



ANANDPHARMACYCOLLEGE, ANAND
(An Autonomous College under UGC Regulations 2023)

Managed by Shri Ramkrishna Seva Mandal

(Approved by PCI, NAAC Accredited – A+ Grade, 3.38 CGPA)

Awarding University: Gujarat Technological University, Ahmedabad



Name of Program: **B. Pharm**

Semester: **VI**

Course Code: **B010601TP**

Course Name: **INDUSTRIAL PHARMACY I**

Course Type: **Core**

Year of Implementation: **2026–27 (Effective from batch 2024-25)**

Teaching and Examination Scheme:

Number of hours/Week			Number of Credits			Total credits	Evaluation Scheme (Marks)									Total Marks
							Sessional Exams						Term End Assessment			
L	Tu	P	L	Tu	P	CIE	E	T	CIE	E	T	T	P			
3	1	4	3	1	2										6	10

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.

Course Outcomes (CO):

Upon completion of the course, student shall be able to

CO1	Understand the principles and significance of pre-formulation in dosage form design and development.
CO2	Explain the manufacturing techniques of tablets, capsules, oral liquids, parenterals, Aerosol and cosmetics.
CO3	Apply the knowledge of excipients and process parameters to design tablets, capsules, oral liquids, parenterals, Aerosol and cosmetics.
CO4	Evaluate the quality and stability attributes for tablets, capsules, oral liquids, parenterals, Aerosol and cosmetics.
CO5	Recall the process & material variables, and quality control parameters of different pharmaceutical dosage forms.
CO6	Formulate and evaluate various pharmaceutical dosage forms as per pharmacopeial standards.


Detailed Syllabus:

Total Teaching hours: **45 hours**

Unit1	Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances	7 Hours
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5. Preparation and evaluation of Tetracycline capsules.
6. Preparation of Calcium Gluconate injection.
7. Preparation of Ascorbic Acid injection.
8. Quality control test of (as per IP) marketed tablets and capsules.
9. Preparation of Eye drops/ and Eye ointments.
10. Preparation of Creams (cold / vanishing cream).
11. Evaluation of Glass containers (as per IP).
12. To formulate and evaluate herbal gel/cosmetic preparation using natural extracts.
13. To demonstrate blister packaging using PVC sheets and tablets, highlighting thermoforming, filling, and heat-sealing principles.
14. To evaluate blister/strip pack integrity using vacuum-dye ingress for detecting leaks or defects.
15. To study the effect of accelerated stability conditions on pharmaceutical dosage forms using a stability chamber.

Recommended Books^:(Latest Editions)

1. H.A. Liberman, Leon Lachman & J.B. Schwartz, Pharmaceutical Dosage Forms: Tablets, Vol. 1–3, Marcel Dekker.
2. H.A. Liberman & Leon Lachman, Pharmaceutical Dosage Forms: Parenteral Medications, Vol. 1–2, Marcel Dekker.
3. H.A. Liberman & Leon Lachman, Pharmaceutical Dosage Forms: Disperse Systems, Vol. 1, Marcel Dekker.
4. Gilbert S. Banker & C.T. Rhodes, Modern Pharmaceutics, 3rd Ed., Marcel Dekker.
5. Alfonso R. Gennaro (Ed.), Remington: The Science and Practice of Pharmacy, 20th Ed., Pharmaceutical Press (RPS).
6. H.A. Liberman & Leon Lachman, Theory and Practice of Industrial Pharmacy, Lea & Febiger.
7. M.E. Aulton, Pharmaceutics: The Science of Dosage Form Design, Latest Ed., Churchill Livingstone.
8. H.C. Ansel, Introduction to Pharmaceutical Dosage Forms, 5th Ed., Lea & Febiger, Philadelphia, 2005.
9. C.T. Carstensen & C.J. Rhodes, Drug Stability: Principles and Practices, Vol. 107, 3rd Ed., Marcel Dekker.

