SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF SCIENCE AND TECHNOLOGY

Syllabus of Third Year B. Pharmacy

2019 PATTERN (Revised)

(EFFECTIVE FROM ACADEMIC YEAR 2021-2022)

Table-VI: Course of study for semester VI

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3/45	1	4
BP602T	Pharmacology III – Theory	3/45	1	4
BP603T	Herbal Drug Technology – Theory	3/45	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3/45	1	4
BP605T	Pharmaceutical Biotechnology – Theory	3/45	1	4
BP606T	Quality Assurance –Theory	3/45	1	4
BP607P	Medicinal chemistry III – Practical	4/60	-	2
BP608P	Pharmacology III – Practical	4/60	-	2
BP609P	Herbal Drug Technology – Practical	4/60	-	2
Total		**30/450**	**6**	**30**

Table-VII: Course of study for semester VII

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3/45	1	4
BP702T	Industrial Pharmacy-II – Theory	3/45	1	4
BP703T	Pharmacy Practice – Theory	3/45	1	4
BP704T	Novel Drug Delivery System – Theory	3/45	1	4
BP705P	Instrumental Methods of Analysis – Practical	4/60	-	2
BP706PS	Practice School*	12/180	-	6
Total		**28/420**	**5**	**24**

***** Non University Examination (NUE)

Semester VI

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP601T	Medicinal Chemistry III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP602T	Pharmacology III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP603T	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP605T	Pharmaceutical Biotechnology– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP606T	Quality Assurance– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP607P	Medicinal chemistry III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP608P	Pharmacology III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP609P	Herbal Drug Technology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**75**	**120**	**18 Hrs**	**195**	**555**	**30 Hrs**	**750**

T.Y.B.PHARM SEMESTER - VI

BP601T. MEDICINAL CHEMISTRY – III (Theory) 45 Hours

Scope :

This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject also discusses the concept of quantitative structure activity relationship (QSAR) in drug design. The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

Objectives:

Upon completion of the course student shall be able to

1 Understand the importance of drug design and different techniques of drug design.
2 Understand the chemistry of drugs with respect to their biological activity.
3 Know the metabolism, adverse effects and therapeutic value of drugs.
4 Know the importance of SAR of drugs.

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs mentioned in bracket []only to be covered

UNIT - I 10 Hours

Antibiotics

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

a) **β-Lactam antibiotics:** Penicillins, Cepholosporins, β-Lactamase inhibitors, Monobactams
b) **Aminoglycosides:** Streptomycin, Neomycin, Kanamycin

c) **Tetracyclines:** Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II **07 Hours**

a) **Antibiotics**

Macrolide: Erythromycin, Clarithromycin, Azithromycin.

Polypeptide antibiotics-Vancomycin, Bacitracin

Miscellaneous: Chloramphenicol, Clindamycin, Linzolide

b) **Antimalarials:** Etiology of malaria.

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

Biguanides and dihydrotriazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone, Halofantrine, Lumefantrine.

[Chloramphenicol, Chloroquine]

UNIT – III **08 Hours**

Antimycobacterial and Antiviral agents

a) **Anti-tubercular Agents**

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

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

b) **Antileprosy agents:** Clofazimine, Dapsone, Rifamycin

c) **Antiviral agents:**

DNA virus inhibitors-Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoridine, Acyclovir, Gancyclovir.

RNA virus inhibitors

Anti-HIV agents- Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine , Ribavirin, Saquinavir, Indinavir, Ritonavir.

[Isoniazid, Ethambutol, Acyclovir]

UNIT – IV **10 Hours**

a) **Antifungal agents**

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

Synthetic Antifungal agents: Clotrimazole, Oxiconazole,Tioconozole, Miconazole, Ketoconazole, Itraconazole, Fluconazole, Tolnaftate.

b) **Anti-protozoal Agents:** Metronidazole, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Atovaquone, Eflornithine.

c) **Anthelmintics:** Diethylcarbamazine citrate, Thiabendazole, Mebendazole, Albendazole, Niclosamide, Oxamniquine, Praziquantel, Ivermectin.

d) **Synthetic anti-infective agents :**

Sulphonamides: Historical development, chemistry and drug resistance

Sulfacetamide, Sulphapyridine, Sulfamethoxazole, Sulphadiazine, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim

Quinolones: Nalidixic Acid, Norfloxacin, Ciprofloxacin, Ofloxacin, Lomefloxacin, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin, Methanamine.

[Fluconazole, Metronidazole, Mebendazole, Sulfamethoxazole, Trimethoprim , Ciprofloxacin]

UNIT – V **07 Hours**

Anti-neoplastic agents:

Alkylating agents: Meclorethamine, Cyclophosphamide, Melphalan,

Chlorambucil, Busulfan, Thiotepa

Antimetabolites: Mercaptopurine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Kinase inhibitors: Gefitinib, Imatinib, Erlotinib

Monoclonal antibodies-Bedvacizumab, Cetuximab

Miscellaneous: Cisplatin, Mitotane.

