UNIVERSITY COLLEGE LONDON

University of London

EXAMINATION FOR INTERNAL STUDENTS

For The Following Qualification:-

M.Eng.

Biochemical Eng E187: Bioprocessing of New Medicines

COURSE CODE	:	**BENGE187**
UNIT VALUE	:	**1.00**
DATE	:	**06-MAY-05**
TIME	:	**10.00**
TIME ALLOWED	:	**3 Hours**

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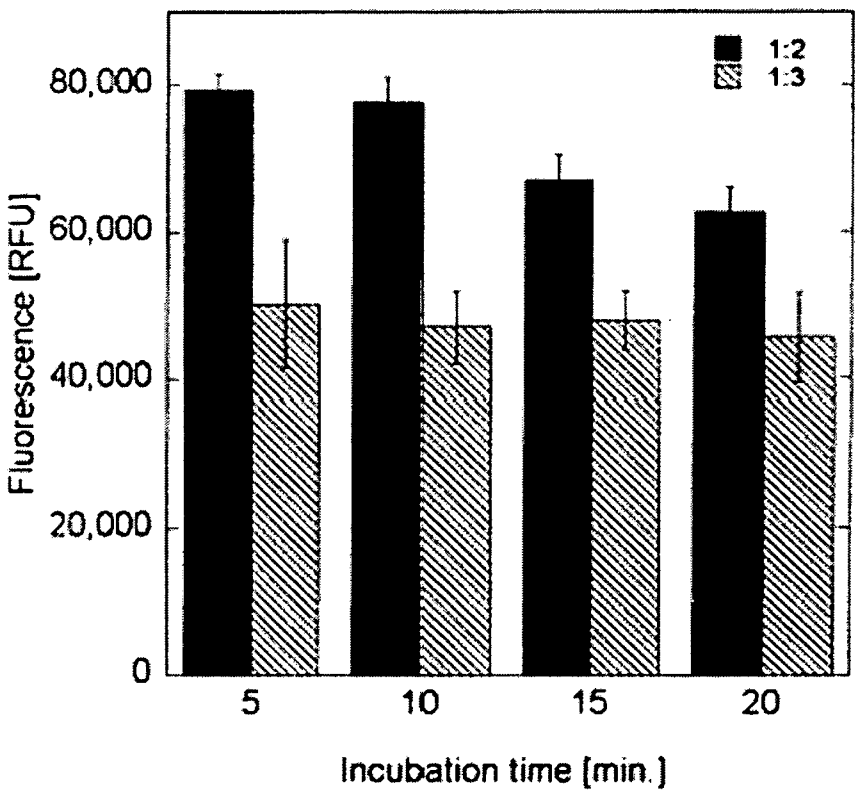
Answer ***THREE QUESTIONS.*** **Only the first three answers given will be marked.**
ALL questions carry a total of ***25 MARKS*** *each, distributed as shown* [ ]

1.

Derouazi et al have been studying the parameters affecting the efficiency of serum-free large scale transfection of CHO cells. They have obtained results shown in the figure below for transfections in agitated 12-well plates. They have used a plasmid coding for green fluorescent protein (GFP) and PEI as complexing agent.
Note: 1:2 and 1:3 refer to DNA:PEI ratio.

(a) Write down a legend for the figure. [5]
(b) Describe a method to quantitate transfection efficiency. [5]
(c) What conclusion(s) can be drawn from results shown and what considerations should be taken for scale-up. [15]



PLEASE TURN OVER

2.

You wish to test the hypothesis that encapsulated cells can secrete a recombinant protein product over 6 weeks of culture *in vitro*.

(a) Describe experiments required to test the hypothesis. Remember to include positive and negative controls. [10]
(b) Explain the rationale behind the analytical methods you propose to use. [10]
(c) Give recommendations for future research in case no secretion is detected. [5]

Materials: BHK cells, pONC coding for a 30 kDa protein, 98% pure alginate, all reagents for cell culture and analysis as required.

3.

Write short notes on:

(a) the importance of cell banking in the context of mammalian cell culture for recombinant product synthesis [5]
(b) key features of stable expression of recombinant proteins from mammalian cells. [5]
(c) key features of transient expression of recombinant proteins from mammalian cells. [5]
(d) strategies to maximise throughput for antibody producing processes. [10]

4.

A tissue-engineered product for skin wound healing is prepared in a laboratory using anchorage dependent cells grown in medium containing 15% foetal calf serum. The cells are grown on a 5 cm^2 bovine collagen matrix placed on individual culture dishes. The culture dishes are placed in an incubator and culture medium needs to be exchanged every 48 hours, complete cell growth takes 4 weeks. The product is delivered fresh at 4 ° C as the clinical application requires more than 80% of cells to be alive when reaching the patient. The potential market for the product is 10 m^2 per annum. As a biochemical engineer you have been asked to prepare a research and development plan for the process. This plan should include:

(a) a summary of your recommended approach. [15]
(b) a summary of the alternatives considered and why you are not recommending them. [10]

Clearly state any assumptions made.

END OF PAPER