

Institute of Pharmacy
Nirma University of Science & Technology
B.Pharm. Semester – VI

1. PHARMACEUTICAL BIOTECHNOLOGY

Sr.No	Course Name	Lecture (hrs.)	Practical (hrs.)	Credits
1	Pharmaceutical Biotechnology	3	3	5

Sr.No.	Contents
1.	Immunology and Immunological Preparations
2.	Genetic Recombination
3.	Fermentation
4.	Microbial transformation
5.	Enzyme immobilization
6.	Study of diagnostic aids

Total Lectures

45

Theory (Detailed Syllabus)

1 Immunology and Immunological Preparations

Principles of immunity and immune system, Nonspecific defense mechanisms of the body. Study of antigens, haptens and types of antibodies, cellular & humoral immunity, antigen-antibody reactions and their applications, hypersensitivity & immunological tolerance.

Active and passive immunization techniques, Vaccines, their preparation, standardization and storage. Study of vaccines: diphtheria, tetanus toxoid, cholera, pertussis, plaque, BCG, rabies, polio, measles, typhoid, new generation vaccines-hepatitis, AIDS, Malaria, Diagnostic preparations, brief study of sera

2 Genetic Recombination:

Introduction to Gene Expression: Structure of DNA and RNA, DNA Replication, Transcription and Translation.

Recombinant DNA Technology: Transformation, conjugation, transduction, protoplast fusion and gene cloning and their applications. Development of hybridoma for monoclonal antibodies.

Drugs produced by biotechnology: Study of Hematopoietic growth factors, Interferon's & Interleukins, Insulin, Growth Hormones, Vaccines & Monoclonal antibody based pharmaceuticals, Recombinant coagulation factors and thrombolytic agents.

3 Fermentation:

Historical development of antibiotics, methods used for their standardization, Screening of soil for organisms producing antibiotics, Isolation and preservation of pure cultures. Mutants, factors influencing rate of mutation. Fermenter, its design, control of different parameters, fermentation process. Media, Sterilization(fermenter, media, air, etc.) Isolation of fermentation products. Detailed production of a) selected antibiotics: penicillins, erythromycin, streptomycins, tetracyclines b) vitamin B 12, Riboflavin c) others: citric acid, alcohol

4 Microbial transformation:

Introduction, types of reactions mediated by microorganisms, design of biotransformation processes & its improvements, selection of organisms, biotransformation process with special reference to steroids

5 Enzyme immobilization:

Introduction, methods and applications of immobilized enzymes. Techniques of immobilization of enzymes, factors affecting enzyme kinetics, Study of enzymes such as hyaluronidase, penicillinase, streptokinase and streptodornase, amylases, proteases, etc., Immobilization of bacterial and plant cells.

6 Study of diagnostic aids produced by biotechnology.

Total Lectures

45

Practicals (Syllabus)

No. Contents

- 1 To prepare Typhoid vaccine
- 2 To prepare Cholera vaccine as per IP.
- 3 To study antigen-antibody reaction
- 4 Demonstration to fermenter and fermentation process
- 5 Inoculum development by shake-flask method for fermentation process
- 6 To carry out Alcohol fermentation from sugarcane juice.
- 7 Recovery & purification of citric acid from given fermented mass
- 8 To screen the given culture for the enzyme production.
- 9 Fermentation of carbohydrates and nitrate reduction test
- 10 Indole production, oxidase and catalase test for bacteria
- 11 Isolation of antibiotic resistant bacterial population by gradient plate method
- 12 Isolation of streptomycin-resistant mutants by replica plating technique
- 13 Ames Test for determination of potential carcinogens
- 14 a. Isolation of Plasmid DNA
b. To perform restriction digestion and ligation of plasmid DNA
c. To perform transformation of bacterial cells
d. Demonstration of genetic recombination in bacteria by conjugation
- 15 Demonstration to genomic DNA extraction process and evaluation

