

**CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ**

Autumn Examinations 2012

Module Title: Biopharmaceutical Upstream

Module Code: BIOT7006

School: Biological Sciences

Programme Title: Bachelor of Science (Honours) in Pharmaceutical Biotechnology
Bachelor of Science (Honours) in Nutrition & Health Science
Bachelor of Science in Good Manufacturing Practice & Technology

Programme Code: SPHBI_8_Y2
SNHSC_8_Y2
SGMPE_7_Y3

External Examiner(s): Dr Stephen Fitzpatrick, Ms Bernadette Whelan
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Internal Examiner(s): Ms Caroline O' Sullivan

Instructions: Answer **FOUR** questions. All questions carry equal marks.

Duration: 2 hours

Sitting: Autumn 2012

Requirements for this examination: Calculator

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.

Question 1

- (a) List the Media Requirements for cell growth 'in-vitro' during Upstream Processing. (5 marks)
- (b) Briefly outline the means of oxygen delivery to large scale cell culture systems. What are the issues which may arise with large scale delivery systems? (10 marks)
- (c) Write a note on Serum Free Media. Include the advantages and disadvantages of using Serum Free Media in your answer. (10 marks)
(25 marks)

Question 2

- (a) Outline the role of the cryoprotectant during cell preservation. (5 marks)
- (b) Write a brief note on the method of Batch Sterilisation for sterilising media in the Upstream Processing. Include advantages and disadvantages in your answer. (8 marks)
- (c) Outline
(i) the principle features of a Wave-Bag Reactor and
(ii) the advantages and disadvantages of Perfusion Cell Culture Process.

*Note parts (i) and (ii) carry equal marks (12 marks)
(25 marks)

Question 3

Table 1 details the results obtained from a batch fermentation of an aerobic bacterium growing in glucose.

- (a) Plot X Vs t . (6 marks)
- (b) Locate the region of exponential growth on this plot. (3 marks)
- (c) It has been suggested that the following equation (model) predicts the relationship between X and t for this bioreaction in the exponential growth region when μ_{net} is 0.29 h^{-1} :

$$X = X_0 e^{\mu_{\text{net}} t}$$

Is this equation an accurate model of this data, provide evidence for your answer.

- (d) Determine $Y_{X/S}$ when ΔS is -30.5 g/L ? (12 marks)
(4 marks)

Table 1: Batch growth data

Time	X
Hours	g/l
0	0.60
2	0.81
4	1.45
6	2.52
8	4.50
10	7.70
12	13.50
14	24.00
16	24.00
18	24.00

Question 4

(a) Outline design features incorporated into the Bioreactor and the Facility in Upstream Processing to prevent introduction of contamination. (10 marks)

(b) Sterilisation, Heat Transfer and Reactor Cleanability are important factors to consider when choosing a material of construction. Write a brief note on this statement. (15 marks)
(25 marks)

Question 5

(a) Define Upstream Processing. (3 marks)

(b) List six tests that are routinely performed to ensure the quality of Water For Injection (WFI). (6 marks)

(c) What does Process Scale-up during Technical Transfer involve? (6 marks)

(d) Write a note on Master Cell Bank and Working Cell Bank. (10 marks)

(25 marks)