

**CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ**

Autumn Examinations 2011

Module Title: Industrial Biotechnology (CA)

Module Code: BIOT7003

School: Biological Science

Programme Title:

Bachelor of Science Applied Biosciences & Biotechnology – Year 3

Bachelor of Science (Honours) Analytical & Pharmaceutical Chemistry – Year 3

Bachelor of Science (Honours) Analytical Chemistry with Quality Assurance – Year 3

Programme Code: SBIBI_7_Y3
SCHEM_7_Y3
SACQA_8_Y3

External Examiner(s): Dr Don Faller

Internal Examiner(s): Ms Margaret Lane

Instructions: Answer 4 Questions.

Duration: 2 Hours

Sitting: Autumn 2011

Requirements for this examination:

Note to Candidates: Please check the Programme Title and the Module Title to ensure that you have received the correct examination paper.
If in doubt please contact an Invigilator.

Q.1 Write descriptive notes on each of the following:

- (a) Membrane filtration
- (b) LAL test
- (c) Formulation
- (d) Cell banking
- (e) Use of serum in mammalian cell fermentations (25 marks)

Q.2 (a) Describe the advantages and disadvantages of using Fed batch, Batch and continuous operating systems in a biotechnology facility. (18 marks)

- (b) Discuss the advantages of using disposable “pipe less” equipment in the production of vaccines. (7 marks)

Q.3 Write a detailed account of virus contamination and removal during the production of pharmaceuticals using mammalian cell lines. (25 marks)

Q.4 Describe the following steps as they occur in the downstream processing of biotechnology products.

- (a) Initial product recovery
- (b) Cell disruption
- (c) Nucleic acid removal
- (d) Product concentration
- (e) Purification (25 marks)

Q.5 Discuss the use of clean rooms in the biotechnology industry.

In your answer consider:

- (a) Purpose of clean rooms
- (b) Clean room classification
- (c) Contamination control in a clean room
- (d) Clean areas of importance for sterile manufacture
- (e) Clean room monitoring

(25 marks)

Q.6 (a) Discuss the regulation of pharmaceutical drugs in the context of preclinical and clinical trials.

(15 marks)

(b) Discuss the role of the FDA in biopharmaceutical drug approval/regulation

(10 Marks)