ENGINEERING TRIPOS PART IIA

Thursday 28 April 2011 9 to 10.30

Module 3G5

BIOMATERIALS

*Answer not more than **three** questions.*

All questions carry the same number of marks.

*The **approximate** number of marks allocated to each part of a question is indicated in the right margin.*

There are no attachments.

STATIONERY REQUIREMENTS	SPECIAL REQUIREMENTS
Single-sided script paper	Engineering Data Book
Graph paper	CUED approved calculator allowed

You may not start to read the questions printed on the subsequent pages of this question paper until instructed that you may do so by the Invigilator

Version 4

1 (a) Describe the key features of the disease type I diabetes mellitus. Describe the current medical device technologies used in the treatment of diabetes and their operating principles. [45%]

(b) How do biological responses create obstacles to the function of diabetes treatment devices? [15%]

(c) Describe two new technologies being developed for diabetes treatment. Include any new advantages or disadvantages of these technologies, in terms of the biological response, when compared with existing technologies. [40%]

2 (a) Define hydrogel materials. Give an expression for the swelling ratio, and list the factors that determine swelling behaviour. Describe the advantages and limitations of hydrogels in biomedical applications. [30%]

(b) Describe the use of hydrogels in drug delivery. What are the key parameters that influence hydrogel drug delivery? Derive an approximate expression for the kinetics of this process. [15%]

(c) Nanoparticles are increasingly used as carriers in combination with hydrogels in drug delivery.

(i) How are nanoparticles characterized for drug delivery applications? Define "targeting" in the context of nanoparticle drug delivery.

(ii) What are PEG and PEGylation? Why is PEG used with nanoparticles in drug delivery?

(iii) Describe the key features of the regulatory framework for materials used in medical devices. Outline a specific challenge associated with regulatory review of nanoparticle-PEG drug delivery systems. [55%]

3 (a) Define what is meant by *sterile*. Describe three different types of sterilization techniques, explaining which types of implant materials are suitable for each sterilization method. [35%]

(b) Describe key features of the immune system in its response to bacteria remaining on a non-sterile medical implant. [20%]

(c) Define sterility assurance limit (SAL) and decimal reduction time. Using the data in Table 1, determine appropriate process times for the sterilization of medical implants A and B, assuming a target SAL of 10^{-6} and an initial bioburden of 120. Suggest reasons why the implants exhibit different behaviour on sterilization. [45%]

Time in autoclave at 121°C (minutes)	Implant A Surviving organisms	Implant B Surviving organisms
1	88	74
3	5	125
8	2	50
11	1 per ten parts	62
13	2 per thousand parts	26.7
16	3 per 10,000 parts	2.6
19	8 per 100,000 parts	5 per ten parts
22	3 per 100,000 parts	1 per hundred parts
23	2 per million parts	2 per thousand parts
27	2 per 10 million parts	1 per thousand parts

Table 1

4 (a) Briefly describe the structure of a human femur at the nano, micro and millimeter scale. [15%]

(b) Describe the changes that may occur in bone in response to sustained increases or decreases in load. What is meant by the term *stress shielding* in the context of a bone-replacement implant? Compare the stress shielding effect produced by Ti-6Al-4V and Al_2O_3 implants, and contrast their relative mechanical and *in vivo* biological performances. [25%]

(c) What are the main causes for hip replacement? Sketch and label the components of an implant to be used for total hip replacement. Describe the loading, corrosion mechanisms and failure modes to which an implant is exposed in the human body. [25%]

(d) Outline the two main options for fixation of an implant in the femur, including the materials commonly used. Briefly describe the main advantages and disadvantages of these fixation routes. Hence explain the choice of method for implant fixation that you would make for an elderly patient, and for a younger patient. [35%]

END OF PAPER