Course Code	Course Title	L	T	P	C
BABIT307	**Pharmaceutical Biotechnology**	**3**	**1**	**0**	**4**
Pre-requisite	BABIT101 - Biochemistry	**Syllabus Version**			
		1			

Course Objectives

1. Understand the pharmacology of drugs and its impact on human health
2. Develop the basic skills necessary for employing biotechnology principles in medicine
3. Equip with the skillset for clinical research organizations

Course Outcomes

1. Understand the basics involved in human-drug interactions
2. Delineate the process involved in drug formulations
3. Evaluate the pharmacokinetics and dynamics of protein drugs
4. Compare the various biologics and its mechanisms
5. Gain knowledge on clinical trials and regulatory affairs

Module:1	**Pharmacokinetics and Pharmacodynamics**	**9 hours**

Pharmacokinetics and Pharmacodynamics; Routes of drug administration; Bioavailability curve; Drug receptor interaction; Adverse drug reaction; Mechanism of action of local and general anesthetics; Opioid analgesics and antagonists; NSAIDs; Antihistamines; Pharmacotherapy of hypertension; peptic ulcer, cough.

Module:2	**Drug Formulations**	**9 hours**

Manufacturing; Quality control and packaging of tablets, capsules; hard and soft gelatin; Parenterals; Aerosols; Solutions; Transdermal patches.

Module:3	**Protein Drug Delivery**	**8 hours**

Pharmacokinetics and pharmacodynamics of peptide and protein drugs; Excipients used in Biotech products; Shelf-life of protein-based drugs; Controlled and site-specific delivery of protein drugs; Peptide nano-materials in drug delivery; Liposomes; Dendrimers.

Module:4	**Biologics**	**9 hours**

Cytokines; Interleukins and interferons; Insulin; Insulin and its analogues; Growth hormone; Progesterone; Modern vaccines - Subunit vaccines; r-DNA vaccines; Monoclonal antibody; Humanized antibody and engineered antibodies; Development of antibody based targeted drug therapy.

Module:5	**Clinical Trials and Regulatory Affairs**	**8 hours**

Clinical trials - Classification, Phases of clinical trials, Clinical trials design, Double blind studies, Placebo effects, Informed consent; Drug regulations - FDA regulations (General) and Indian drug regulations (CDSCO); Adulterated,

Spurious, and Misbranded drugs; GCP, NDA and ANDA, BIOSIMILARS regulations.		
Module:6	**Contemporary Topics**	**2 hours**
Contemporary Topics		
	Total Lecture Hours:	**45 hours**
	Tutorial Hours:	**15 hours**
Text Book(s)		
Satoskar RS, Bhandarkar SD, Rege NN, "**Pharmacology and Pharmacotherapeutics**", Elsevier New Delhi, 26th Edition, **2020** Allen V Loyd, Howard C Ansel, "**Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems**", Lippincott Williams and Wilkins Philadelphia, 11th Edition, **2018**		
Reference Books		
Laurence Brunton, Bruce Chabner, Bjorn Knollman, "**Goodman and Gilman's The Pharmacological Basis of Therapeutics**", McGraw Hill New York USA, 13th Edition, **2017**		
Mode of Evaluation : Continuous Assessment Test, Digital Assignment, Quiz, Final Assessment Test, Seminar, Presentaion		
Recommended by Board of Studies :	26-05-2025	
Approved by Academic Council : No. 78	12-06-2025	