; David Preece, Routledge, Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, 2002.
3. Edward E. Lawler, Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report, 2001.
4. James W. Fairfield-Sonn, Corporate Culture and the Quality Organization, Quorum Books, 2001.
5. Christine Avery; Diane Zabel, Routledge, the Quality Management Sourcebook: An International Guide to Materials and Resources 1997.
6. Nancy R. Tague, the Quality Toolbox, Second Edition, ASQ Publications.
7. Joseph M. Juran and Joseph A., De Feo, Juran's Quality Handbook, Sixth Edition, ASQ Publications.
8. Duke Okes, Root Cause Analysis, the Core of Problem Solving and Corrective Action, 2009, ASQ Publications.

QUALITY CONTROL AND QUALITY ASSURANCE (MQA 103T)	60 Hrs
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, GLP and regulatory affairs. **Objectives** **Upon completion of this course the student should be able to** • Understand the cGMP aspects in a pharmaceutical industry • To appreciate the importance of documentation • To understand the scope of quality certifications applicable to Pharmaceutical industries To understand the responsibilities of QA & QC departments.	
UNIT-I • **Introduction**: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.	**12 Hrs**
UNIT-II • **cGMP guidelines according to schedule M, USFDA (inclusive ofCDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering**: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.	**12 Hrs**
UNIT-III • Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. 126 In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).	**12 Hrs**
UNIT-IV • **Documentation in pharmaceutical industry**: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. • Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non	**16 Hrs**

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I (MPL 103T)

SCOPE

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various *in-vitro* and *in-vivo* preclinical evaluation processes

OBJECTIVES

Upon completion of the course the student shall be able to,

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

THEORY **60 Hrs**

Unit-I **Laboratory Animals** **12 Hrs**

Common Laboratory animals: Description, handling and applications of different species and strains of animals.
Transgenic animals: Production, maintenance and applications.
CPCSEA Guidelines for experimental animals.
Anesthesia and euthanasia of experimental animals
Maintenance and breeding of laboratory animals.
Good laboratory Practice.

Unit -II **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro* and other possible alternative methods in animals.** **12 Hrs**

CNS Pharmacology:
General principles of preclinical screening, screening of behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics, nootropics, Parkinsonism and Alzheimer's.
Drugs acting on Autonomic nervous system.

Unit-III **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro* and other possible alternative methods in animals.** **12 Hrs**

Respiratory Pharmacology:
Anti-asthmatics, drugs for COPD and anti-allergic.
Reproductive Pharmacology: Aphrodisiacs and ant-fertility agents
Gastrointestinal drugs:

Anti-ulcer, anti-emetic, anti-diarrheal and laxatives
Analgesic, anti-inflammatory and anti-pyretic drugs.

Unit-IV **Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro* and other possible alternative methods in animals.** **12 Hrs**

Cardiovascular Pharmacology:
Anti-hypertensive, anti-arrhythmic, anti-anginals, anti-atherosclerotic, and diuretics.
Drugs for metabolic disorders:
Anti-diabetic, anti-hyperlipidemic and anti-cancer drugs.
Methods for screening of Hepatoprotective drugs.

Unit-V **Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro* and other possible alternative methods in animals.** **12 Hrs**

Immunosuppressant's and immunomodulators
General principles of immunoassay: Theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay system. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin.
Limitation of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans.

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
2. Screening methods in Pharmacology by Robert Turner. A.
3. Evaluation of drugs activities by Laurence and Bachrach.
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M. N. Ghosh.
6. Pharmacological experiment on intact preparations by Churchill Livingstone.
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R. K. Goyal.
9. Preclinical evaluation of new drugs by S. K. Gupta.
10. Handbook of Experimental Pharmacology, S. K. Kulkarni.
11. Practical Pharmacology and Clinical Pharmacy, S. K. Kulkarni, 3rd Edition.
12. David R. Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Rodents for Pharmacological Experiments, Dr. Tapan Kumar Chatterjee.
14. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi , Ajay Prakash.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II (MPL202T)

SCOPE

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug and new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

OBJECTIVES

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

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills require conducting the preclinical toxicity studies.

THEORY **60 Hrs**

Unit-I	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice. History, concept and its importance in drug development	**12 Hrs**
Unit -II	Acute, Sub-acute and chronic-oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicity studies.	**12 Hrs**
Unit-III	Reproductive toxicity studies, Male reproductive toxicity studies, Female reproductive studies (segment I and III), teratogenicity studies (segment II) Genotoxicity studies (Ames Test, *in vitro* and *in vivo* Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	**12 Hrs**
Unit-IV	IND enabling studies (IND studies): Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies: origin, concepts and importance of safety pharmacology Tier 1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier 2- GI, renal and other studies.	**12 Hrs**
Unit-V	Toxicokinetics – Toxicokinetic evaluation in preclinical studies, saturation kinetics. Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	**12 Hrs**

REFERENCES

1. Hand book on GLP, Quality practices for regulated non–clinical research and development (http://www.who.int/tdr/publications/documents/glp– handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules,2005, ministry of health and family welfare (department of health) New Delhi.
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan.
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals

   (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL204T)

SCOPE:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will reach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

OBJECTIVES:

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

- Explain the regulatory requirements for conducting clinical trial.
- Demonstrate the types of clinical trial designs.
- Explain the responsibilities of key players involved in clinical trials.
- Execute safety monitoring, reporting and close-out activities.
- Explain the principles of Pharmacovigilance.
- Detect new adverse drug reaction and their assessment.
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance.

THEORY **60 Hrs**

Unit-I **Regulatory Perspective of Clinical Trials:** **12 Hrs**

Origin and Principles of International Conference on Harmonization-Good Clinical Practice (ICH-GCP) guidelines.

Ethical Committee: Institutional Review Board, Ethical guidelines for Biomedical Research and Human Participant Schedule Y, ICMR.

Inform Consent Process: Structure and content of an Inform Consent Process Ethical principles governing informed consent process.

Unit -II **Clinical Trials: Types and Design** **12 Hrs**

Experimental Study- RCT and Non RCT

Observation Study: Cohort , Case control, Cross sectional

Clinical trial Study Team

Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

Unit-III **Clinical Trial Documentation**- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring Safety monitoring in CT **12 Hrs**

Adverse Drug Reactions: definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions ; terminologies of ADR

Unit-IV **Basic aspects, terminologies and establishment of Pharmacovigilance** **12 Hrs**

History and progress of Pharmacovigilance, Significant of safety

monitoring, pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centers in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

Unit-V **Methods, ADR reporting and tools used in Pharmacovigilance** **12 Hrs**

International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Arugs, Aris G Pharmacovigilance, Vigiflow, Statistical methods for evaluating medication safety data. Introduction to pharmacoepidemiology and pharmacoeconomics.

REFERENCES

1. Central Drugs Standard Control Organization– Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical guidelines for Biomediical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical trials by David Machin, Simon Day and Sylvan Green. 2005. John Wiley and Sons.
5. Clinical Data management edited by R. K. Rondels, S A Varley, C F Webbs. Second edition, 2000. Wiley Publications.
6. Handbook of Clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di lgnazio, di Giovanna and Haynes.