

This examination paper consists of 2 pages

Time Allowed:	3 hours
Total Marks:	100
Special Requirements:	None

INSTRUCTIONS TO CANDIDATES

- 1. Answer Four (4) Questions. Each question carries 25 marks.
- 2. Where a question contains subdivisions, the mark value for each subdivision is given in brackets.
- 3. Illustrate your answer where appropriate with large, clearly labelled diagrams.

1. (a) Give an account of the likely industrial production of an insulin homologue according to principles employed by an American or Scandinavian Biopharmaceutical giant.

(13 marks)

(b) With the aid of a detailed flowchart, describe the industrial production of a veterinary biopharmaceutical using a live insect expression system. (12 marks)

2. (a) Briefly review ultra-filtration and tangential flow filtration with respect to biopharmaceutical production. (13 marks)

(b) Outline key analytical methods that are essential in monitoring and quality control of a biopharmaceutical protein. (12 marks)

3. (a) Give an outline of the main animal cell lines employed in biopharmaceuticals production highlighting their key characteristics. (10 marks)

(b) Describe the generation of industrial working cell bank (WCB) and master cell bank (MCB). (15 marks)

4. (a) Briefly outline the key parameters of an ideal vaccine and describe the industrial production of a recombinant DNA-based subunit vaccine. (15marks)

(b) Briefly review the advantages and challenges of DNA-based vaccines. (10 marks)

5. (a) Give an account of the industrial production, purification, polishing and formulation of a beta-lactam antibiotic. (15 marks)

(b) Give an account of the industrial production of a named beta-interferon.

(10 marks)

6. (a) Describe the mechanism of action of conjugated and unconjugated therapeutic monoclonal antibodies. (13 marks)

(b) Design a comparative protocol for extracting, purifying and polishing biopharmaceuticals from an extra- and intracellular expression system. (12 marks)

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END OF EXAMINATION

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