

CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ

Autumn Examinations 2015-2016

Module Title: Industrial Biotechnology

Module Code: BIOT 7003

School: Science

Programme Title: BSc Applied Biosciences& Biotechnology
BSc (Hons) in Analytical Chemistry with Quality Assurance
BSc Analytical and Pharmaceutical Chemistry

Programme Code: SBIBI_7_Y3
SCHQA_8
SCHEM_7

External Examiner(s):Dr Brendan O Donnell
Internal Examiner(s):Ms Margaret Lane

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

Duration: 2 hours

Sitting: Autumn 2016

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.

Q1(a) Explain the role of the FDA in the regulation of biopharmaceuticals. (5 marks)

(b) Describe the process required by a company to obtain a marketing licence from the FDA for a new drug. (20 marks)

Q2. (a) What is endotoxin and why is its detection in the pharmaceutical industry crucial? (8Marks)

(b) Explain the basis of the LAL test. (5 marks)

(c) Describe the three ways in which the LAL test can be performed. (12 marks)

Q3 Describe the following methods of operating a Bioreactor.

Batch method

Fed batch method

Continuous method (mention Perfusion)

Include in your answer the advantages and disadvantages of each method and give examples of where each is used. (25 marks)

Q4. (a) List the basic requirements for a bioreactor (4 marks)

(b) List and briefly discuss the criteria which must be considered when designing a bioreactor.

(6 marks)

(c) Describe the basic features and uses of each of the following Bioreactors.

Bubble Column

Airlift loop

Hollow Fibre

Packed bed

Wave bag

(15 marks)

Q5. (a) Explain using a diagram the process of scale up for an industrial fermentation using the following points

The method of scale up, the purpose of scale up, and the criteria for a healthy inoculum. (7 marks)

(b) Discuss mammalian cell cultivation media considering each of the following.

Animal cell Catabolism

The basis for cell culture media

Serum

Serum Free Media

Vitamins

Growth factors

Safety Considerations

Sterilization of Media

(18 marks)

Q6 (a) Describe how cells can be genetically engineered to produce a desired protein commercially and how the production of the protein can be regulated. (7 marks)

(b) Discuss the advantages and disadvantages of using Bacterial cells, Mammalian cells or Yeast cells to produce heterologous proteins. (18 marks)