

GUJARAT TECHNOLOGICAL UNIVERSITY**BE - SEMESTER-VI(NEW) EXAMINATION – WINTER 2022****Subject Code:3160416****Date:17-12-2022****Subject Name:Biosimilars technology****Time:02:30 PM TO 05:00 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 codon optimization? Explain its significance.	03
(b) Write a brief note on genetic stability and identity testing for cell bank.	04
(c) Explain working of KYMIRAH	07
Q.2 (a) Compare generics, biologics and biosimilars.	03
(b) Explain the stages of biosimilar drug development.	04
(c) Write a short note on End of Production Cell bank.	07
OR	
(c) What is Kozak sequence? Why is it necessary to add it in the vector?	07
Q.3 (a) Explain the terms switching and interchangibility.	03
(b) Give difference between Mother Cell Bank and Working Cell Bank.	04
(c) Explain clone selection and expansion with an example.	07
OR	
Q.3 (a) Define bioequivalence. What are types of bioequivalence?	03
(b) Explain the importance of the patent search step for biosimilar production	04
(c) Enlist methods for transfection and explain any one in detail.	07
Q.4 (a) Give application of CART cells.	03
(b) Explain Bulk Harvest testing.	04
(c) Explain principle and application of Affinity Chromatography. What is significance of spacer arm?	07
OR	
Q.4 (a) Explain challenges in development and regulation of Biosimilar drugs.	03
(b) Enlist various factors affecting immunogenicity of biosimilar drug and explain any one in detail.	04
(c) Explain principle and application of Gel Permeation Chromatography.	07
Q.5 (a) Why is it necessary to add signal sequence to a biological drug?	03
(b) What is multimodal or mixed mode chromatography?	04
(c) Write a note on Host Cell Residual DNA Analysis.	07
OR	
Q.5 (a) What is Hydrophobic Interaction Chromatography?	03
(b) Write a note on formulation of biosimilar drug.	04
(c) Write a note on Host Cell Protein Detection and Quantification.	07
