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RAN-2303001110010002**M. Sc. Integrated Biotechnology (Sem. -X) Examination April - 2023****Essential Skills for Pharmaceutical Industry****Time: 3 Hours]****[Total Marks: 70****સૂચના : / Instructions**

(1)

નીચે દર્શાવેલ નિશાનીવાળી વિગતો ઉત્તરવહી પર અવશ્ય લખવી.
Fill up strictly the details of signs on your answer book

Name of the Examination:

M. Sc. Integrated Biotechnology (Sem. -X)

Name of the Subject :

Essential Skills for Pharmaceutical Industry

Subject Code No.: 2303001110010002

Seat No.:

Student's Signature

- (2) Figures to the right indicate full marks.
(3) Draw neat and labelled diagrams wherever necessary.

Q. 1. Answer the following : (Any Two) 18

- Enlist merits and demerits of *Escherichia coli* for the production of biopharmaceuticals.
- Briefly describe production and purification of tPA from the milk of transgenic goat.
- Write a note on microbial cell fermentation.

Q. 2. Answer the following : (Any Two) 18

- Enlist advantages and disadvantages of HPLC system.
- Write a note on stabilizing excipients used in product formulations.
- Why it is important to remove nucleic acid from cell homogenate? Explain methods for the removal of nucleic acids.

Q. 3. Answer the following : (Any Two) 18

- Explain any three classes of biopharmaceuticals.
- Describe issues associated with pharmacokinetics and toxicological studies.
- Explain manufacturing process of Insulin Lispro. How it improves the quality of life?

Q. 4. Answer the following : (Any Two)

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- a) What are pyrogens? Briefly explain endotoxin.
 - b) How validation studies for biopharmaceuticals are carried out?
 - c) Write a note on microbial and viral contaminants.
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