**III Year II Semester**

**PHR16321 - PHARMACEUTICAL TECHNOLOGY – II (50Hrs)**

**UNIT – I ` 06**

**Capsules:** Advantage and disadvantages of capsule dosage forms, material for production of hard and soft gelatin capsules, sizes of capsules, capsule filling, soft processing problems in capsule manufacturing, importance of base absorption and minimum/gm factors in soft capsules, quality control, stability testing and storage of capsule dosage forms.

**LO:** To understand Capsule formulation, Types, Manufacturing and evaluation – Quality Control – Stability testing-storage**.**

**UNIT - II**  **10**

**Microencapsulation:** Types of microencapsulation and importance of microencapsulation in pharmacy, microcapsulation by coacervation phase separator, multi orifice centrifugal separation. Spray drying, spray congealing, polymerization complex emulsion, air suspension technique, and pan coating techniques, evaluation of microcapsules.

**LO:** To understand microencapsulation – Applications, Methods of Preparations. evaluation – Applications of Microcapsules.

**UNIT - III** **10**

**Tablets:** Formulation of different types of tablets, granulation technology on large-scale by various techniques, types of tablet compression machinery and the equipments employed evaluation of tablets.

**LO:** To understand tablet formulations, additives- manufacturing methods-equipment-Evaluation of quality & Control.

**UNIT - IV** **08**

**Coating of Tablets:** Types of coating, coating materials and their selection, formulation of coating solution, equipment for coating, coating processes, evaluation of coated tablets.

**LO:** To understand types of tablet coating – coating solutions- Equipment-Process- Evaluation of Coating tablets.

**UNIT – V 10**

**Parenteral Products**

1. Preformulation factors, routes of administration, water for injection, treatment

 apyrogenicity, non-aqueous vehicles, isotonicity and methods of its adjustment.

1. Formulation details, container and closures and selection.
2. Prefilling treatment, washing and sterilization of containers and closures, preparation of

 solution and suspensions, filling and closing of ampules, vials, infusion fluids,

 lyophilization & preparation of sterile powders, equipment for large-scale manufacture

 and evaluation of parenteral products.

1. Aseptic techniques, sources of contamination and method of prevention. Design of

 aseptic area, laminar flow benches, services and maintenance.

**LO :** To understand Formulations, Preformulations, additives, Manufacturing methods, containers, Packaging, evaluation of Parentrals – quality control , Types of sterile powders, aseptic processing facilities

**UNIT – VI 06**

**Packaging of Pharmaceutical products:**

Packaging components, types, specifications and methods of evaluation as per I.P. Factors influencing choice of containers, package testing, legal and other official requirements for containers, packing testing.

Methods of packing of solid, liquid and semi-solid dosage forms, Factors influencing packing material, stability aspects of packaging.

**LO :** To understand Packaging components- types, specifications and evaluation methods of packaging materials and containers- legal and official requirements

### **TEXT BOOKS**

1. L. Lachman, H.A, Lieberman and J.L. Kanig, Theory & Practice of industrial pharmacy,

 Lea & Febieger, Philadelphia Latest Edn

1. HC Ansel introduction to Pharmaceutical Dosage forms
2. Pharmaceutical Dosage forms Tablet by Lieberman, Lachman
3. CVS. Subramanyam, Pharmaceutical production and management, Vallabh Prakashan,

 New Delhi 2005.

**REFERENCES**

1. Sagarian & MS Balsam, Cosmetics Sciences &Technology,Vol.1, 2 & 3
2. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences
3. E.A.Rawlkins Bentley’s Text Book of Pharmaceutics, Elbs publ
4. S.H. Willing, M.M Tucherman and W.S. Hitchings IV, Good Manufacturing Practices for

 Pharmaceuticals: A Plan for Total Quality Control, 2nd ed, Marcel Dekker, Inc., New York

 1998.

1. Gilbert S. Banker and Christopher T Rhodes, Modern Pharmaceutics, IVth ed, marcel

 dekker, usa, 2005.

