MEDICAL & PHARMACEUTICAL BIOTECHNOLOGY
(BIOT 4233)

Time Allotted : 2½ hrs **Full Marks : 60**

Figures out of the right margin indicate full marks.

Candidates are required to answer Group A and any 4 (four) from Group B to E, taking one from each group.

Candidates are required to give answer in their own words as far as practicable.

Group – A

1. Answer any twelve: **12 × 1 = 12**

Choose the correct alternative for the following

(i) Which of the following is not a thrombolytic agent?
(a) Recombinant human activase (b) Urokinase
(c) Streptokinase (d) **β**-galactosidase

(ii) Which of the following DOES NOT constitute a test on a potential new drug in the preclinical phase of drug development?
(a) Pharmacokinetic profile (b) Pharmacodynamic profile
(c) Bioequivalence and bioavailability (d) Global tolerance

(iii) Glucagon is a hormone that has which one of the following characteristics?
(a) Single chain polypeptide of 29 amino acid residues
(b) Synthesized by the B cells of the Islets of Langerhans
(c) Can cause hypoglycaemia
(d) Has an overall anabolic effect.

(iv) Intrabodies are used to inhibit expression of gene at
(a) DNA level (b) RNA level
(c) Protein level (d) All of the above

(v) The process of using the patient's own adipose tissue to extract the stem cells is known as
(a) Harvesting (b) Separation
(c) Activation (d) Treatment

(vi) Ceprotin (human protein C concentrate) is a protein based anticoagulant. In its preparation from pooled human plasma, special precautionary steps are undertaken to ensure that the finished product Ceprotin is pathogen free. Which of the following represents such a precautionary step?
(a) Ultrafiltration
(b) Incubation with polysorbate 80 (viral inactivation)
(c) IgG based immunoaffinity chromatography
(d) none of the above

(vii) Of the biopharmaceutical proteins that have been produced by recombinant means, the ones that have been expressed in yeast have which one of the expression level percentages?
(a) 30% (b) 20%
(c) 50% (d) None of (a), (b) & (c)

(viii) Which of the following is not true about High pressure liquid chromatography (HPLC)?
(a) It requires high pressure for the separation of the specious
(b) There is no need to vaporise the samples
(c) It is performed in columns
(d) It has high sensitivity

(ix) LDH 2 is present in
(a) Liver (b) Lungs
(c) Red blood cells (d) Skeletal muscles

(x) Biosensors which detect changes in potential differences is known as
(a) Calorimetric biosensors (b) Piezoelectric biosensors
(c) Amperometric biosensors (d) Optical biosensors

Fill in the blanks with the correct word

(xi) The first enzyme that rise in the blood after an obstruction in the bile duct is _____.

(xii) The Quartz crystal is used in _____ biosensor.

(xiii) A and D in ADMET stands for _____ and _____.

(xiv) _____ is an enzyme commonly used in ELISA.

(xv) CD4 markers are present on the surface of _____.

Group - B

2. (a) Recombinant (human) Interferonβ (RhIFN-β) has been found to have therapeutic applications in the treatment of autoimmune diseases including B.TECH/BT/6TH SEM/BIOT 3221/2023 BIOT 3221 3 relapse-remission multiple schlerosis , a chronic disease of the nervous system. How does this disease progress? What are the clinical presentations of this disease? Such recombinant biopharmaceutical products of IFN-β have been clinically approved in two cellular expression systems. What are they? Briefly explain your answers. Suppose the Rh-IFN-β under production was in a E. coli expression system. What are the anticipated structural differences between native and recombinant IFN-β?

[(CO1)(Understand-analyze/IOCQ)]

(b) Using a labelled flowchart overview for the manufacture of a (RhIFN-β) explain the role of E.coli fermentation, use of inclusion bodies (IB) and the downstream processing part of this purification process. How is shelf-life of this recombinant biopharmaceutical stabilized in this purification process?

