

Seat No./Enrollment No.: _____

GUJARAT TECHNOLOGICAL UNIVERSITY
BACHELOR OF ENGINEERING – SEMESTER 6 – EXAMINATION – SUMMER 2026

Subject Code: 3160416

Date: 01/06/2026

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.**

- Q.1**
- (a) Define biosimilars and differentiate them from biologics. **03**
 - (b) Discuss the market potential and economic significance of biosimilars. **04**
 - (c) Discuss the complete developmental pipeline of biosimilars along with regulatory considerations. **07**

- Q.2**
- (a) What are enzyme biosimilars? Give one example. **03**
 - (b) Discuss therapeutic applications of monoclonal antibody biosimilars with suitable examples. **04**
 - (c) Discuss nucleic acid-based therapies including DNA, RNA, and gene therapy approaches. **07**

OR

- Q.2**
- (c) Explain cell-based therapies and stem-cell technologies used in biosimilar development. **07**
- Q.3**
- (a) Define mother cell bank and working cell bank. **03**
 - (b) Explain the role of restriction enzyme recognition sites in cloning design. **04**
 - (c) Explain the design and construction of recombinant expression vectors for biosimilar production. **07**

OR

- Q.3**
- (a) Define codon optimization and mention its significance. **03**
 - (b) Discuss media optimization in upstream processing. **04**
 - (c) Explain downstream processing techniques used in purification of recombinant biosimilars. **07**
- Q.4**
- (a) Mention factors affecting immunogenicity of biosimilars. **03**
 - (b) Discuss structural and post-translational modifications affecting biosimilar safety. **04**
 - (c) Analyze the role of regulatory databases such as Orange Book and Purple Book in biosimilar approval. **07**

OR

- Q.4**
- (a) Mention significance of whole-cell assays in biosimilar evaluation. **03**
 - (b) Discuss replicated crossover experimental designs in bioequivalence studies. **04**

(c) Discuss analytical, immunological, and statistical evaluation methods used in biosimilar characterization. **07**

- Q.5**
- (a) Mention therapeutic applications and advantages of growth hormone biosimilars. **03**
 - (b) Discuss therapeutic applications of erythropoietin biosimilars. **04**
 - (c) Explain Adalimumab (Humira) biosimilars with emphasis on mechanism of action and regulatory considerations. **07**

OR

- Q.5**
- (a) Define CAR-T cell therapy and mention its therapeutic applications. **03**
 - (b) Explain the significance of KYMRIAH in personalized medicine. **04**
 - (c) Discuss challenges associated with commercialization and regulation of advanced biosimilar therapeutics. **07**
