Total No. of Questions : 11]

SEAT No. :

P1132

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[4659]-358

B.E.(Biotechnology)

C-BIO-THERAPEUTICS TECHNOLOGY (415461)

(Elective I) (2008 Pattern)(Semester-I)

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

Instructions to the candidates:

1) ***Answers to the two sections should be written in separate answer-books.***
2) ***Answer Q1 or 2, Q3 or 4, Q5 or 6 from section I and Q7 or 8, Q9 and Q10 or Q11 from section II.***
3) ***Neat diagrams must be drawn wherever necessary.***
4) ***Figures to the right side indicate full marks.***
5) ***Use of Calculator is allowed.***
6) ***Assume Suitable data if necessary.***

SECTION-I

Q1) Giving examples give an account of biotherapeutics products. **[18]**

OR

Q2) Give comparative account of traditional drugs and Biopharmaceuticals. **[18]**

Q3) a) Giving examples explain how the insect cell lines are used for production of biotherapeutics. **[8]**

b) Enlist 5 recombinant proteins and briefly write on the applications and host used for production. **[8]**

OR

Q4) a) With the help of flow chart give outline of hybridoma technique for production of MAb. **[8]**

b) Describe ADME of monoclonal antibody given by parenteral route. **[8]**

Q5) Describe in detail advantages and disadvantages of various sources of Biotherapeutic proteins. **[16]**

OR

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Q6) What are the methods of production of recombinant biotherapeutic proteins using plants and animals. **[16]**

SECTION-II

Q7) Describe the process of decontamination, sanitation and Generation of water for biopharmaceutical manufacturing. **[18]**

OR

Q8) Give an overview of range and significance of biopharmaceutical product impurities like microorganisms, viruses, contaminant proteins, DNA and pyrogens. **[18]**

Q9) Write short notes on any two- **[16]**

a) QC of final biopharmaceutical product,

b) Stability of biopharmaceuticals,

c) Biopharmaceutical validation,

d) Nano drug delivery.

Q10) Give an account of various types of clinical trials and role of DCGI. **[16]**

OR

Q11) Write notes on any TWO: **[16]**

a) IPR and Patents,

b) GMP,

c) Toxicity studies,

d) Pre-clinical studies.

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