Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

BE - SEMESTER–VI (NEW) EXAMINATION – SUMMER 2023

Subject Code:3160416 Date:14-07-2023

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.**
4. **Simple and non-programmable scientific calculators are allowed.**

			Marks
Q.1	**(a)**	Compare generics, biologics and biosimilars.	**03**
	(b)	Explain the different stages for development of Biosimilars.	**04**
	(c)	compare various cell lines used in biosimilar development.	**07**
Q.2	**(a)**	What is transient transfection?	**03**
	(b)	Write down the selection of key differences in EU and in Us.	**04**
	(c)	Explain the difference between a generic drug and a biosimilar drug, and justify the need for a short pathway for introduction of a biosimilar drug into the market.	**07**
		OR	
	(c)	Explain any two Biosimilar drugs in brief.	**07**
Q.3	**(a)**	Explain challenges in development and regulation of Biosimilar drugs.	**03**
	(b)	Write a note on formulation of biosimilar drug.	**04**
	(c)	Enlist various factors affecting immunogenicity of biosimilar drug and explain any one in detail.	**07**
		OR	
Q.3	**(a)**	Explain allergenicity in bioequivalence studies.	**03**
	(b)	Compare orange book and purple book.	**04**
	(c)	Explain briefly about types of Bioequivalence studies.	**07**
Q.4	**(a)**	Define bioequivalence in details.	**03**
	(b)	Explain the terms switching and interchangibility.	**04**
	(c)	Explain in details about Cell based biosimilars.	**07**
		OR	
Q.4	**(a)**	Give advantages of KYMRIAH.	**03**
	(b)	Write a note on Erythroprotein.	**04**
	(c)	Discuss Hydrophobic interaction chromatography in detail.	**07**
Q.5	**(a)**	What are expression vectors?	**03**
	(b)	What is codon optimization? What is its role in biosimilars development?	**04**
	(c)	Explain in details about CAR-T cells	**07**

OR

Q.5	**(a)**	Discuss genetic stability of cell line.	**03**
	(b)	Discuss use of kozak sequence in biosimilars development.	**04**
	(c)	Discuss Ion exchange chromatography in detail.	**07**

****