Total Hours

45

Books Recommended

1. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi
2. Vyas, S. P., Pharmaceutical Biotechnology, CBS Publishers & Distributors, 2002, Delhi
3. Klefenz, Heinrich, Industrial Pharmaceutical Biotechnology, Weinheim : Wiley-VCH Verlag GmbH, 2002
4. El-Mansi, Mansi, Fermentation Microbiology and Biotechnology, New York : Taylor & Francis, 2003
5. Thiel, Teresa, Biotechnology: DNA to Protein: a Laboratory Project in Molecular Biology, New Delhi : Tata McGraw-Hill Publishing Company Ltd., 2002
6. Crommelin, Daan J.A., Pharmaceutical Biotechnology : An Introduction for Pharmacists, and Pharmaceutical Scientists, 2nd ed. London : Routledge, 2002
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New delhi
8. Chand, Subhash, Fermentation Biotechnology: Industrial Perspective, w Delhi : All India Biotech Association, 2001
9. Industrial Microbiology, Casida E., L., New Age International Publishers
10. I.P., B. P., USP
11. Walsh G., Biopharmaceuticals: Biochemistry & Biotechnology

Institute of Pharmacy
Nirma University of Science & Technology
B.Pharm. Semester – VI

2. PHARMACEUTICAL TECHNOLOGY-II (STERILE PREPARATIONS, AEROSOLS & COSMETICS)

Sr.No	Course Name	Lecture (hrs.)	Practical (hrs.)	Credits
2	Pharmaceutical Technology-II (sterile preparations, Aerosols & CosmeticS)	3	3	5

Sr. No.	Contents
1	Parenteral products
2	Pharmaceutical aerosols
3	Cosmeticology and cosmetic preparations

Total Lectures

45

Theory (Detailed Syllabus)

1 Parenteral products:

Preformulation factors, routes of administration, vehicles- aqueous, nonaqueous; pyrogenicity, Pyrogen testing, isotonicity and methods of its adjustment, Modern methods for preparing WFI

Formulation details, containers and closures -types, characteristics, selection. Pre-filling treatment- washing of containers and closures, an introduction to glass, plastic and rubber as materials of containers and closures of parenteral products. preparation of solution and suspensions, filling and closing of ampoules , vials, infusion fluids, ophthalmic preparations, lyophilization & preparation of sterile powders, equipment for large scale manufacturing and evaluation of parenteral products. FFS technology

Aseptic techniques, sources of contamination and method of prevention, Design of aseptic area, Laminar flow benches, services and maintenance.

2 Pharmaceutical aerosols:

Definition, propellants, general formulation, containers, Selection of components manufacturing and packaging methods, pharmaceuticals applications, Evaluation of aerosols.

3 **Cosmeticology and cosmetic preparations:**

Fundamentals of cosmetic science, structure and functions of skin and hair, Formulation, preparation and packaging of cosmetics for skin - Sunscreen, moisturizers, cold cream, and vanishing cream, like nail polish, lipsticks.

Formulation, preparation and packaging of cosmetics for hair - Shampoo and conditioners.

Dentifrice products- powders, gels, paste

Depilatories, Manicure preparations, eye liners and eye lashes

Brief introduction on baby care products

Total Lectures

45

PRACTICALS (SYLLABUS)

Preparation and evaluation of parenteral and ophthalmic formulations. Preparation of various cosmetics for skin, hair and dentifrice.

Sr. No.	Contents
1.	Introduction to Parenteral dosage forms
2.	Preparation & Evaluation of Nutrient Replenisher
3.	Preparation & Evaluation of Isotonic supplements
4.	Preparation & Evaluation of vitamin injections.
5.	Preparation & Evaluation of injections using water miscible base.
6.	Preparation & Evaluation of injections using oily base.
7.	Preparation & Evaluation of sterile powders.
8.	Preparation & Evaluation of Dentifrice products (Toothpaste, Tooth powders, Dental gels)
9.	Preparation & Evaluation of Face powder
10.	Preparation & Evaluation of liquid shampoos and clear shampoos
11.	Preparation & Evaluation of Cold cream and Vanishing cream
12.	Preparation & Evaluation of Leather shaving cream
13.	Preparation & Evaluation of Leather shaving cream
14.	Preparation & Evaluation of Nail polish
15.	Preparation & Evaluation of Eye ointment

