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Printed Page:-4 **Subject Code:- BBT0411**

Roll. No:

NOIDA INSTITUTE OF ENGINEERING AND TECHNOLOGY, GREATER NOIDA
(An Autonomous Institute Affiliated to AKTU, Lucknow)
B.Tech
SEM: IV - THEORY EXAMINATION (2025 - 2026)
Subject: Biosimilars Technology

Time: 3 Hours **Max. Marks: 100**

General Instructions:

IMP: *Verify that you have received the question paper with the correct course, code, branch etc.*
1. *This Question paper comprises of* ***three Sections -A, B, & C.*** *It consists of Multiple Choice Questions (MCQ's) & Subjective type questions.*
2. *Maximum marks for each question are indicated on right -hand side of each question.*
3. *Illustrate your answers with neat sketches wherever necessary.*
4. *Assume suitable data if necessary.*
5. *Preferably, write the answers in sequential order.*
6. *No sheet should be left blank. Any written material after a blank sheet will not be evaluated/checked.*

SECTION-A 20

1. Attempt all parts:-

(1.1) Biologics made via (CO1, K1) 1

(a) Cell culture
(b) Chemical synthesis
(c) Grinding
(d) Mixing

(1.2) Biosimilars vs generics differ in (CO1, K1) 1

(a) Complexity
(b) Cost
(c) Regulation
(d) All

(1.3) Glycosylation is analyzed in (CO2, K1) 1

(a) Small drugs
(b) Biologics
(c) Metals
(d) Salts

(1.4) In vitro bioassays measure (CO2, K1) 1

(a) Toxicity only
(b) Biological function
(c) Packaging
(d) Price

(1.5) ELISA is used for (CO3, K1) 1

(a) Potency
(b) Packaging
(c) Label
(d) Storage

(1.6) GMP requires (CO3, K1) 1

(a) Training
(b) Cost
(c) Demand
(d) Label

(1.7) Comparability protocol ensures (CO4, K1) 1

(a) Similarity
(b) Identity
(c) Difference
(d) None

(1.8) Clinical endpoint studies measure (CO4, K1) 1

(a) Efficacy
(b) Cost
(c) Label
(d) Packaging

(1.9) Insulin biosimilars used in (CO5, K1) 1

(a) Diabetes
(b) Cancer
(c) Infection
(d) Allergy

(1.10) Risk management plans are part of (CO5, K1) 1

(a) Pharmacovigilance
(b) Marketing
(c) QC
(d) Packaging

2. Attempt all parts:-

(2.1) Define biologics. (CO1, K1) 2

(2.2) List any two steps involved in biosimilar development. (CO2, K1) 2

(2.3) What is safety testing in QC? (CO3, K1) 2

(2.4) What are pharmacodynamics (PD) studies? (CO4, K1) 2

(2.5) Mention one safety concern associated with biosimilars. (CO5, K1) 2

SECTION-B 30

Answer any one of the following:-

(3.1) Explain the concept of biosimilarity and its significance in drug development. (CO1, K2) 6

(3.2) Discuss the advantages of biosimilars in healthcare systems. (CO1, K2) 6

Answer any one of the following:-

(3.3)	Define reference product and explain its importance in biosimilar development. (CO2, K2)	6
(3.4)	A biosimilar shows slight variation in glycosylation pattern. Explain how analytical characterization can address this issue. (CO2, K2)	6

Answer any one of the following:-

(3.5)	Explain the stages of downstream process design and their significance. (CO3, K2)	6
(3.6)	Perform a stepwise approach to ensure safety testing of a biologic product before release. (CO3, K3)	6

Answer any one of the following:-

(3.7)	Discuss the role of WHO in harmonizing global biosimilar regulations. (CO4, K2)	6
(3.8)	Determine appropriate regulatory requirements for interchangeability approval. (CO4, K3)	6

Answer any one of the following:-

(3.9)	Analyze the role of immunogenicity in limiting biosimilar acceptance. (CO5, K4)	6
(3.10)	Analyze ethical concerns in substitution and interchangeability of biosimilars. (CO5, K4)	6

SECTION-C 50

4. Answer any one of the following:-

(4.1)	A drug regulator compares approval pathways. Discuss differences between biosimilar and generic approval processes. (CO1, K2)	10
(4.2)	A country promotes biosimilars for public health. Discuss rationale for biosimilar development. (CO1, K2)	10

5. Answer any one of the following:-

(5.1)	Determine the key factors influencing the selection of a reference product from different regions. (CO2, K3)	10
(5.2)	Discuss the relationship between structural characterization and functional performance of biosimilars. (CO2, K2)	10

6. Answer any one of the following:-

(6.1)	Explain how oxygen transfer rate affects cell growth in a bioreactor system. (CO3, K2)	10
(6.2)	Explain how pH and ionic strength influence protein formulation stability. (CO3, K2)	10

7. Answer any one of the following:-

(7.1)	Explain the CDSCO approval pathway for biosimilars with emphasis on recent updates. (CO4, K2)	10
(7.2)	Apply EMA guidelines to outline a regulatory submission plan for a biosimilar entering the European market. (CO4, K3)	10

8. Answer any one of the following:-

(8.1)	Describe the contribution of leading biosimilar companies to market expansion with suitable examples. (CO5, K1)	10

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(8.2)	Analyze the clinical and economic impact of infliximab biosimilars in autoimmune disease management. (CO5, K4)	10