1. Yiew chien, novel drug delivery systems, 2nd ed, marcel dekker 2003.
2. Robert. A. Nash, Pharmaceutical Process Validation, 3rd Ed Marcel Dekker, 2003.
3. Good Manufacturing Practices – Schedule M. Read With The Drugs And Cosmetic Rules

 1945

1. M.E. Aulton, Pharmaceuitcs- The science of Dosage form Design 2nd ed.

**III Year II Semester**

**PHR16322 - PHARMACEUTICAL BIOTECHNOLOGY (50Hrs)**

**UNIT – I 10**

**Fermentation Technology:** Isolation, Selection, Screening of Industrial important microbes, Strain improvement. Types, design & operation of Bioreactor. Types of fermentations, optimization of fermentation process, Principle and Procedure involving in downstream process and effluent treatment.

**LO:** To understand principles of fermentation technology- types of bioreactor – optimization of fermentation process – principles of effluent treatment

**UNIT – II 10**

**Specific Fermentations:** Selection of organism, fermentation & purification of various antibiotics, vitamins, aminoacids, organic acids, solvents like penicillin, streptomycin, tertacyclin, erythromycin, riboflavin, cynacobalamin, glutamic acid, lysin, citric acid, lactic acid, alcohol, acetone etc.

**LO:** To understand Fermentations of various types of industrial and medicinal compounds.

**UNIT – III 08**

**Microbial Transformations:** Types, Methods of bioconversions & Application in Pharma Industry, Steroidal transformation.

**Recombinant DNA Technology:** Introduction to R-DNA technology and genetic engineering, steps involved, isolation of enzymes, vectors, recombination and cloning of genes.

Production of bio technology derived therapeutic proteins like humulin, humatrop, activase, intron a, monoclonal antibodies by hybridoma technique, recombivax HB (Hepatitis B).

**LO:** To understand types, methods and applications of bioconversion – principles and production technology of recombinant DNA technology with examples.

**UNIT – IV 08**

**Immunology & Immunological Preparations:** Principles of Immunity, Humoral immunity, cell mediated immunity, antigen – antibody reactions, hypersensitivity and its applications.

Active & passive immunizations vaccine preparation, standardization & storage of BCG, cholera, smallpox, polio, typhus, tetanus toxoide, immuno serum & diagnostic agents.

**LO :** To understand principles of Immunology, Antigen- Antibody reactions – applications, active and passive immunizations – study of various vaccines and sera.

**UNIT – V 08**

**Enzyme Technology: T**echniques of immobilization of enzymes, factors affecting enzyme kinetics, advantages of immobilization over isolated enzymes.

Study of enzymes such as hyaluronidas, penicillinase, streptokinase, streptodornase, amylase, protease etc. immobilization of bacteria & plant cells.

**LO:** To understand techniques, applications and productions enzymes of medicinal importance

.

**UNIT – VI 06**

Introduction, role, collection, process & storage of blood products, plasma substitutes like Whole human blood, Human normal immunoglobulins, dextran. Sutures & ligatures like catgut etc.

Definition & applications of bioinformatics, proteomics and genomics.

**LO:** To understand Blood products – collection processing, storage and uses of various blood products.

**TEXT BOOKS**

* 1. Wulf Crueger and Anneliese Crueger, Biotechnology, 2nd Ed, Publ- Panima publication

 co-operation, New Delhi.

* 1. P. F. Stanbury & A. Whitaker, Principles of fermentation technology, Pergamon Press
	2. B.P. Nagori & Roshan Issari, Foundations in Pharmaceutical Biotechnology
	3. Sambamurthy. K, Text Book of Pharmaceutical Biotechnology.
	4. S. S. Kori, Pharmaceutical biotechnology.

**REFERENCES**

1. Prescott and Dunne, “Industrial Microbiology” MC Caraw Hill Bool Company
2. Peppler “Microbial Technology” Vol. 1 & 2.
3. K. Kielsliched “Biotechnology” Vol 6, Verlegchemic, Switzerland.
4. PF Standury & A. Whitaker, “Principles of fermentation Technology” Pergamon Press.
5. OP Ward” Fermentation Technology, Principles, Processes products” Open University

 press, Milton Keynes, UK.

1. A. M. Campbelli, Monoclinical antibody technology.
2. A. Wiseman, Handbook of enzyme biotechnology.
3. J. D. Watson, Recombinant DNA technology.
4. Smith and Hood, Molecular biology and biotechnology.
5. E.A. Rawlins, Bentley’s, A text book of pharmaceutics, 8th Ed, 1982 Bailler Tindall &

 Co.