[Chlorambucil, Mercaptopurine, Methotrexate)

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

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

Biopharmaceutical classification system, theories of dissolution, dissolution test apparatus, dissolution models, *in-vitro-in-vivo* correlations

UNIT- III **10 Hours**

Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, bioequivalence studies and study designs, Review of regulatory requirements for conducting bioequivalence study, bio-waivers, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT- IV **10 Hours**

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model (a) Intravenous Injection (Bolus) (b) Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - K_E, $t_{1/2}$, Vd, AUC, Ka, CL_T and CL_R- definitions methods of eliminations, understanding of their significance and application. Introduction to multi-compartment model.

UNIT- V **05 Hours**

Nonlinear Pharmacokinetics: Introduction, Factors causing Non-linearity, Michaelis-menten equation, Determination of V_{max} and K_m. Significance of nonlinear pharmacokinetics, Explanation with example of drugs.

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall Inernational edition.USA

4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Rowland M, Tozer T, Ed 4, WolterKluwers – Lippincott,Williams and Wilkins.
9. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
Remington‟s Pharmaceutical Sciences, ByMack Publishing Company, Pennsylvnia.

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY(Theory) 45 Hours

- Biotechnology has a long promise to revolutionize the biological sciences and technology.
- Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technologymakes the subjectinteresting.
- Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceuticaldrugs.
- Biotechnology has already produced transgenic crops and animals and thefuture promises lot more.
- It is basically a research-basedsubject.

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

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies inIndustries
4. Appreciate the use of microorganisms in fermentationtechnology

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 DNAligase.

Recombinant DNA technology. Application of genetic engineering inmedicine.

Application of r DNA technology and genetic engineering in the productionof:

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

Brief introduction toPCR139

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 vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.

Storage conditions and stability of official vaccines

Hybridoma technology- Production, Purification and Applications

Unit IV **08Hours**

Immuno blotting techniques- ELISA, Western blotting, Southern blotting.

Microbial genetics including transformation, transduction, conjugation, plasmidsand transposons.

Introduction to Microbial biotransformation andapplications.

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 variouscontrols.

Study of the production of - penicillins, Vitamin B12, Glutamicacid,

Blood Products: Collection, Processing and Storage of whole human blood,dried human plasma, plasmaSubstituties.

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles andApplications of Recombinant DNA: ASM Press WashingtonD.C.
2. RA Goldshyet. al., :KubyImmunology.
3. J.W. Goding: MonoclonalAntibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology byRoyal Society ofChemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland,Ohio.

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

5. How to Practice GMP‟s – P P Sharma.
6. ISO 9000 and Total QualityManagement – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysisand Quality specification for Pharmaceutical Substances, Excipients and Dosageforms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines142
10. Pharmaceutical Quality Assurance – Sohan Chitlange, Sanjeevani Deshkar, Rupali Kale and Bhupesh Patil

BP607P. MEDICINAL CHEMISTRY-III (Practical) 4 Hours / week

I Preparation of drugs and intermediates (Any six) 10 turns

1. Sulphanilamide
2. 7-Hydroxy, 4-methyl coumarin
3. Chlorobutanol
4. Triphenyl imidazole
5. Tolbutamide
6. Hexamine
7 Paracetamol
8. Methyl salicylate
9. Caprolactum

II Preparation of medicinally important compounds or intermediates by Microwave synthesis (any two) **02 turns**

III Drawing structures and reactions using Chem draw® **01 turn**

IV Determination of physicochemical properties such as logP, clogP, MR, Molecular weight **01 turn**

V Hydrogen bond donors and acceptors for class of drugs using drug design software Drug likeliness screening (Lipinskies RO5) **01 turn**

Recommended Books (Latest Editions)

1. Martindale‟s extra pharmacopoeia.
2. Organic Chemistry by I. L. Finar Vol II

3. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.
4. Indian Pharmacopoeia.
5. Text book of practical organic chemistry-A.I.Vogel.
6. Medicinal Chemistry By Ashutosh Kar
7. Practical Pharmaceutical Chemistry: Part II Fourth Edition, A. H. Beckett, J. B. Stenlake.

BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

Sr. No	**Experiment**
1.	Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
2.	Study of effect of drugs on gastrointestinal motility
3.	Effect of agonist and antagonists on guinea pig ileum
4.	Estimation of serum biochemical parameters by using semi- autoanalyser
5.	Effect of saline purgative on frog intestine
6.	Hypoglycemic effect of insulin in rabbit
7.	Test for pyrogens (rabbit method)
8.	Determination of acute oral toxicity (LD50) of a drug from a given data
9.	Determination of acute skin irritation / corrosion of a test substance
10.	Determination of acute eye irritation / corrosion of a test substance
11.	Calculation of pharmacokinetic parameters from a given data
12.	Biostatistics methods in experimental pharmacology(student‟s t test, ANOVA)
13.	Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)
14.	Bioassay of serotonin using rat fundus strip by three point bioassay.
15.	Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
16.	Study of mydriatic and miotic effects on rabbit eye.

*Experiments are demonstrated by simulated experiments/videos

Recommended Books (Latest Editions)

1. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
2. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.
3. Goyal RK. Practicals in Pharmacology, BS Shaha Prakashan.
4. Kasture SB. A handbook of experiments in pre-clinical pharmacology, Career Publications.
5. Bikas Medhi, Ajay Prakash. Practical Manual of Experimental and Clinical Pharmacology. Jaypee Publications.

BP 609 P. 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)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
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