

**CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ**

Semester 1 Examinations 2012/13

Module Title: Industrial Biotechnology
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Module Code: **BIOT7003**

School: Science & Informatics

Programme Title:

Bachelor of Science in Applied Biosciences & Biotechnology – Year 3

Bachelor of Science (Honours) in Pharmaceutical Biotechnology – Year 3

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

Bachelor of Science Analytical and Pharmaceutical Chemistry – Year 3

Programme Code: **SBIBI_7_Y3**
 SPHBI_8_Y3
 SCHQA_8_Y3
 SCHEM_7_Y3

External Examiner(s): **Dr Gillian Gardiner**

Internal Examiner(s): **Ms Margaret Lane**

Instructions: **Answer 4 Questions .All questions carry equal marks.**

Duration: 2 Hours

Sitting: Winter 2012/2013

Requirements for this examination:

<p>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.</p>
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- Q1. (a) Discuss and describe the most commonly used types of bioreactors, for mammalian cell fermentation, used in the production of pharmaceutical drugs.
Explain the advantages, for mammalian fermentations, of each of the bioreactors mentioned. (15 marks)
- (b) Describe the operating system you consider to be the most suitable for a mammalian cell fermentation. (10 marks)
- Q2. Write a descriptive account of:
- (a) Media used for bacterial cell fermentations. (10 marks)
- (b) Importance of and categories of water used in a pharmaceutical biotechnology process. (15 marks)
- Q3. (a) Describe how a cell bank is constructed. (7 marks)
- (b) Comment on cell bank characterisation and cell bank consistency checks. (8 marks)
- (c) Describe the process used when removing mammalian cells from storage to commence a fermentation. (10 marks)
- Q4. Growth of cells in a fermentation is indicative of the rate of product production.
- (a) Discuss the methods that can be used to assess cell biomass in a fermenter. (13 marks)
- (b) Indicate which methods can be used online and offline. (4 marks)
- (c) Mention the principles that should be applied to any biomass measurement technique. (8 marks)
- Q5. Write a detailed account of endotoxin testing in the pharmaceutical industry.
Discuss the methods used, the principle of the method and the regulations concerning the presence of endotoxins in pharmaceuticals and medical devices. (25 marks)
- Q6. Write an account of the methods used for protein purification, virus removal and nucleic acid removal during downstream processing of a monoclonal antibody in a biotechnology facility. (25 marks)