MEDICAL AND PHARMACEUTICAL BIOTECHNOLOGY
(BIOT 3221)

Time Allotted : 3 hrs **Full Marks : 70**

Figures out of the right margin indicate full marks.

Candidates are required to answer Group A and any 5 (five) from Group B to E, taking at least one from each group.

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

Group – A
(Multiple Choice Type Questions)

1. Choose the correct alternative for the following: **10 × 1 = 10**

(i) Which of the following is NOT a class of antibiotics?
(a) RNA synthesis inhibitors (b) Protein synthesis inhibitors
(c) Folic acid antagonists (d) Catecholamines

(ii) Which of the following enzymes take part in bone growth and development
(a) Lactate dehydrogenase (b) Creatine Kinase
(c) Alkaline phosphatase (d) Acid phosphatase

(iii) Which of the following descriptions apply to methylprednisolone?
(a) It is a synthetic glucocorticoid
(b) It is used as an anti-inflammatory agent
(c) (a) and (b)
(d) none of the above

(iv) The plasma or elimination half life, $t_{1/2}$, is represented correctly by which of the following choices?
(a) this is the time required for plasma concentration to decline by 50% following its i.v. administration
(b) $t_{1/2}=0.693 \times V_d/Cl_{int}$
(c) values of $t_{1/2}$ range from 1 to 24 hours
(d) all of the above

(v) Detection of antibody by Evanescent wave is a type of
(a) Piezoelectric Biosensors (b) Calorimetric Biosensors
(c) Optical Biosensors (d) Amperometric Biosensors

(vi) Which of the following is NOT an example of a Bio-recognition element?
(a) Enzyme (b) Antibody
(c) Glass (d) None of these

(vii) For the IFN-α family of human interferons, the producing cells are
(a) Fibroblasts
(b) T-lymphocytes
(c) Lymphocytes, monocytes, macrophages
(d) NK-cells

(viii) Live, attenuated or killed pathogen are used in
(a) 1st Generation Vaccines (b) 2nd Generation Vaccines
(c) 3rd Generation Vaccines (d) None of these

(ix) Peptide Nucleic Acids (PNA) are used to inhibit expression of gene at
(a) DNA level (b) RNA level
(c) Both of them (d) None of the above

(x) Which one of the following represents the *first generation immunoassay* formats?
(a) methods based on the agglutination reaction
(b) methods where fluorescein isothiocyanate (FITC) is the derivative used to label antibodies
(c) methods where the antibodies can be labelled by the addition of marker enzymes like horseradish peroxidase (HRP) or alkaline peroxidase (AP)
(d) method where multi-antibody binding events can be detected by using rare earth lanthanides as labels.

Group – B

2. (a) Define the term "biopharmaceutical" in an inclusive sense with examples. Enumerate the four categories of nonclinical/preclinical tests that are applied to biopharmaceuticals. Which two of these categories exhibit a somewhat unique response for biopharmaceuticals compared to small molecule pharmaceuticals?

(b) Name the two catecholamine hormones that form part of the steroid group of biopharmaceuticals. What is their common biosynthetic precursor? How do these two hormones induce their biological effects?

(c) What do pharmacokinetic (PK) parameters of a drug quantify? Name and mathematically define the three main parameters that help in establishing the PK profile of a drug. What two clinical parameters of a drug are established by clear definition of the aforementioned three PK parameters?

(1 + 2 + 1) + (1 + 1 + 2) + (1 + 2 + 1) = 12

3. (a) What are the multiple objectives of a Phase I clinical trial for a representative biopharmaceutical? What are the essential parameters for a Phase I evaluation? Use a flowchart to explain briefly the importance of planning in a typical biopharmaceutical production scale up procedure(s).

(b) What areas of cytokine biology and subsequent therapeutic applications thereof benefitted from developments in rDNA and monoclonal antibody *technologies?* Your answer should be clear in its detail. Define a biosimilar "biopharmaceutical product" with examples from monoclonal antibodies.

(c) What are the clinical indications of Interferon-alpha (IFN-α)? Use a simple flowchart *only* to show the essential upstream and downstream processing steps of IFN-α production. What is the clinical indication for recombinant pegylated IFN- α-2B? How is the polyethylene glycol(PEG) linked to the IFN molecule? What is the important difference in pharmacokinetic properties between PEGylated and nonPEGYlated interferons?

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

Group – C

4. (a) Explain the methodology for the separation of a mixture of heterogeneous cells using FACS.

(b) Identify the different accessible sources of stem cells in an adult.

(c) Cite the advantages of a DNA Vaccine.

6 + 3 + 3 = 12

5. (a) Explain the concept, methodology development and applications of the Amplichip.

(b) What is the role of PNA in Gene therapy?

6 + 6 = 12

Group – D

6. (a) Erythropoietin (EPO) is a haemopoietic growth factor that stimulates erythropoiesis. Use a schematic diagram for the production of a recombinant human EPO (rh-EPO) to explain the role of various chromatographic separation methodologies in the production of this biopharmaceutical.

(b) What are the essential principles behind quantitative mass spectrometry for proteins? Tabulate the applications AND a comparative evaluation of the following three quantitative mass spectrometry methods: Chemical protein labelling (MS), Chemical peptide labelling (MS/MS) and label-free (ion intensity). Use accuracy, quantitative range and linear dynamic range as your evaluation parameters.

(c) Briefly answer the following questions with respect to uses of proteomics for identification of disease state biomarkers: (i) Give three examples of *types* of biomarkers (ii) Why are proteins suitable for use as disease biomarkers? (iii) How can proteomics be useful in the development of a more specific disease index from a combination of non specific biomarkers? (iv) For the infectious disease SARS, what was the name of the serum biomarker and name the proteomic detection technique(s) used.

4 + (1 + 3) + 4 = 12

7. (a) Use a diagram to represent the classical immunoassay method based on the *agglutination* reaction. Explain the mechanism and exclusive conditions necessary for an agglutination reaction to occur. Briefly describe two relatively

recent modifications of the agglutination reaction that are used in sensitive immunoassays. Cite one obvious biology based disadvantage of an immunoassay.

(b) Explain the methodology and technology behind these two modern immunoassay formats (i) DELFIA (ii) multi-analyte protein microdot based IA. Use a flowchart as appropriate.

(c) If you were developing a new immunoassay, what are the parameters you would select (i) for "proof of concept" of your assay and (ii) validation of your assay.

(1 + 1 + 2 + 1) + (2 + 2) + (1.5 × 2) = 12

Group – E

8. (a) How can you detect target antigen in a sample with the help of an Optical biosensor?

(b) Explain the role of creatine kinase in our body.

7 + 5 = 12

9. (a) Using a table compare microbial biosensors with enzyme biosensors.

(b) Explain how Gaucher's cells are formed? What is implied by a Gold Standard test?

6 + (3 + 3) = 12

Department & Section	Submission Link
BT	https://classroom.google.com/c/MzE3MzAyNDY2ODI5/a/MzY1MTQ5OTUyODg5/details