Name : .....

Roll No. : .....

Invigilator's Signature : .....

CS/M.TECH(BT)(O)/SEM-3/MBT-304C/2012-13

2012

BIOPHARMACEUTICALS

Time Allotted : 3 Hours *Full Marks* : 70

The figures in the margin indicate full marks.

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

GROUP – A
(Multiple Choice Type Questions)

1. Choose the correct alternatives for any *ten* of the following : $10 \times 1 = 10$

i) Thromocytoperia disease occurs due to

a) reduced blood platelet levels

b) abnormal platelet cell

c) reduced prothormbin

d) abnormal proconvertin.

ii) Humatrope is the

a) recombinant human glucagons

b) recombinant human growth hormone

c) recombinant human tPA

d) recombinant human hCG.

iii) OKT3 is the

a) first MAbs got the approval as drug

b) first MAbs purified

c) first gene therapy product in the market

d) first polyclonal Ab in the market.

iv) A pulmonary drug delivery system can have a bioavailability higher than 50% because of

a) passage through the vascular endothelium

b) very large surface area of lungs

c) epithelial cells lining the lung

d) all of these.

v) Which of the following tests is conducted routinely as part of the pre-clinical phase of a drug trial ?

a) Pharmacodynamic profile

b) CDS of the manufacturing area

c) CDS of process equipment

d) All of these.

vi) Lymphotoxin is another name of

a) TNF-alpha b) TNF-beta

c) TGF-beta d) interleukins.

vii) SOP (Standard operating procedures) documents in a pharmaceutical manufacturing plant deal with which one of the following options ?

a) Detailing procedures for maintenance / validation procedures for specific items of equipment

b) Detailing procedures for synthesis of new natural products

c) Detailing procedures for energy minimization of ligand-protein interactions

d) Detailing procedures for the parallel synthesis of peptides.

viii) Rapid arrest of blood loss is known as

a) haemostasis b) hemopiesis

c) hemophelia d) hemolysis.

ix) Which is the first interleukin to be medically approved by FDA ?

a) IL-2 b) IL-4

c) IL-6 d) IL-10.

x) Heparin is a

a) glycoprotein b) prteolycan

c) polysaccharide d) protein.

xi) Which of the following is part of the cytokine group of regulatory molecules ?

a) Thrombopoeitin b) *c*-AMP kinase

c) Protein kinase d) Dopamine receptor.

xii) Insulin Lispro is

a) first recombinant fast-acting insulin analogue

b) first recombinant slow-acting insulin analogue

c) first recombinant human insulin.

GROUP – B

(Short Answer Type Questions)

Answer any *three* of the following $3 \times 5 = 15$

2. What are Janus kinases ? Why were they named as such ? What are the JAK family proteins that have been characterized to date ? What are their distinguishing structural properties ? 1 + 1 + 1 + 2

3. Describe with diagram the production of monoclonal antibodies (Mabs) by hybridoma technology and the application of MAbs.

4. Describe the use and mechanism of action of Anti-*D* immunoglobulin acts as a biopharmaceuticals.

5. "The unique property of angiogenesis is nowadays being used in cancer therapeutics." Justify the statement with reference to clinical studies.

6. "Destruction of cellular macromolecules occurs by some radicals." Explain how these radicals are formed and how the enzyme removes these.

7. a) How does protein modification affect the efficacy of a biopharmaceutical ?

   b) Is this any different than a small molecule drug modification ? Illustrate with one example. 2 + 2 + 1

GROUP – C
(Long Answer Type Questions)

Answer any *three* of the following. 3 × 15 = 45

8. a) Pharmaceutical Good manufacturing practices (GMP) worldwide include comprehensive documentation. Why is the necessary ? What are the main categories of pharmaceutical plant documentation ?

   b) Briefly discuss two newer drug delivery routes and their characteristics in terms of measurable parameters. What medical realities caused R&D and subsequent scientific/technological improvements with respect to these two routes ? What were these technological improvements ? (3 + 4) + (4 + 2 + 2)

9. a) What are the limitations in the development of AIDS vaccine ?

   b) Discuss with an example one recent development in the research of AIDS vaccine.

   c) Illustrate the importance of growth factors in the production of biopharmaceuticals.

   d) What makes IL-2 the most studied member of the IL family ? 3 + 5 + 4 + 3

10. a) Write names of four different biopharmaceuticals which are human hormones and their therapeutic uses.

    b) Describe with diagram the proteolytic processing of pro-insulin to mature insulin.

    c) Describe in details with diagram, the production of human insulin by *r*DNA technology.

    d) Write commercial names of three different recombinant human hormones and names of the company which produces that. 4 + 3 + 5 + 3

11. a) What is plurpoietin ?

    b) Briefly discuss the following :

       i) Granulocyte colony stimulating factor

       ii) Macrophage colony stimulating factor

       iii) Granulocyte-macrophage-CSF

       iv) Leukemia inhibitory factor. 1 + (4 × 3½)

12. a) Write the mechanism of action tPA as thrmbolytic agent (with a diagram only).

    b) Write the mechanism of production of tPA by recombinant method. Write the names of two biopharmaceuticals which are used as thrombolytic agents and the names of the company which produces that.

    c) What factors limit the usefulness of conventional vaccines ?

    d) Write four names disease for which recombinant vaccines are currently developed.

    e) Discuss development of a peptide vaccine against virus.

    3 + 6 + 2 + 4

13. a) Define biosimilar drugs with examples. What are the criteria for labelling a drug biosimilar ? Explain briefly the reasons for the spurt in interest in biosimilar drugs. What are the technical reasons behind IPR based controversies with biosimilar drugs.

    b) Outline the 4 key steps necessary for patenting a new drug. What are the components of a new drug application (NDA) ? List the substances (in biopharmaceuticals production category) that are generally regulated by a drug regulatory authority.

    (2 + 2 + 2 + 2) + (2 + 3 + 2)

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