L=Lecture, Tu=Tutorial, P=Practical, T=Theory

^This is not an exhaustive list



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Awarding University: Gujarat Technological University, Ahmedabad



Name of Program: **B. Pharm**

Semester: **VI**

Course Code: **B010602TP**

Course Name: **MEDICINAL CHEMISTRY-III**

Course Type: **Core**

Year of Implementation: **2026–27 (Effective from batch-2024-25)**

Teaching and Examination Scheme:

Number of hours/Week			Number of Credits			Total credits	Evaluation Scheme (Marks)								Total Marks
							Sessional Exams						Term End Assessment		
L	Tu	P	L	Tu	P		Theory			Practical			T	P	
3	1	4	3	1	2	6	10	15	25	10	15	25	75	75	200

Scope:

This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

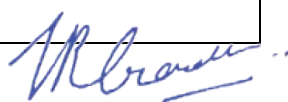
Course Outcomes (CO):

Upon completion of the course, student shall be able to

CO1	Understand the principles of medicinal chemistry of drugs with respect to their pharmacological activity, structure, classification and uses.
CO2	Know the metabolic pathways of drugs, including their adverse effects, therapeutic importance and chemical synthesis of selected drugs.
CO3	Recognise the Structure-Activity Relationship (SAR) of different drug classes to understand how structural modifications impact biological activity.
CO4	Understand and apply the concept of drug design approaches such as QSAR, pharmacophore modelling, docking and combinatorial chemistry in rational drug discovery.
CO5	Recall synthesis, preparation, assay of drugs and intermediates underlying experiments.
CO6	Apply experimental skills for drug assay, monograph analysis, synthesis of drugs, intermediates using conventional laboratory techniques and apply computational tools.



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	Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.	
Unit4	<p>Antifungal agents:</p> <p>Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.</p> <p>Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconazole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.</p> <p>Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.</p> <p>Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.</p> <p>Sulphonamides and Sulfones</p> <p>Historical development, chemistry, classification and SAR of Sulfonamides:</p> <p>Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.</p> <p>Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.</p> <p>Sulfones: Dapsone*.</p>	<p>03 Hours</p> <p>01 Hour</p> <p>01 Hours</p> <p>03 Hours</p>
Unit5	<p>Introduction to Drug Design</p> <p>Various approaches used in drug design.</p> <p>A brief introduction to Quantitative Structure Activity Relationship (QSAR): History and Development of QSAR, Physicochemical Parameters: partition coefficient, Hammett's electronic parameter, Taft's steric parameter</p> <p>QSAR Methods: Hansch analysis and Free Wilson Analysis</p> <p>Pharmacophore modelling and docking techniques.</p> <p>Combinatorial Chemistry: Concept and applications</p> <p>chemistry: solid phase and solution phase synthesis.</p>	<p>05 Hours</p> <p>02 Hours</p>

Tutorials

Tutorials will be based on the above syllabus

Tutorial hours: 15 Hours

List of Practicals

I Preparation of drugs and intermediates

1. Sulphanilamide
2. 7-Hydroxy, 4-methyl coumarin
3. Chlorobutanol



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4. Triphenyl imidazole
5. Tolbutamide
6. Hexamine

II Assay of drugs

1. Isonicotinic acid hydrazide
2. Chloroquine
3. Metronidazole
4. Dapsone
5. Chlorpheniramine maleate
6. Benzyl penicillin

III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV Drawing structures and reactions using chem draw®

V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Demonstration of Molecular Modelling Technique using Molecular Modelling Software

Recommended Books^:(Latest Editions)

1. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
2. William. O. Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
3. Burgers, Medicinal Chemistry, M. E. Welly Medicinal Chemistry M.E. Walfed Johnwiley and Sons, Wiley Interscience Publication, New York, Toronto.
4. Smith HJ, Williams H. Introduction to the Principles of Drug Design. Elsevier.
5. Remington JP. Remington: The Science and Practice of Pharmacy. Lippincott Williams & Wilkins.
6. Martindale W. The Extra Pharmacopoeia. HK Lewis.
7. Finar IL. Organic Chemistry, Volume 2: Stereochemistry and The Chemistry Natural Products. Pearson Education India.
8. Lednicer D, Mitscher LA. The Organic Chemistry of Drug Synthesis, volume 1 to 5. John Wiley & Sons.
9. Indian Pharmacopoeia., The Controller of Publications, New Delhi.
10. Vogel AI. Practical Organic Chemistry. Longmans.

