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

EXAMINATION FOR THE DIPLOMA IN PHARMACEUTICAL MEDICINE

20 OCTOBER 2008

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. 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.
7. On each page used, you must fill in your candidate number and the section (A). On each page of each SAQ, please also fill in the question number and the page number, e.g. Ques1/Page1, Ques1/Page 2.

Question No	Question	Available Marks
1.	List the advantages and disadvantages of administration of drugs by the following routes: - oral - subcutaneous	10
2.	You have been provided with a complete package of pre-clinical data for a new drug which is ready to be administered to man for the first time. What is the important information needed from this package to allow determination of the starting dose for the first clinical study in man?	6
	What are the different ways in which this information can be used to set the starting dose?	4
3.	What is the International Conference on Harmonisation (ICH) and what is its membership?	3
	Outline the type of guidelines produced by ICH, illustrating your answer with examples for each type.	4
	What are some of the achievements of ICH?	3
4.	a) What is the 'null hypothesis' and what does it mean if the null hypothesis is rejected?	2
	b) What are "confidence intervals" and how are they calculated?	3
	c) What is a "p-value"?	1
	d) What is standard deviation, what is its use and what data elements are needed to calculate it?	4
5.	Outline the types of costs associated with a therapeutic intervention, illustrating your answer with examples.	4
	Briefly describe the ways in which the costs and benefits of a new treatment can be analysed.	6
6.	Outline the ways in which the therapeutic effects of a drug may be monitored.	3
	What are the circumstances in which drug concentration monitoring is desirable?	7
	Illustrate your answer with examples.	
7.	Outline the contents of a Risk Management Plan to support submission of a Marketing Authorisation Application in the EU.	10
8.	After multiple statistical tests have been applied to the data available, a clinical study report states that "the experimental drug significantly (p=0.05) reduces plasma marker x from 200 mcg/ml to 160 mcg/ml in the evaluable population. The corresponding reduction in the placebo treatment group was from 200 mcg/ml to 180 mcg/ml."	
	Write brief notes on the conclusions that can be drawn from this statement?	3
	What other information do you need to interpret this statement fully?	7
9.	List the factors that should be taken into account when deciding whether an adverse event is likely to be causally related to drug.	8
	Give 4 examples of rare serious adverse events which are likely to be drug-related.	2
10.	List the advantages and disadvantages of crossover and parallel designs for clinical trials.	10