GANPAT UNIVERSITY

FACULTY OF ENGINEERING & TECHNOLOGY

Program	Bachelor of Technology				Branch/Spec.	Biotechnology		
Semester	VII				Version	1.0.0.0		
Effective from Academic Year	2025-2026				Effective for the batch Admitted in	July 2022		
Course code	2BT7101	Course Name			Pharmaceutical Biotechnology			
Teaching scheme					Examination scheme (Marks)			
(Per week)	Lecture (DT)		Practical (Lab.)	Total		CE	SEE	Total
	L	TU	P	TW				
Credit	3	-	1	-	4	Theory	40	60	100
Hours	3	-	2	-	5	Practical	30	20	50

Pre-requisites

Prior knowledge of biology, chemistry, genetics, molecular biology, bioprocessing and laboratory techniques is required.

Course Outcomes

On successful completion of the course, the students will be able to:

CO1	**Understand** the Role and Development of Biopharmaceuticals in Modern Healthcare
CO2	**Develop** Effective Drug Discovery Approaches and Delivery Systems
CO3	**Apply** Biotechnological Innovations in Drug Discovery and Manufacturing
CO4	**Understand** the Principles of Drug Discovery, Clinical Pharmacology, and Toxicology
CO5	**Evaluate** Regulatory Affairs, Drug Approval Processes, and Quality Management Systems
CO6	**Demonstrate** Knowledge of Biopharmaceuticals, Hormonal Therapies, and Their Therapeutic Applications

Theory syllabus

Unit	Content	Hrs.
1	INTRODUCTION TO BIOPHARMACEUTICALS AND DRUG DEVELOPMENT PROCESS: Introduction to Biotechnology and Biopharmaceuticals, Historical perspective, transforming molecular entities into drugs, current trends in drug development, industry perspective on drug development, Drug discovery approaches, modulatory effects, binding strength, effective and inhibitory concentration, side effects, ADME, Lipinski rule, pharmacokinetics, pharmacodynamics, routes of drug administration, Patenting, phases of clinical studies, design and conduct of clinical trials, Case Studies in Drug Discovery.	9
2	DRUG ABSORPTION AND DISTRIBUTION: Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non-per oral extravascular routes, Distribution of drugs, Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs.	9
3	ELIMINATION: Drug metabolism, metabolic pathways, factors affecting metabolism, renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non- renal routes of drug excretion of drugs. BIOAVAILABILITY AND BIOEQUIVALENCE: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs	10
4	PHARMACOKINETICS: Introduction to Pharmacokinetics, Pharmacokinetic models, One compartment open model Intravenous Bolus Injection – Intravenous infusion - Extra vascular administrations.	9

	Determination of pharmacokinetics parameters and their significance - Absorption Rate Constant (ka), Elimination Rate Constant (K) & Elimination Half- life (t½), AUC, Cmax, and tmax. Apparent Volume of Distribution (Vd) & Renal Clearance (Q).	
5	ECONOMIC ASPECTS AND CASE STUDIES IN BIOPHARMACEUTICAL DEVELOPMENT: Life cycle of a drug, cost calculation principles, biotechnology manufacturing costs, investments, production concept, technology transfer, supply chain management, Case studies by practioners of biopharmaceutical development and manufacturing.	8

Practical Contents	
Practicals and term work are based on the above syllabus.	
Text Books	
1	Biopharmaceuticals: Biochemistry and Biotechnology by Gary Walsh, Pub.: Wiley-Blackwell.
2	Basic Pharmacokinetics and Pharmacodynamics: An Integrated Textbook and Computer Simulations by Rosenbaum, S. E. Pub.: John Wiley & Sons.
3	Pharmaceutical biotechnology: concepts and applications by Walsh G. Pub.:John Wiley & Sons
Reference Books	
1	Biotechnology and Biopharmaceuticals. Transforming Proteins and Genes into Drugs by Ho RJ, Gibaldi M. Pub.:
2	Drug Discovery and Development. Technology in Transition. Rang HP. Pub.: Elsevier.
3	Biopharmaceutics and Pharmacokinetics: a Treatise by Brahmankar, D.M. and Jaiswal, S.B. Pub.: Alig publication.
ICT References	
1	https://archive.nptel.ac.in/courses/102/108/102108077/
2	https://onlinecourses.swayam2.ac.in/cec20_lb05/preview

Mapping of CO with PO and PSO:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**
CO1	2	3	2	1	1	3	1	1	1	2	2	1	3	2	2
CO2	3	3	3	2	3	2	1	0	0	3	0	1	3	3	2
CO3	3	3	3	3	3	3	1	1	1	3	3	1	3	3	2
CO4	2	3	3	3	2	3	1	0	0	3	0	2	3	3	2
CO5	2	3	2	1	3	2	2	1	1	3	2	2	3	3	3
CO6	3	3	3	2	2	3	1	1	1	3	2	2	3	3	3