

UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCESDEPARTMENT OF PHARMACYTHIRD BPHARM PART II EXAMINATION – JUNE 2026PH3233 PHARMACEUTICAL BIOTECHNOLOGY – SEQ

TIME: TWO HOURS

INSTRUCTIONS

- There are four questions in part A and B of this SEQ paper.
- Answer all questions.
- No paper should be removed from the examination hall.
- Do not use any correction fluid.
- Use illustrations where necessary.

PART A

1. Downstream processing is employed to recover pure and stable biopharmaceutical products from a crude broth.

- 1.1. Define the term downstream processing and state three of its principal objectives.

(15 marks)

- 1.2. Briefly describe four methods of cell disruption used for the recovery of intracellular products.

(20 marks)

- 1.3. Briefly explain the principle of high-performance liquid chromatography (HPLC) and state the functions of five major components of an HPLC system.

(25 marks)

- 1.4. Propose a suitable downstream processing strategy for the recovery and purification of a therapeutic protein secreted into the culture medium.

(40 marks)

2. Molecular biology and animal cell culture provide essential tools for modern pharmaceutical biotechnology.

- 2.1. Briefly describe the four main steps involved in the extraction of DNA from animal cells.

(15 marks)

- 2.2. Explain the principle of polymerase chain reaction (PCR) and list three of its diagnostic applications.

(20 marks)

- 2.3. Outline the steps involved in cloning a gene into a bacterial host using a plasmid vector.

(25 marks)

- 2.4. Propose an experimental approach using an animal cell culture system to evaluate the toxicity of a new drug candidate.

(40 marks)

PART B

3. Microbial fermentation is a cornerstone for the industrial-scale production of enzymes, which serve as highly specific biocatalysts in pharmaceutical manufacturing.
- 3.1. Write the key steps involved in a typical fermentation process. (15 marks)
- 3.2. List four reasons for the selection of microbial sources for the commercial production of enzymes. (20 marks)
- 3.3. Compare and contrast three enzyme immobilization techniques, highlighting their principles, advantages, and limitations in industrial applications. (30 marks)
- 3.4. Discuss the major challenges associated with scaling up fermentation processes from laboratory scale to industrial scale. (35 marks)
- 4.
- 4.1.
- 4.1.1. State the principle of edible vaccines. (10 marks)
- 4.1.2. List four limitations associated with the use of edible vaccines. (20 marks)
- 4.2.
- 4.2.1. List the five major classes of immunoglobulins and state the specific type of heavy chain associated with each class. (20 marks)
- 4.2.2. Discuss the major applications of monoclonal antibodies in the pharmaceutical industry, providing suitable examples. (20 marks)
- 4.2.3. Describe the immunological techniques: enzyme-linked immunosorbent assay (ELISA) and Western blotting used in pharmaceutical research. (30 marks)

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