ENGINEERING TRIPOS PART IIA

Thursday 22 April 2010 9 to 10.30

ENGINEERING TRIPOS PART IIA: Module 3G5

BIOMATERIALS

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

All questions carry the same number of marks.

*The **approximate** percentage 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
	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: Final

1 (a) Describe the differences between bulk and surface erosion with reference to polymeric implants. Give three different criteria that illustrate whether an implant will erode by a bulk or surface mechanism, clearly defining all terms and describing the physical meaning of the parameters. [50%]

(b) A surgeon selects a multi-filament co-polymer suture made of poly(lactic acid) and poly(glycolic acid) for an abdominal internal repair.

(i) Describe how the composition of the co-polymer will influence the suture performance in the physiological environment.

(ii) Explain the rationale for selecting a multi-filament suture instead of a monofilament suture with the same diameter; use illustrations and calculations as appropriate. Note any disadvantages associated with multi-filament sutures. [50%]

2 A small company, LigaNew, hires you as an expert on medical implant manufacturing, to help guide them through the process of commercializing a novel tissue-engineered ligament replacement. The implant uses autologous cells embedded in a hydrogel polymer. The Board of Directors of the company consists of venture capitalists with no background in the medical devices field. Provide briefing notes for them on the following topics.

(a) The basic premise of tissue engineering and any advantages or disadvantages associated with the use of autologous cells. [20%]

(b) The current state of the market for tissue-engineered products and how existing commercial products compare with LigaNew. [15%]

(c) The process of regulatory approval for this implant and how this process differs in the US and the UK. [15%]

(d) The typical biological wound-healing process, and how this relates to implantation of the LigaNew product. [25%]

(e) The sterilization, packaging and storage requirements for the implant. [25%]

3 (a) Sketch the amount of drug in the body as a function of time for a controlled-release drug delivery scheme with a constant drug infusion rate. Clearly label any asymptotic limits. Compare this approach with traditional methods of drug delivery. [30%]

(b) The Higuchi (1961) solution gives the cumulative amount of drug released as a function of time as:

$$M_t = A\,[(2C_0 - C_s)C_s\,D\,t]^{1/2}$$

Define all terms in this expression. Describe the key assumptions on which the use of this expression relies. [25%]

(c) Two drug release profiles are given in Fig. 1. Identify the mechanism(s) active in each profile and describe the underlying physical processes that give rise to each shape. [45%]

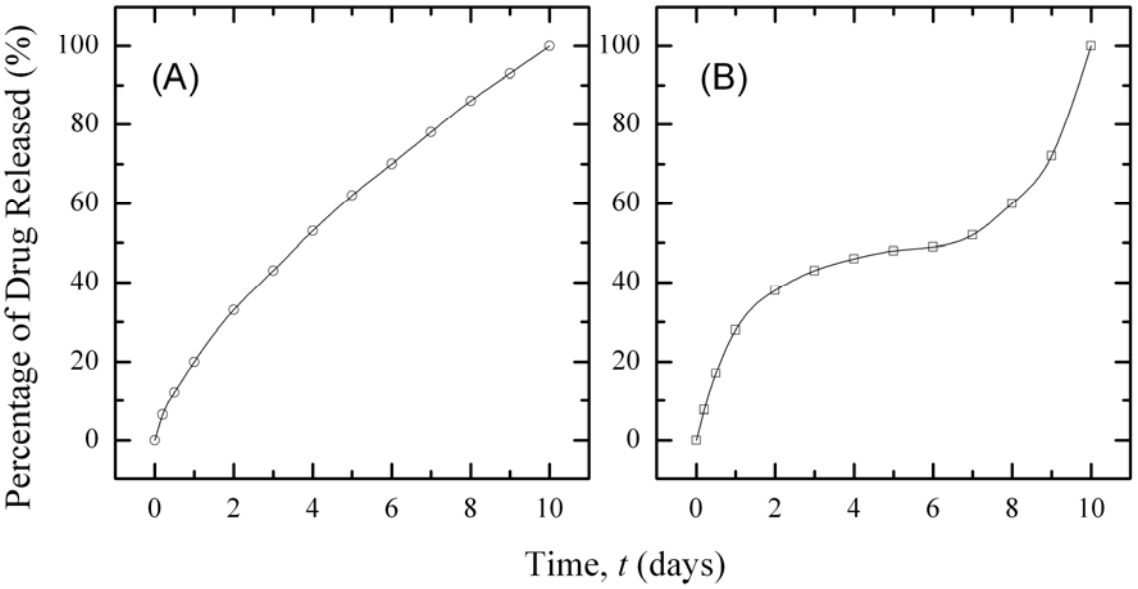

Fig. 1

4 (a) With the aid of a diagram or plot, describe the influence of mechanical strain on the determination of skeletal structure. What strains characterise the transitions between the different types of behaviour? Why is this phenomenon important in the design of orthopaedic implants? [25%]

(b) Briefly describe an experiment which could be used to determine the forces and moments experienced in a prosthetic hip during daily activities. Which forces or moments are regarded as the most likely to endanger the stability of the implant? [15%]

(c) Describe and sketch the construction of an implant to be used for total hip replacement. For each component, explain the criteria which should be used to choose appropriate materials, and give examples of which materials are used. In cases where different *classes* of material could be used for the same component, indicate their advantages and disadvantages. [45%]

(d) Coatings are sometimes used on the stems of prostheses. Briefly describe two such coatings, explaining their function. [15%]

END OF PAPER