[48/A-6]

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SEAT No._____ No. of printed page: [02]

SARDAR PATEL UNIVERSITY

M. Sc. Integrated Biotechnology (IG-IBT) 10th Semester
Theory Examination – March 2019
PS10CIGIB1 – Biopharmaceuticals & Biotherapeutics
18th March 2019 (Monday), 10:00 am to 1:00 pm

Maximum Marks: 70

Note: (1) All the Questions are compulsory. (2) Figures on the right indicate marks.

Q.1. Choose the correct option **1 × 8 = 8**

(i) _____ involves the passage of the drug from its site of administration into the blood.
[A] Distribution [B] Absorption
[C] Insertion [D] None of these

(ii) _____ provides a high-level assurance that medicines are manufactured in a way that ensures their safety, efficacy and quality.
[A] GLP [B] Quality control
[C] GMP [D] None of these

(iii) A group of proteins therapeutics with special targeting deals with____
[A] Interfering with a molecule.
[B] Delivering other compounds/proteins.
[C] Both (A) and (B).
[D] None of these.

(iv) In early stages of development of the modern pharmaceutical industry, _____ was used to treat syphilis.
[A] Digitalis [B] Mercury
[C] Quinine [D] All of these

(v) Which of the following are the 'type I interferons' or 'acid stable interferons': true?
[A] IFN-α and INF γ [B] IFN-α and INF β
[C] IFN-β and INF γ [D] None of these

(vi) IL-2 are produced by _____
[A] Dendtritic cells [B] Fibroblasts
[C] T-lymphocytes [D] Astrocytes

(vii) Which of the following is the first recombinant fast acting insulin analogue to gain marking?
[A] Insulin Aspart [B] Insulin Lispro
[C] Lantus [D] Optisulin

(viii) Which of the following is/are limitation of conventional dosage _____.
[A] Poor patient compliance [B] Drug fluctuation can lead adverse effect
[C] Frequency of drug increases [D] All of these

(P.T.O.)

Q.2. Attempt any Seven of the following $2 \times 7 = 14$

(a) Define the terms pharmaceuticals and biopharmaceuticals.
(b) What is SOP? Describe in brief about SOP's role in manufacturing.
(c) Enlist the factors that influence bioavailability of drug.
(d) Enlist the challenges faced by protein therapeutics.
(e) Enlist the applications of Glucagon.
(f) Define the term blood substitute.
(g) Enlist at least four polyclonal antibody preparations of human or animal origin used to induce passive immunity against specific biological agents.
(h) Enlist the characteristics of an ideal adjuvant used in vaccine preparations.
(i) Veterinary uses of gonadotrophins.

Q. 3. [A] Discuss in detail the safety issues with aspect to manufacturing and application of Biotechnology-derived drugs. [06]

[B] Discuss in detail *E. coli* as a source of recombinant, therapeutic proteins. [06]

OR

Q. 3. [B] What is protein therapeutics? State the advantages of protein therapeutics and classification & it's applications in Biopharmaceuticals. [06]

Q. 4. [A] Write a detailed note on GMP and Biosafety level with respect to pharma industry. [06]

[B] Discuss the factors affecting the safe manufacture of quality bio-drugs. [06]

OR

Q. 4. [B] Discuss in detail the routes of drug administration. [06]

Q. 5. [A] Describe the biological activity of interferons with its production in detail. [06]

[B] Discuss the role of Tumour necrosis factors (TNF) and its role in immunity and inflammation. [06]

OR

Q. 5. [B] Describe the biological activity of insulin with its recombinant DNA technology for production in detail. [06]

Q. 6. [A] Explain in detail Anticoagulant Hirudin and its production. [06]

[B] Describe the general design and principle for controlled - release drug delivery systems with the comparison between controlled - release and conventional dosage forms. [06]

OR

Q. 6. [B] Discuss in detail Enzymes of therapeutic value siting suitable examples. [06]