FACULTY OF PHARMACEUTICAL MEDICINE
of the Royal Colleges of Physicians of the United Kingdom

EXAMINATION FOR THE DIPLOMA IN PHARMACEUTICAL MEDICINE

22 OCTOBER 2007

SECTION A

SHORT ANSWER QUESTIONS

INSTRUCTIONS TO CANDIDATES

1. **Two hours and 30 minutes** are allowed for answering this section.
2. Answer all ten (10) questions in this section.
3. Allow 15 minutes for each question.
4. To be eligible for a Pass you must attempt at least eight (8) questions.
5. You must complete the front cover of the answer book with your last name, forename(s), candidate number and signature.
6. On each page used, you must fill in your candidate number and the section (A). On each page of an SAQ, please also fill in the question number and the page number, e.g. Ques1/Page1, Ques1/Page 2. Please begin each SAQ on a new page and only write on one side. The questions do not have to be answered in numerical order.

Question No	Question	Available Marks
1.	With respect to hypothesis testing, what is meant by the terms type I and type II error?	3
	What factors should be taken into consideration when establishing the sample size in a clinical trial?	7
2.	You have been asked to write a clinical development plan for a new product in a therapeutic area in which you have little previous experience. What are the sources of information that you could access that would enable you to write this plan and what sorts of information might each provide?	10
3.	What is meant by the term adverse event?	1
	List the methods available for identifying adverse events in pre-registration clinical trials.	5
	What features of an adverse event would require it to be reported on an expedited basis by the Sponsor?	4
4.	You wish to conduct a phase III study of a novel treatment for migraine in reproductively active men and women. Outline the package of reproductive toxicology studies needed to support this study in Europe.	7
	How might this package differ if you were conducting a phase IIa study in the same population in the United States?	3
5.	What is the purpose of the Summary of Product Characteristics?	2
	Briefly outline the structure and contents of this document.	8
6.	What is an Abbreviated Advertisement in the UK?	3
	What prescribing information must be provided in an Abbreviated Advertisement?	7
7.	What is meant by the term bioequivalence?	3
	Outline the design of a study to test whether two slow release oral formulations are bioequivalent.	7
8.	What is a Periodic Safety Update Report (PSUR)?	3
	Write brief notes on the timings of submissions of a PSUR and its format and content.	7
9.	Define the following terms: a) biomarker, b) surrogate endpoint and c) clinical endpoint, illustrating your answer with examples.	6
	Outline the features of a good surrogate endpoint.	4
10.	You are writing the concomitant medication section of the protocol for a Phase III study of an investigational medicinal product with a target indication of secondary prevention of myocardial infarction. What concomitant medicines are these patients likely to be taking?	3
	What principles need to be considered when deciding which concomitant medication should be permitted, and which restricted, in clinical trials?	7