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **B. Pharm**

Semester: **VI**

Course Code: **B010603TP**

Course Name: **PHARMACOLOGY-III**

Course Type: **Core**

Year of Introduction: **2026 – 27 (Effective from batch 2024-25)**

Teaching Scheme:

Number of hours/Week			Number of credits			Total credits	Evaluation Scheme (Marks)								Total Marks
							Sessional Exams						End Semester Assessment		
Theory		Practical				End Semester Assessment		Total Marks							
L	Tu	P	L	Tu	P	CIE	E	T	CIE	E	T	T	P	Total Marks	
3	1	4	3	1	2	6	10	15	25	5	20	25	75	75	200

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.

Course Outcomes (CO):

Upon completion of the course student shall be able to

CO1	Demonstrate a comprehensive understanding of the fundamental principles of Chemotherapy.
CO2	Apply pharmacological knowledge of Immunopharmacology and Chronopharmacology
CO3	Illustrate the principles of toxicology with emphasis on clinical symptoms and management of selected toxic substances
CO4	Utilize the pharmacology of drugs acting on Respiratory system and Gastrointestinal Tract.
CO5	Demonstrate understanding of experimental pharmacological methods for evaluating drug actions, toxicity, and therapeutic potential through simulated/video-based demonstrations.
CO6	Analyze and interpret experimental and statistical data to calculate pharmacokinetic, pharmacodynamic, and biochemical parameters for preclinical drug evaluation.



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Course Contents:

Total Teaching hours: 45 hours

Unit 1	<p>Pharmacology of drugs acting on Respiratory system</p> <p>a. Anti -asthmatic drugs b. Drugs used in the management of COPD c. Expectorants and antitussives d. Nasal decongestants e. Respiratory stimulants</p> <p>Pharmacology of drugs acting on the Gastrointestinal Tract</p> <p>a. Antiulcer agents. b. Drugs for constipation and diarrhoea. c. Appetite stimulants and suppressants. d. Digestants and carminatives. e. Emetics and anti-emetics.</p>	<p>2 Hours 0.5 Hour 1 Hour 0.5 Hour 0.5 Hour</p> <p>1.5 Hours 1.5 Hour 0.5 Hour 0.5 Hour 1.5 Hours</p>
Unit 2	<p>Chemotherapy</p> <p>a. General principles of chemotherapy. b. Sulfonamides and cotrimoxazole. c. Antibiotics - Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides</p>	<p>3 Hours 1 Hour 6 Hours</p>
Unit 3	<p>Chemotherapy</p> <p>a. Antitubercular agents b. Antileprotic agents c. Antifungal agents d. Antiviral drugs e. Anthelmintics f. Antimalarial drugs g. Antiamoebic agents</p>	<p>2 Hours 0.5 Hour 2 Hours 2 Hours 0.5 Hour 2 Hours 1 Hour</p>
Unit 4	<p>Chemotherapy</p> <p>a. Urinary tract infections and sexually transmitted diseases. b. Chemotherapy of malignancy</p> <p>Immunopharmacology</p> <p>a. Immunostimulants b. Immunosuppressant Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars</p>	<p>2 Hours 3 Hours</p> <p>1 Hour 2 Hours</p>
Unit 5	<p>Principles of toxicology</p> <p>a. Definition and basic knowledge of acute, subacute and chronic toxicity. b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity</p>	<p>1 Hour 1 Hour 0.5 Hour</p>



	<p>c. General principles of treatment of poisoning d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning</p> <p>Chronopharmacology a. Definition of rhythm and cycles. b. Biological clock and their significance leading to chronotherapy.</p>	<p>2.5 Hours</p> <p>0.5 Hour 1.5 Hour</p>
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Tutorials

Tutorial hours: 15 Hours

Tutorials will be based on above syllabus

List of Practicals

Course Contents:

Total Teaching hours: 60 hours

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data using pK solver
14. Biostatistics methods in experimental pharmacology (student's t test, ANOVA) using Microsoft excel/graph pad prism
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test) using Microsoft excel/graph pad prism

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos. The dataset shall be given to understand the application of biostatistics in preclinical research wherever possible

Recommended Books^: (Latest Editions)