1. Alexander N. Glazer & Hiroshi Nikaido, Microbial biotechnology, W. H. Freeman Co.
2. Ahwood.T.K, Introduction to Bio Informatics.
3. Cassida, Industrial microbiology.
4. H.K. Das, Textbook of Biochemistry.

**III Year II Semester**

**PHR16323 - PHARMACOLOGY – II (50Hrs)**

**UNIT – I 08**

Pharmacology of Cardiovascular System – Drugs used in congestive heart failure & Cardiotonics.

Drugs used in cardiac arrythmias, Antihypertensives, Drugs used in the treatment of Angina pectoris,

Drugs used in the therapy of shock.

**LO:** To acquire knowledge on CVS and its regulatory mechanisms, pathophysiology related to CVS diseases and disorders and Pharmacology of drugs used in the Cardio vascular diseases.

**UNIT – II 06**

Drugs acting on blood forming organs: Anti-coagulants, Anti-platelets, Thrombolytics & hematinics.

Drugs acting on urinary system: Fluid and electrolyte balance, Diuretics & Antidiuretics.

**LO:** Grasping knowledge on treatment of blood disorders, kidney disorders.

**UNIT – III 08**

Drugs acting on Endocrine system

Pancreatic hormone and Antidiabetic drugs, Thyroid & Antithyroid drugs, Gonadal hormones & Inhibitors, Adrenocorticosteroids & Adrenocortical antagonists, Hypothalamic & Pituitary Hormones.

**LO:** Grasping knowledge on Physiological role of Endocrine glands and its pathological conditions and the Pharmacology of drugs used.

**UNIT – IV 06**

Autacoids: Histamine, Serotonin (5-HT) & their antagonists, Prostaglandins & leukotrienes, Pentagastrin, cholecystokinin, angiotensin, vasoactive peptides.

**LO:** To acquire knowledge on Autocoids, synthesis, metabolism and their Pharmacology.

**UNIT – V 06**

Drugs Acting on the Respiratory System

Anti-asthamatic drugs including bronchodilators, Anti-tussives & expectorants, Respiratory stimulants.

**LO:** Impart knowledge on respiratory diseases and the Pharmacology of drugs.

**UNIT – VI 16**

Chemotherapeutic agents and their applications: General principles of chemotherapy,

Sulphonamides and co-trimoxazole, Antibiotics: Penicillins, cephalosoporins, betalactams,

Chemotherapeutic agents and their applications: Tetracyclines aminoglycosides, chloramphenicol, erythromycin, quinolones and miscellaneous antibiotics.

Chemotherapy of tuberculosis & leprosy.

Chemotherapy of fungal diseases, viral diseases, urinary tract infections and sexually transmitted diseases.

Chemotherapy of malignancy and immunosuppressive Agents.

**LO:** To gain knowledge on Chemotherapeutics and various classes of drugs used for infection and diseases.

**TEXT BOOKS**

1. Sathoskar, Pharmacology and pharmaco therapeutics Vol. 1 & 2, Publ by Popular Prakashan, Mumbai.
2. Tripathi, Textbook of Pharmacology, JAYPEE.
3. H.P Rang, M. M. dale & J.M. Ritter, Pharmacology, Churchill living stone.
4. F.S.K. Barar, Text book of Pharmacology, S.Chand.
5. F.S.K Barar, Essentials of Pharamcotheraptics.

**REFERENCES**

1. J.G. Hardman and Lee E. Limbard, Good Mann & Gilmann: The Pharmacological Basis of Therapeutics, Mc Graw hill, Health Professions Dvn.
2. Bertram. G. Katzung, Basic and clinical pharmacology, 9th Edn, Mc Graw hill.
3. J. Crossland, Lewis ‘s Pharmacology, Church living stone.
4. Leilani Grajeda, Understanding Pharmacology: A Physiological Approach

**III Year II Semester**

**PHR16324 - MEDICINAL CHEMISTRY-III (50Hrs)**

**UNIT I 08**

A general introduction to advances in medicinal chemistry with emphasis on the principles of combinatorial chemistry, high throughput screening and QSAR studies.