Total Hours

45

Books Recommended

1. Theory and Practice of Industrial Pharmacy by Lachman.
2. Remington's Pharmaceutical Sciences.
3. Pharmaceutical Dosage Forms: Parenteral Medication by Lieberman and others.
4. Pharmaceutical Dosage Forms and Drug Delivery Systems by Ansel & others.
5. Encyclopedia of Pharmaceutical Technology, Swarbrick, James, Marcel Dekker, Inc., New York
6. Text book of Pharmaceutics by Gilbert Banker
7. Cosmetics and Toiletries Industry by Williams and Schmitt.
8. Cosmetics by Poucher.
9. Cosmetics by Sagarin
10. Cosmetics: Formulation Manufacture and Quality Control by P.P. Sharma

Institute of Pharmacy
Nirma University of Science & Technology
B.Pharm. Semester – VI

3. Medicinal Chemistry – II (Drugs Acting on CNS and CVS)

Sr. No.	Course Name	Lecture (hrs.)	Practical (hrs.)	Credits
3	Medicinal Chemistry – II (Drugs Acting on CNS and CVS)	3	3	5

Sr.No.	Contents
1.	Chemistry of Autocoids
2.	Drugs acting on Central Nervous System
3.	Drugs acting on Cardio Vascular System
4.	Hormones

Total Lectures

45

Theory (Detailed Syllabus)

The following classes of drugs will be discussed in relation to:

- a. Introduction to the rational development of the drug (if any) including the principles of isosterism
- b. Chemical classification (if any)
- c. Chemical nomenclature
- d. Mechanism of action
- e. Synthesis of at least one agent from each chemical class
- f. Structure activity relationship
- g. Prodrug approach

1 Chemistry of Autocoids

- Eicosanoids and their synthesis inhibitors
- NSAIDS
- Anti – allergic agents

2 Drugs acting on Central Nervous System

- General and local anesthetics
- Hypnotics and sedatives
- Opioid analgesics
- Anti – convulsants
- Anti – Parkinsonism drugs
- CNS stimulants
- Neuroleptics
- Anti – depressants
- Anxiolytics

- 3 **Drugs acting on Cardio Vascular System**
- Anti – hypertensives
 - Anti-arrhythmic agents
 - Anti-anginal agents
 - Anti-hyperlipidemic agents
 - Cardiotonics
 - Diuretics
 - Anti-coagulants, thrombolytics, platelet aggregation inhibitors
- 4 **Hormones**
- Discussion of the chemistry and design of drug acting on them
 - Thyroid hormone and anti-thyroid agents
 - Insulin and hypoglycemic agents
 - Steroid hormones – adrenal cortex hormones and sex hormones including their synthetic substitutes and their SAR

Total Lectures

45

Practicals (Syllabus)

- | Sr.No. | Contents |
|--------|--|
| 1. | Organic spotting of binary mixtures of liquid + solid and liquid + liquid types along with identification of the type of mixture, micro-scale chemical separation, identification of the individual components, establishment of the identity of the separated components with the help of derivative preparation and TLC. |
| 2. | Workshop on preparation of stereo models of some selected drugs. |
| 3. | Synthesis of some intermediates used in drug synthesis. |