[(CO1)(Understand-apply/IOCQ)]

(c) Use a table to represent the ADRs (adverse drug responses) associated with administration of IFN-β. Why is it difficult to predict such side effects and what clinical means have been adopted to counteract such ADRs? *[(CO2)(Analyze/IOCQ)]*

5 + 4 + 3 = 12

3. (a) Describe the synthesis process for recombinant human Erythropoietin (EPO). *[(CO3)(Describe/HOCQ)]*

(b) Why are mammalian cell lines (like CHO cells) preferred over bacterial systems for the production of such complex glycoproteins? *[(CO4)(Remember/LOCQ)]*

(c) Discuss the role of microbial biotransformation in the industrial synthesis of corticosteroids. Why is a semi-synthetic approach starting from plant sterols often more viable than total chemical synthesis? *[(CO3)(Analyze/IOCQ)]*

4 + 2 + (4 + 2) = 12

Group - C

4. (a) Explain the process of inhibiting the expression of the gene at the DNA level. *[(CO4)(Analyse/IOCQ)]*

(b) State the benefits of pharmacogenomics. *[(CO4)(Remember/LOCQ)]*

(c) Illustrate the procedure of a stem cell therapy. *[(CO4)(Illustrate/HOCQ)]*

4 + 4 + 4 = 12

5. (a) Illustrate the process of sorting diffuse large B-cell lymphoma (DLBCL) and anaplastic large cell lymphoma (ALCL) by FACS. *[(CO3)(Analyse/HOCQ)]*

(b) Enumerate the process of inserting the therapeutic DNA within the cells by Gene gun. *[(CO4)(Explain/IOCQ)]*

6 + 6 = 12

Group - D

6. Capillary Electrophoresis's (CE) microscale nature has made it a method of choice for separation of a wide spectrum of biomolecules including amino acids, peptides, proteins and DNA fragments. Answer the following questions with respect to CE and its applications to protein separations (i) Why is a stabilising medium not needed in a capillary? (ii) Write out the equations for migration time and separation efficiency for CE; define all the terms and their significance in biomolecule separations (iii) Draw a typical capillary electrophoretograph for separation of any five random structurally related peptides. Assume the following parameters: column length 100 cm, separation voltage 50kV, peptide detection by UV absorbance at 200 nm; assume a run time of 25-30 minutes. (iv) Give four specific examples of how CE has been successfully used for separation of biomolecules other than proteins or peptides. *[(CO3)(Analyse/HOCQ)]*

[2 + (4 + 1) + 3 + 2] = 12

7. (a) Describe the fundamental difference between a Competitive ELISA and a Sandwich ELISA. In what clinical scenario would a Sandwich ELISA be preferred over a Competitive format, and why? *[(CO3)(Describe/IOCQ)]*

(b) Discuss the criteria that a protein-based molecule must meet to be classified as a "Validated Cancer Biomarker." *[(CO2)(Discuss/IOCQ)]*

(c) Explain the role of functional proteomics in the drug development process. *[(CO3)(Explain/IOCQ)]*

(3 + 2) + 3 + 4 = 12

Group - E

8. (a) Briefly explain the role of lactate dehydrogenase as biomarker. *[(CO6)(Analyse/IOCQ)]*

(b) Explain with a schematic diagram the components of a typical biosensor. *[(CO5)(Explain/IOCQ)]*

(c) What do you mean by a Gold Standard in a diagnostic kit? *[(CO6)(Remember/LOCQ)]*

5 + 5 + 2 = 12

9. (a) Illustrate the assay to determine the alkaline phosphatase activity. *[(CO6)(Illustrate/IOCQ)]*

(b) Explain briefly the working principle of an Amperometric biosensor. Give example. *[(CO5)(Explain/HOCQ)]*

(c) Enumerate some limitations of a biosensor. *[(CO5)(Remember/LOCQ)]*

4 + 4 + 4 = 12

Cognition Level	LOCQ	IOCQ	HOCQ
Percentage distribution	12.50	56.25	31.25