**LO:** General concepts, principles, procedures, advantages, equations and methodologies.

**UNIT II 08**

1. Types of receptors, interaction forces
2. Preliminary aspects of molecular modeling studies: docking, pharmacophore

modeling

**LO:** General concepts, principles, procedures, advantages and methodologies.

**UNIT III 10**

1. **Steroidal anti-inflammatory agents:** classification, structures, SAR, uses and

toxicity

1. **Bile acids:** classification, structures and functions
2. **Estrogens and progesterone:** structures, functions, interconversion of estrogens,

uses of natural and synthetic estrogens, synthesis of progesterone from diosgenin.

**LO:** Acquaintance with steroidal structures, features, properties, uses, mode of action.

**UNIT IV 08**

1. **Antiarrhythmics:** classification, mode of action, uses and synthesis of procainamide.
2. **Cardiac glycosides:** classification, structures and structural features, mode of action and therapeutic uses.

**LO:** Introduction to cardiovascular diseases**,** uses, mode of action.

**UNIT V 08**

1. **Antihypertenssives:** classification, mode of action, SAR, currently used drugs and synthesis of methyldopa, clonidine, Losartan
2. **Antianginals and coronary vasodilators:** classification, mode of action, SAR and uses, synthesis of isosorbide dinitrate.

**LO:** Introduction to cardiovascular diseases**,** uses, mode of action.

**UNIT VI 08**

1. **Diuretics:** Definition, classification, mode of action, SAR of different classes, uses and synthesis of acetazolamide, ethacrynic acid and hydrochlorthiazide.
2. **Antihyperlipidemics (Hypocholesteremic drugs)**  - Definition, classification, mode of action, SAR of different classes, uses and synthesis of Clofibrate.

**LO:** Introduction, structures, methodology of synthesis, advantages.

### **TEXT BOOKS**

1. William O. Foye, Textbook of Medicinal Chemistry by, Lea Febiger, Philadelphia.
2. JM Beale, Wilson & Giswold’s Textbook of organic Medicinal Chemistry and Pharmaceutical chemistry by (Eds), 11th Ed, Lipcott, Raven, Philadelphia, 2004.
3. S. N. Pandeya, Textbook of mediacinal chemistry, SG Publ. Varanasi, 2003.

**REFERENCES**

1. D. Abraham (Ed), Burger Medicinal chemistry ad Drug discovery, Vol. 1 & 2. John Wiley & Sons, New York 2003, 6th Ed.
2. Lippincott Williams and Wilkins: Remington Pharmaceutical Sciences
3. L. M. Atherden, Bentley and Driver’s Textbook of Pharmaceutical Chemistry. Oxford University Press, Delhi.
4. B.N. Lads, MG.Mandel and F.I. way, Fundamentals of drug metabolism & disposition, William & welking co, Baltimore USA.
5. C. Hansch, Comprehensive medicinal chemistry, Vol 1 – 6 Elsevier pergmon press, oxford
6. Daniel lednicer, Strategies For Organic Drug Synthesis And Design, John Wiley, N. Y. 1998.
7. D. Lednicer, Organic drug synthesis, Vol, 1 – 6, J.Wiley N.Y.

**III Year II Semester**

**PHR16325 - REGULATORY AFFAIRS, IPR & PATENTS (50Hrs)**

**Unit-I 10**

Preformulations and Formulation Development – Regulatory requirements in Preformulations and Formulation Development of Solid, liquid and Semisolid dosage.

**LO:** To understand preformulations – protocols – regulatory – requirements – Formulation Development of Solid, liquid and Semisolid dosage.

**Unit-II 10**

Manufacturing- Regulatory requirements related to manufacturing- manufacturing formula,Records, Validations involved-GMP

Validations: Types- Validation of Process and Equipment – Raw materials, Excipients and solvents.

**LO:** To understand regulatory requirements related to manufacturing, validation – types, Validation of process, equipment, raw materials, excipients.

**Unit-III 10**

Regulatory requirements of packaging materials- Evaluation of Packaging materials.

Stability – Regulation for Stability testing of API, Solid and liquid dosage form as per ICH guidelines.

**LO:** To understand regulatory requirements of packaging materials, evaluation of packaging materials, stability testing as per ICH.

**Unit – IV 07**

Clinical Trials: Phase –I, II, III & IV studies – Regulations involved

**LO:** To understand regulatory requirements of Clinical Trials, Phase –I, II, III & IV studies.

**Unit- V 06**

A Study of Intellectual Property Rights : Definitions – Guidelines – National and international – Examples.