Total Hours

45

Books Recommended

1. J. N. Delagado and W. A. R. Remers, Eds, Wilson and Giswold's Textbook of Organic, Medicinal and Pharmaceutical Chemistry, J. Lipponcott Co. Philadelphia.
2. W. C. Foye, Principles of Medicinal Chemistry, Lea & Febiger, Philadelphia.
3. H. E. Wolff, Ed. Burger's Medicinal Chemistry, John Wiley & Sons, New York
4. Oxford University Press, Oxford.
5. Daniel Lednicer, Strategies for Organic Drug Synthesis & Design, John Wiley & sons, USA.
6. B. N. Ladu, H. G. Mandel & E. L. Way, Fundamental of Drug Metabolism & Disposition, William & Wilkins co., Baltimore.
7. I. L. Finar, Organic Chemistry, Vol. I & II, ELBS/ Longman, London.
8. Vogel's Text book of Practical Organic Chemistry, ELBS/ Longman, London
9. Mann & Saunder, Practical Organic Chemistry, Orient Longman, London.
10. Shriner, Hermann, Morrill, Curtin & Fuson, The Syntematic Identification of Organic Compounds, John Wiley & Sons. USA.
11. R. M. Silverstein, G. Claytron Bassel's, T. C. Mowvill, Spectormetric identification of Organic compounds, John Wiley & Sons, USA

Institute of Pharmacy
Nirma University of Science & Technology
B.Pharm. Semester – VI

4. PHARMACEUTICAL BIOCHEMISTRY-II

Sr No.	Course Name	Lecture (hrs.)	Practical (hrs.)	Credits
4	Pharmaceutical Biochemistry-II	3	3	5

Sr. No.	Contents
1.	Lipid Metabolism
2.	Nucleic Acids
3.	Genetic code and protein synthesis
4.	Vitamins As Coenzymes
5.	Porphyrin metabolism
6.	Water And Mineral Metabolism
7.	Xenobiotics

Total Lectures

45

Theory (Detailed Syllabus)

- 1 **Lipid Metabolism:** oxidation of fatty acids, ketogenesis and its significance, lipid biosynthesis and its regulation, triacylglycerol biosynthesis, cholesterol biosynthesis, metabolism and regulation of these processes, study of eicosanoids and their synthesis in the body.
- 2 **Nucleic Acids:** Biosynthesis of nucleotides and nucleic acids, Denovo synthesis of purine nucleotides, salvage pathway for purine biosynthesis, pyrimidine biosynthesis.
- 3 **Genetic code and protein synthesis:** Genetic code, DNA structure and its replication, RNA types and structure, transcription and translation, post-translational modifications, regulation of these processes and inhibitors of translation, mutations, physical and mutagenesis or carcinogenesis and DNA repair mechanisms.

- 4 **Vitamins As Coenzymes:** Classification, Biochemical Significance, Chemistry, Biochemical Role, Dietary Sources, Deficiency Diseases, and Antagonists (Wherever Applicable) of all the Vitamins.
- 5 **Porphyrim metabolism:** Importance in the body, Properties and Biosynthesis of porphyrins, Synthesis of haemoglobin, Disorders related to these metabolic pathways.
- 6 **Water And Mineral Metabolism:** Role of various minerals in the different tissues of the body, Regulation of pH of blood and other body fluids.
- 7 **Xenobiotics:** Introduction and its importance, phases of metabolism, illustrative examples.

Total Lectures

45

Practicals (Syllabus)

Sr.No.	Contents
1.	Study of techniques like spectrophotometry, centrifugation, eletrophoresis and different types of chromatography.
2.	Extraction and purification of nucleic acids.
3.	Quantitative estimation of amino acids.
4.	Quantitative estimation of proteins.
5.	Quantitative estimation of serum glucose by various methods.
6.	Quantitative estimation of serum creatinine, cholesterol, urea, etc
7.	Quantitative estimation of SGOT, SGPT, BRN, etc.

