U.S.N.										

B.M.S.College of Engineering, Bengaluru-560019

Autonomous Institute Affiliated to VTU

June 2025 Semester End Main Examinations

Programme: B.E. **Semester: VII**

Branch: Biotechnology **Duration: 3 hrs.**

Course Code: 22BT7PEBNB **Max Marks: 100**

Course: Biological & Biopharmaceuticals

Instructions: 1. Answer any FIVE full questions, choosing one full question from each unit.
2. Missing data, if any, may be suitably assumed.

Important Note: Completing your answers, compulsorily draw diagonal cross lines on the remaining blank pages. Revealing of identification, appeal to evaluator will be treated as malpractice.

			UNIT - I	*CO*	*PO*	Marks
1	a)		Given a case study on an adverse reaction to a biosimilar, how would you implement pharmacovigilance strategies?	*CO 1*	*PO 6*	**7**
	b)		Design an ethical framework for conducting clinical trials of a new biologic drug.	*CO 1*	*PO 8*	**7**
	c)		What factors determine the market success of a newly developed biosimilar?	*CO 1*	*PO 8*	**6**
			OR			
2	a)		What ethical dilemmas might arise from the commercialization of biosimilars, and how can they be addressed?	*CO 1*	*PO 6*	**7**
	b)		Propose a strategy for improving public awareness of ethical concerns in biopharmaceuticals.	*CO 1*	*PO 8*	**7**
	c)		Compare and contrast the pharmacovigilance requirements in FDA regulations.	*CO 1*	*PO 8*	**6**
			UNIT - II			
3	a)		Why are solubility enhancers crucial in biotherapeutic formulations?	*CO2*	*PO6*	**6**
	b)		How to choose an appropriate anti-aggregating agent for a monoclonal antibody formulation?	*CO2*	*PO6*	**6**
	c)		Design a novel formulation strategy to enhance the stability of an unstable peptide therapeutic.	*CO2*	*PO6*	**8**
			OR			
4	a)		Why are preservatives necessary in biopharmaceutical formulations, and what risks do they mitigate?	*CO2*	*PO6*	**6**
	b)		How to modify a biopharmaceutical formulation to improve its resistance to temperature fluctuations?	*CO2*	*PO6*	**6**
	c)		Propose an innovative packaging solution for a temperature-sensitive biopharmaceutical.	*CO2*	*PO6*	**8**

			UNIT - III			
	5	a)	Why are growth factors such as IGF and EGF important in regenerative medicine?	*CO3*	*PO1*	**8**
		b)	How to determine the most suitable formulation for insulin in a patient with high insulin resistance?	*CO3*	*PO1*	**8**
		c)	Compare the effectiveness of different neurotrophic factors in treating neurodegenerative diseases.	*CO3*	*PO6*	**4**
			OR			
	6	a)	What factors determine the bioavailability of engineered insulins in diabetic patients?	*CO3*	*PO1*	**7**
		b)	How to adjust the formulation of an insulin analog to improve its absorption rate?	*CO3*	*PO1*	**7**
		c)	Develop a hypothetical case study on the clinical application of thrombolytic drugs in stroke treatment.	*CO3*	*PO6*	**6**
			UNIT - IV			
	7	a)	How do cytokines influence immune responses in different disease conditions?	*CO 3*	*PO 6*	**7**
		b)	Why is vaccine-adjuvant technology critical for immunotherapy?	*CO 3*	*PO 6*	**8**
		c)	Critically examine the future potential of mRNA vaccines beyond COVID-19.	*CO3*	*PO6*	**5**
			OR			
	8	a)	How to modify an existing CAR-T cell therapy to improve its efficacy against solid tumors?	*CO3*	*PO 6*	**5**
		b)	Compare the effectiveness of mRNA vaccines versus genetically engineered vaccines.	*CO 3*	*PO 6*	**7**
		c)	Develop a hypothetical immunotherapeutic intervention for a rare genetic disorder.	*CO3*	*PO 6*	**8**
			UNIT - V			
	9	a)	How to utilize nanotechnology to enhance the delivery of therapeutic peptides?	*CO4*	*PO 1*	**7**
		b)	Compare the advantages and limitations of rate-controlled versus site-specific drug delivery.	*CO4*	*PO 6*	**7**
		c)	How to design a nanoparticle-based system for targeting cancer cells?	*CO 4*	*PO 6*	**6**
			OR			
	10	a)	What are the major challenges in designing intracellular delivery systems for nucleic acids?	*CO 4*	*PO 1*	**7**
		b)	Assess the regulatory challenges in approving novel biopharmaceutical delivery systems.	*CO 4*	*PO 6*	**7**
		c)	Develop a delivery strategy for an unstable biopharmaceutical requiring controlled release.	*CO 4*	*PO 6*	**6**

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