Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

BE - SEMESTER–VI (NEW) EXAMINATION – SUMMER 2022

Subject Code:3160416 Date:10/06/2022

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)**	What is the target for Adalimumab and explain working of the drug in case of rheumatoid arthritis.	**03**
	(b)	Can we use Kymriah, as the first drug, the moment one is diagnosed with ALL? Why?	**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**
Q.2	**(a)**	What will be the economic consequences of not adding the secretion signal to the gene construct of the biological drug that you want to produce?	**03**
	(b)	What is the significance of adding a Kozak sequence to gene construct that we are going to clone into a vector. The vector also has an oriC site, explain why it is put into the vector, even though the final biological drug is going to be a eukaryotic protein.	**04**
	(c)	Explain the significance of the End of production cell bank. What tests do we conduct to make sure that the final biosimilar molecule is free from contaminations?	**07**
		OR	
	(c)	Explain the procedure for making a mother cell bank and working cell bank. Why is cryopreservation important? Why do we prefer mammalian cell lines for the production of biosimilar drugs	**07**
Q.3	**(a)**	What definitive information will you get after doing patent search on the originator biological drug? What more information about the protein biological drug do you need to predict its immunogenicity or how long it will stay in the patient's body?	**03**
	(b)	Explain the principle of ion exchange chromatography and the desorbtion of the protein from the column with a diagram.	**04**
	(c)	Elaborate on the purification and formulation of biosimilar products.	**07**
		OR	
Q.3	**(a)**	After transfecting a cell line with the designed transgenic DNA, you need to select clones. Is the statement true or false, why?	**03**
	(b)	Gunaji has compared the originator biological protein and the biosimilar he created through peptide finger printing using proteases and through SDS PAGE for molecular weight analysis. He found that the biosimilar and the originator had similar charachteristics. Is this evidence enough for launching the biosimilar into the market? Explain your answer.	**04**

	(c)	Elaborate about the different types of biologicals that are possible.	**07**
Q.4	**(a)**	Explain the conditions that are required for proteins/biological drugs to get adsorbed on HIC columns. How do you elute proteins that are adhered to HIC columns.	**03**
	(b)	Explain the principle of gel filtration chromatography.	**04**
	(c)	How is Kymriah a biological drug? Explain the process of administering this drug to a patient.	**07**
		OR	
Q.4	**(a)**	Define bioequivalence? What tests can we do to ensure biosimilarity or bioequivalence?	**03**
	(b)	Explain the principle of affinity chromatography, give two examples of ligands used for affinity chromatography.	**04**
	(c)	Explain the structural and post translational features that might affect immunogenicity of a biological drug.	**07**
Q.5	**(a)**	Explian the phenomenon of switching vs interchangability	**03**
	(b)	If you are going to engineer	**04**
	(c)	Explain with the case study of erythropoietin, components and formulation impurities that might lead to immunogenecity	**07**
		OR	
Q.5	**(a)**	Give three examples of cell lines that you can use to produce a biological protein drug.	**03**
	(b)	Explain the significance of the patent search step for biosimilar production.	**04**
	(c)	CHO cells are aerobic cells, and are used as host cells for the production of biosimilar molecules. Apart from pH, Temperature and Media composition and inoculum parameters, what parameters will you control while scaling up? Elaborate on methods for measuring this parameter.	**07**

****