1. Rang, H. P., Dale, M. M., Ritter, J. M., & Flower, R. J. Rang and Dale's Pharmacology. Churchill Livingstone Elsevier.
2. Katzung, B. G., Masters, S. B., & Trevor, A. J. Basic and Clinical Pharmacology. Tata McGraw-Hill.
3. Goodman & Gilman. The Pharmacological Basis of Therapeutics.
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robin L. C., Joseph G. B., Wayne A. K., &



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- Bradley R. W. Applied Therapeutics: The Clinical Use of Drugs. The Point Lippincott Williams & Wilkins.
5. Mycek, M. J., Gelnet, S. B., & Perper, M. M. Lippincott's Illustrated Reviews: Pharmacology.
 6. Tripathi, K. D. Essentials of Medical Pharmacology. Jaypee Brothers Medical Publishers (P) Ltd, New Delhi.
 7. Sharma, H. L., & Sharma, K. K. Principles of Pharmacology. Paras Medical Publisher.
 8. Craig, C. R., & Stitzel, R. E. Modern Pharmacology with Clinical Applications.
 9. Ghosh, M. N. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
 10. Kulkarni, S. K. Handbook of Experimental Pharmacology. Vallabh Prakashan.
 11. Essentials of Medical Pharmacology + Pharmacological Classification of Drugs - KD Tripathi
 12. David E. Golan's Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy,
 13. Tara V. Shanbhag's Pharmacology for Medical Graduates, · Publisher: Elsevier
 14. Barar F.S.K. Textbook of Pharmacology, S Chand And Company Limited
 15. Basic Biostatistics for Pharmacy. By: Jani, G. K, Atul Prakashan
 16. Mahajan's Methods in Biostatistics for Medical Students and Research Workers, Publisher. Jaypee Brothers Medical Publishers

L= Lecture, Tu= Tutorial, P= Practical, T = Theory

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Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **B. Pharm**

Semester: **VI**

Course Code: **B010604TT**

Course Name: **PHARMACEUTICAL JURISPRUDENCE**

Course Type: **Core**

Year of Implementation: **2026–27 (Effective from batch 2024-25)**

Teaching and Examination Scheme:

Number of hours/Week			Number of Credits			Total credits	Evaluation Scheme (Marks)									Total Marks
							Sessional Exams						Term End Assessment			
L	Tu	P	L	Tu	P	CIE	E	T	CIE	E	T	T	P			
3	1	-	3	1	-										4	10

Course Outcomes (CO):

Upon completion of the course, student shall be able to

CO1	Understand objectives, scope and key provisions of major pharmaceutical legislations and acts.
CO2	Recognize the ethical responsibilities for effective practice in pharmacy.
CO3	Apply legal and ethical guidelines to manufacture, sale, import and export of drug and its finished products.
CO4	Recall the offences and penalties of legal violations or ethical issues in Pharmacy practice.

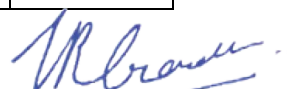
Detailed Syllabus:

Total Teaching hours: **45 hours**

Unit 1	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 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	03 Hours 10 Hour
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	manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.	
Unit 2	<p>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 – Classes of Drugs prohibited to be sold, 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</p>	10 Hours
Unit 3	<p>Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties</p> <p>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.</p> <p>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</p>	<p>04 Hours</p> <p>03 Hours</p> <p>03 Hours</p>
Unit 4	<p>Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties</p> <p>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</p> <p>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)</p>	<p>03 Hours</p> <p>03 Hours</p> <p>02 Hours</p>
Unit 5	<p>Medical Termination of Pregnancy Act: Objective, Definitions, Provisions of the Act, Offences and Penalties</p>	<p>02 Hours</p> <p>01 Hour</p>



	<p>Right to Information Act: Objectives, Definition, Schedule of Act and Rules, Offences and Penalties</p> <p>Introduction to Intellectual Property Rights (IPR): Important Legislation, Objective, Definitions, Provision of the Act, Offences and Penalties</p>	<p>01 Hour</p>
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Tutorials

Tutorial hours: 15 Hours

Tutorials will be based on the above syllabus

Recommended Books :(Latest Editions)

