Enrollment No./Seat No.:

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Engineering - SEMESTER - VI EXAMINATION - SUMMER 2025

Subject Code: 3160416 **Date: 30-05-2025**

Subject Name: Biosimilars technology

Time: 10:30 AM TO 01:00 PM **Total Marks: 70**

Instructions

1. Attempt all questions.

2. Make suitable assumptions wherever necessary.

3. Figures to the right indicate full marks.

			Marks
Q.1	**(a)**	Write steps for manufacturing of bio-pharmaceuticals.	**03**
	(b)	Write difference between generics and biosimilars.	**04**
	(c)	Write a note on immunogenenicity and allergenicity of biosimilars.	**07**
Q.2	**(a)**	What are developmental and regulatory challenges in biosimilar development.	**03**
	(b)	Write a note on organ book.	**04**
	(c)	Briefly describe biosimilar of hGH hormone.	**07**
		OR	
	(c)	Explain biosimilar drugs: Nucleic acid based therapies.	**07**
Q.3	**(a)**	What is KLa in upstream optimization of recombinant protein biosimilar?	**03**
	(b)	Write a note on types of bioequivalence.	**04**
	(c)	Give brief note on Case study of KYMRIAH.	**07**
		OR	
	(a)	Write a note on cGMP requirements.	**03**
	(b)	Give experimental designs for bio equivalence studies.	**04**
	(c)	Write case study on any one biosimilar antibody used for treatment of cancer.	**07**
Q.4	**(a)**	Expand the term ECP. Give 2 key aspects of ECP.	**03**
	(b)	Write principle and working of affinity chromatography.	**04**
	(c)	Describe process pipeline for searching for candidate biosimilar with patent search and nucleotide database.	**07**
		OR	
	(a)	Describe market value of biosimilars.	**03**
	(b)	Write merits and demerits of size exclusion chromatography.	**04**
	(c)	Write an note on humira biosimilar.	**07**
Q.5	**(a)**	What are the steps for formulation of final biosimilar product?	**03**

(b)	Give process pipeline for selection of vector for recombinant protein biosimilar.	**04**
(c)	What are biosimilar insulins? Briefly describe.	**07**

OR

(a)	Enlist prerequisites for development of biosimilars.	**03**
(b)	How will you evaluate genetic stability of cell line?	**04**
(c)	Briefly describe upstream optimization of recombinant protein biosimilar.	**07**

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