Total Hours

45

Books Recommended

1. E. E. Conn and P. K. Stumpf, Out lines of Biochemistry, John Wiley & Sons, New York.
2. A. L. Lehninger, Principles of Biochemsitry, CBS Publishers and Distributors.
3. R. K. Murry, D. K. Granner, P.A. Mayes, V. W. Rodwell, Harper's Biochemistry, Prentice Hall International Inc., Latest Edition.
4. S. C. Rastogi, Biochemistry, Tata McGraw Hill, New Delhi, Latest Editon.
5. M. Cohn, K. S. Roth, Biochemistry and Disease, William and Wilkins Co., Baltiomore, Latest Edition.
6. U. Satyanarayana, Biochemistry, Books and Allied (P) Ltd., Calcutta, Latest Edition.
7. G. F. Zubay, W. W. Parson, D. E. Vance, Principles of Biochemsitry, WBC Publishers, England, Latest Edition.
8. S. Ramakrishnan, K. G. Prasannan, R. Rajan, Textbook of Medical Biochemistry, Orient Longman, Madras, Latest Editon.
9. S. K. Sawhney, Randhir Singh Eds, Introductory Practical Biochemistry, Narosa Publishing House, New Delhi.
10. D. T. Plummer, An Introduction to Practical Biochemistry, Tata McGraw Hill, New Delhi.
11. J. Jayaraman, Laboratory Manual in Biochemistry, Willey, Eastern Limited, New Delhi.
12. Lehninger Principles of Biochemistry, 3rd ed London : Macmillan Press Ltd., 2000
13. Harper's Biochemistry, 25th ed New York : McGraw-Hill, Inc., 2002

14. A Text Book of Biochemistry for Medical Students, 9th ed. New Delhi : UBS Publisher's Distributors Ltd., 2003
15. Textbook of Medical Biochemistry, 5th ed. New Delhi : Jaypee Brothers Medical Publishers (P) Ltd , 2002
16. Varley's Practical Clinical Biochemistry, 6th ed. Delhi : CBS Publishers & Distributors, 2002
17. Practical Biochemistry: Principles and Techniques, 5th ed. Cambridge : Cambridge University Press, 2003
18. Biochemistry, 3rd ed. India : Pearson Education Asia Pte. Ltd., 2003
19. Theory and Problems of Biochemistry, 2nd ed. New Delhi : Tata McGraw-Hill Publishing Company Ltd., 2003
20. Biochemistry Terminology, Delhi : Lakshay Publicaton, 2003
21. Biochemistry and Molecular Biology, 2nd ed. New Delhi : Oxford University Press, 2003
22. Introductory Practical Biochemistry, New Delhi : Narosa Publishing House, 2002
23. Practicals and Viva in Medical Biochemistry, Amsterdam : Elsevier Science, 2004

Institute of Pharmacy
Nirma University of Science & Technology
B.Pharm. Semester – VI

5. Pharmacology – III (Drugs acting on CVS, Chemotherapy of Diseases and Toxicology)

Sr No	Course Name	Lecture (hrs.)	Practical (hrs.)	Credits
5	Pharmacology – III (Drugs acting on CVS, Chemotherapy of Diseases and Toxicology)	3	3	5

Introduction	
This course will provide an opportunity for the student to learn about the drugs acting on cardiovascular system, blood, blood forming agents and renal system. Apart from this, pharmacology of chemotherapeutic agents and principles of toxicology will also be dealt with in detail.	

Sr.No.	Contents
1.	Drugs affecting renal and cardiovascular function
2.	Drug acting on the blood and the blood forming organs
3.	Chemotherapy
4.	Toxicology

Total Lectures

45

Theory (Detailed Syllabus)

- 1 **Drugs affecting renal and cardiovascular function**
 - a) Diuretics
 - b) Pharmacological treatment of congestive heart failure
 - c) Anti hypertensive agents
 - d) Anti anginal, vasodilator agents and drugs used for the treatment of myocardial ischaemia
 - e) Antiarrhythmic agents
 - f) Drug therapy for hypercholesterolemia and dyslipidemia
- 2 **Drug acting on the blood and the blood forming organs**
 - a) Haematopoietic agents
 - b) Anti-coagulants, thrombolytics, fibrinolytic and anti platelet agents
 - c) Blood and plasma volume expanders
- 3 **Chemotherapy**
 - a) Basic principles of chemotherapy
 - b) Chemotherapy of neoplastic diseases
 - c) Chemotherapy of microbial diseases
 - General considerations
 - Sulfonamides, co-trimoxazole, Quinolones, agents for urinary tract infections
 - B-lactam antibiotics: Penicillins, cephalosporins and other B-lactam antibiotics