1. Suresh, B. Forensic Pharmacy: Pharmaceutical Jurisprudence. Delhi: Birla Publications Pvt. Ltd.; 2009
2. Mithal, B. M. *A Textbook of Forensic Pharmacy*. 10th ed., Vallabh Prakashan, Delhi, 1999; reprinted 2024
3. Mehra, M. L. *The Handbook of Drug Laws*. 9th ed., University Book Agency (Allahabad), 1997. 923 pages
4. Jain, N. K. *A Textbook of Forensic Pharmacy*. 8th ed., Vallabh Prakashan, New Delhi, 2014 (Reprint 2021)
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)
10. Indian Government websites related with latest update for the rules and regulation

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 Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **B. Pharm**

Semester: **VI**

Course Code: **B010605TT**

Course Name: **PHARMACEUTICAL BIOTECHNOLOGY**

Course Type: **Core**

Year of Implementation: **2026–27 (Effective from batch 2024-25)**

Teaching and Examination Scheme:

Number of hours/Week			Number of Credits			Total credits	Evaluation Scheme (Marks)								Total Marks
							Sessional Exams						Term End Assessment		
L	Tu	P	L	Tu	P	4	Theory			Practical			Assessment		
							CIE	E	T	CIE	E	T	T	P	
3	1	-	3	1	-		10	15	25	-	-	-	75	-	100

Course Outcomes (CO):

Upon completion of the course, student shall be able to

CO1	Understand the fundamentals of biotechnology with reference to pharmaceutical sciences, genetic and protein engineering.
CO2	Recognize the role of microbes in industry for preparation of vaccines, sera, antibiotics and vitamins using fermentation technology and bioprocess engineering.
CO3	Apply the principles of pharmaceutical biotechnology in collection, processing and storage of blood products.
CO4	Analyze the concepts of immunity & immunology, immuno-blotting techniques, microbial genetics, mutation and recombinant DNA technology.


Detailed Syllabus:

Total Teaching hours: **45 Hours**

Unit1	Fundamentals of Biotechnology & Enzyme Technology	10 Hours
	a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences. b) Enzyme immobilization- Methods of enzyme immobilization and applications in pharmaceutical and food industry. c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries. d) Protein Engineering - Introduction, methods and applications. e) Use of microbes in industry, Production of Enzymes- General consideration- Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase. f) Basic principles of genetic engineering	



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Unit2	Molecular Biotechnology & Recombinant DNA Technology a) Study of cloning vectors, restriction endonucleases and DNA ligase. b) Recombinant DNA technology. Application of genetic engineering in medicine. c) Application of rDNA technology and genetic engineering in the production of; i) Interferon ii) Vaccines- hepatitis- B iii) Hormones- Insulin. d) Brief introduction to PCR	10 Hours
Unit3	Immunity and Immunology Types of immunity- humoral immunity, cellular immunity a) Structure of Immunoglobulins b) Structure and Function of Major Histocompatibility Complex c) Hypersensitivity reactions, Immune stimulation and Immune suppressions. d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity. e) Storage conditions and stability of official vaccines f) Hybridoma technology- production, purification and applications g) Blood products and Plasma Substitutes. Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, and plasma substitutes.	10 Hours
Unit4	Advanced Microbial Genetics and Industrial Biotransformation a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting. b) Genetic organization of Eukaryotes and Prokaryotes c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons. d) Introduction to Microbial biotransformation and applications. e) Mutation: Types of mutation/mutants.	08 Hours
Unit5	Fermentation Technology and Bioprocess Engineering a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring. b) Large scale production fermenter design and its various controls. c) Study of the production of - penicillin, citric acid, Vitamin B12, Glutamic acid, Griseofulvin etc.	07 Hours

Tutorials

Tutorial hours: 15 Hours

Tutorials will be based on the above syllabus

Recommended Books^:(Latest Editions)

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
2. *Kuby Immunology*. 7th edition. New York: W. H. Freeman, 2013.