**LO:** To understand IPR with examples

**Unit- VI 07**

Patents: patenting laws and Regulations – Procedures for obtaining and writing a patent – Examples.

**LO:** To understand patents, patent laws, procedures with examples.

### **TEXT BOOKS**

1. How to Practice GMPs By P.P.Sharma, Vandhana Publications, Agra.

2. Quality Assurance and Quality Management in Pharmaceutical Industry, Anjaneyulu Y.

3. Good Manufacturing Practices and Inspection, W.H.O, Vol – II.

4. I.P.R: Hand book for pharma students and researchers, Bansal.

**References :**

1. Quality Assurance guide by organization of Pharmaceutical Procedures of India

2. Drug formulation manual by D.P.S.Kohli and D.H.Shah. Eastern Publishers, New

 Delhi.

3. Pharmaceutical Process Validation by FRA.R.Berry and Robert.A.Nash.

5. Pharmaceutical Preformulations by J.J.Wells.

6. Applied Production and Operations management by Evans, Anderson, Sweeny and

 Williams.

7. Basic principles of Clinical Research and methodology by Guptha.

8. Biopharmaceutics and Clinical Pharmacokinetics – An Introduction ; 4th Edition,

 Revised and Expanded by Robert E. Notary, Marcel Dekker incm, New york and

 Basel, 1987.

**III Year II Semester**

**PHR16326 - PHARMACEUTICAL TECHNOLOGY – II LAB**

**At least 25 Pharmaceutical preparations related to the topics are to be prepared**

1. Experiments to illustrate preparation, stabilization, physical, chemical and biological evaluation of pharmaceutical products like capsules (2\*), tablets (8\*), Parenterals – Ampoules (4\*), Large Volume Parenterals (4\*), Microcapsules (2\*).
2. Quality control test for Tablets (2\*) and Capsules (2\*) as per IP 2014.
3. Quality control test for Glasses as per IP 2014.

\* indicates number of experiments

**III Year II-Semester**

**PHR16327 - PHARMACOLOGY LAB**

1. To study the inotropic and chronotropic effects of drugs on isolated frog heart.
2. To study the effect of drugs on rat ileum.
3. To study the effects of drugs on isolated normal and hypodynamic frog heart.
4. To determine the dose-response curve of acetylcholine using rectus abdominus muscle of

 frog.

1. To determine he potentiating effect of neostigmine on the action of acetylcholine on

 Rectus abdominus muscle of frog.

1. To find the antagonistic effect of pancuronium against the action of acetylcholine on

 Rectus abdominus muscle of frog.

1. To record the CRC of 5-HT on rat fundus preparation.
2. To record the CRC of histamine on guinea pig ileum preparation.
3. Experiments pertaining to analgesia. (*Only demonstration)*.
4. Experiments pertaining to anti-convulsant activity. (*Only demonstration)*.
5. Experiments pertaining to anti-inflammatory activity (*Only demonstration)*.
6. To determine the hypoglycemic activity of drugs (second generation antidiabetic

 drugs) on rabbits / albino rats. (*Only demonstration)*.

**III Year II-Semester**

**PHR16328 - PHARMACEUTICAL BIOTECHNOLOGY LAB**

1. Isolation of antibiotic producing microorganism from soil.
2. Enzyme immobilization by Ca-alginate method.
3. Determination of minimum inhibitory concentration of the given antibiotic. Antibiotic assay by cup plate method.
4. Collection, Processing, Storage and fractionation of blood.
5. Standardization of Cultures.
6. Microbiological assay of Antibiotics / Vitamins.
7. Production of alcohol by fermentation techniques.
8. Comparison of efficacy of immobilized cells.
9. Sterility testing of Pharmaceutical products.
10. Isolation of mutants by gradient plate technique.
11. Preparation of bacterial vaccine.
12. Preparation of blood products / Human normal immunoglobulin injection.
13. Extraction of DNA (***demonstration only)***
14. Separation techniques: Various types of Gel Electrophoresis, Centrifugation.

**TEXT BOOK**

1. Ashish S Verma, et.al., Laboratory Manual for Biotechnology, S.Chand.