- Aminoglycoside antibiotics
- Tetracyclines & chloramphenicol
- Macrolide antibiotics
- Chemotherapy of tuberculosis, M.Avium complex disease and leprosy
- Anti fungal agents
- Anti-viral agents (non-retroviral)
- Anti-retroviral agents
- d) Chemotherapy of parasitic infections
 - Anti-malarial agents
 - Anthelmintic agents
 - Agents affective against amebiasis, giardiasis, trichomoniasis, trypanosomiasis & leishmaniasis
- e) Drugs used for immuno-modulation
 - Immunomodulation: Immunosuppressive agents, tolerogens and immuno-stimulant agents

4 **Toxicology**

- Heavy metals (Iron, lead, Mercury, Arsenic) and heavy metal antagonists
- General principles and treatment of acute and chronic poisoning with special reference to barbiturates, opioids, organophosphorus, atropine, alcohol, Benzodiazepines, Anti-depressants, Neuroleptics etc.

Total Lectures

45

Practicals

Scheme of Practical Classes

Sr.No.	Contents
1.	To study the effect of various drugs on isolated / perfused frog's heart.
2.	To demonstrate the cardiotoxic effects of drugs on frog's isolated / perfused hypodynamic heart preparation.
3.	To study the effect of drugs on peripheral blood vessels using perfused blood vessel preparation of frog.
4.	To demonstrate the diuretic effect of the drug using suitable animal model.
5.	To test whether the given sample of parenteral preparation is pyrogen free or not.
6.	To demonstrate the effect of drugs on the coronary blood flow and heart rate of isolated rat's heart (Lagendorff's heart preparation).
7.	To demonstrate the effect of various drugs on the blood pressure of anaesthetized rat.

Total Hours

45

Books Recommended

- 1 Goodman Gilman A., Rall T.W., Nies A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics, 10th edition, 2001. Mc Graw Hill, Pergamon Press.
- 2 Rang, H.P. and Dale, M.M. Pharmacology, 5th edition, 2003. Publisher : Churchill Livingstone.
- 3 Craig, C.R. and Stitzel, R.E. Modern Pharmacology, Latest Edition, Little Brown and Company.
- 4 Katzung, B.G. Basic and Clinical Pharmacology, 8th Edition, McGraw Hill, New York, 2001
- 5 Satoskar, R.S. and Bhandarkar, S.D. Pharmacology and Pharmacotherapeutics, 16th edition (single volume), 1999, Popular, Dubai
- 6 Kulkarni S.K. Handbook of experimental pharmacology, 3rd edition, 1999, Vallabh Prakashan, New Delhi.
- 7 Goyal R.K. et al: Practical in Pharmacology, 3rd edition, 2003, B.S.Shah Prakashan, Ahmedabad – 1.
- 8 Macleod, L.J. Pharmacological experiments on intact preparations, January 1971, Elsevier Health Sciences.
- 9 Macleod, L.J. Pharmacological experiments on isolated preparations, January 1971, Elsevier Health Sciences.
- 10 Ghosh, M.N. fundamentals of experimental pharmacology, 1954, Scientific Book agency, Kolkata.
- 11 H.G. Vogel et al. Drug Discovery and Evaluation. Pharmacological Assays. 2nd Ed., August 2002, Springer-Verlag New-york.
- 12 Introduction to pharmacology, Manfred A. Hollinger, 2nd Edition, 2003, Taylor and Francis, London.
- 13 Pharmacology: Drug actions and Reactions Ruth R. Levine, 2000, Parthenon Publishing Group.
- 14 Pharmacology (Board review series) by Gary C. Rosenfeld, David S. Loose-Mitchell, 3rd Edition, 1998, Williams and Wilkins.