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3. J.W. Goding: Monoclonal Antibodies: *Principles and Practise*, Academic Press, London (Orlando)
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

L=Lecture, Tu=Tutorial, P=Practical, T=Theory

^This is not an exhaustive list




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ANANDPHARMACYCOLLEGE, ANAND
(An Autonomous Institute under UGC Regulations 2023)
Managed by Shri Ramkrishna Seva Mandal



(Approved by PCI, NAAC Accredited – A+ Grade, 3.38 CGPA)
Awarding University: Gujarat Technological University, Ahmedabad

Name of Program: **B. Pharm**

Semester: **VI**

Course Code: **B010606TT**

Course Name: **BIostatISTICS AND RESEARCH METHODOLOGY**

Course Type: **Core**

Year of Implementation: **2026 –27 (Effective from batch 2024-25)**

Teaching and Examination Scheme:

Number of hours/Week			Number of Credits			Total credits	Evaluation Scheme (Marks)									Total Marks
							Sessional Exams						Term End Assessment			
L	Tu	P	L	Tu	P	4	Theory			Practical			T		P	
							CIE	E	T	CIE	E	T				
3	1	0	3	1	0		10	15	25	0	0	0	75	0	100	

Scope: To understand the applications of Biostatistics 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, analysing the statistical data using Excel.

Course Outcomes (CO):

Upon completion of the course, student shall be able to

CO1	Understand fundamental concepts of statistics and biostatistics, and apply measures of central tendency, dispersion, correlation, regression, and probability in pharmaceutical data analysis.
CO2	Analyse and solve numerical problems using parametric and non-parametric tests, and assess sampling, hypothesis testing, and error types in pharmaceutical and clinical data.
CO3	Recognise the basics of research methodology, experimental designs, graphical data, and develop protocols for pharmaceutical research, clinical trials, and report writing.
CO4	Apply advanced statistical tools, regression modelling, factorial designs, and response surface methodology using software to optimize experiments.

Detailed Syllabus:

Total Teaching hours: **45 hours**



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Unit1	Introduction: Statistics, Biostatistics, Frequency distribution	4 Hours
	Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples	
	Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems	3 Hours
	Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples	3 Hours
Unit2	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	2 Hours
	Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution	2 Hours
	Properties - problems Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis	2 Hours
	Sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples	
	Parametric test: t-test (Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference	2 Hours
	Non-Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test	2 Hours
	Blocking and confounding system for Two-level factorials	
Unit3	Introduction to Research: Need for research, Steps of research, Need for design of Experiments, Experiential Design Technique, plagiarism, how to avoid plagiarism, detection tool	2 Hours
	Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph	2 Hours
	Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies	2 Hours
	Designing clinical trials, various phases.	2 Hours
	Experimental studies	2 Hours
Unit4	Regression modeling: Hypothesis testing in Simple and Multiple regression models	2 Hours
	Introduction to Practical components of Industrial and Clinical Trials	2 Hours
	Problems: Demonstration of Statistical Analysis Using Excel, SPSS, Graph Pad, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach	4 Hours
Unit5	Design and Analysis of experiments: Basic Steps in Experimental Design, Introduction to screening design, Factorial Design: Definition, 2^2 , 2^3 design. Advantages of factorial design	5 Hours



	Response Surface methodology: Overview, types, and application in optimization Central composite design: Historical design, Optimization Techniques	2 Hours
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Tutorials

Tutorial hours: 15 Hours

Tutorials will be based on the above syllabus

Recommended Books^(Latest Editions)

1. Sanford Bolton, Pharmaceutical statistics- Practical and clinical applications. Published by Marcel Dekker Inc. New York.
2. Gupta S C. Fundamental of Statistics published by Himalaya Publishing House. New Delhi.
3. R. Panneerselvam. Design and Analysis of Experiments published by PHI Learning Private Limited.
4. Douglas and C. Montgomery Design and Analysis of Experiments – Wiley Students Edition.
5. Khanal AB. Mahajan's methods in biostatistics for medical students and research workers published by Jaypee Brothers.
6. Kothari C. R. Research Methodology: Methods and Techniques. Published by New Age International Publishers.
7. James E. De Muth. Basic Statistics and Pharmaceutical Statistical Applications. Publisher, Taylor & Francis Limited.
8. Khanal AB. Mahajan's methods in biostatistics for medical students and research workers. Jaypee Brothers.
9. Rastogi V. B. Fundamentals of Biostatistics. Published by Ane Books India

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