



**Certificate in Pharmaceutical Medicine
/Part 1 Diploma in Pharmaceutical Medicine Exam Sample Questions**

This selection of 12 sample questions addresses a range of characteristic subject matters within the Certificate in Pharmaceutical Medicine (CPM)/Part 1 DPM syllabus. This non-exhaustive resource is intended solely for revision purposes and to assist candidates in practising the required answer style.

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In early drug development, lead optimisation can:

- A. Confirm the chemical structure of the lead compound
- B. Improve binding to the target
- C. Improve understanding of biomarker changes in the target population
- D. Optimise the primary endpoint characterisation for the clinical programme
- E. Validate the proposed target

A Target Product Profile (TPP):

- A. Describes a medicine's desired characteristics
- B. Describes the intended population for a novel medicine
- C. Informs decisions on continuation or discontinuation during product development
- D. Is a regulatory requirement
- E. Is updated after Phase 2 studies are complete

The following are generally required for a new chemical entity before its first administration to healthy male volunteers:

- A. 28-day toxicology studies
- B. repeat dose toxicology studies in two rodent species
- C. reproductive toxicology studies
- D. in vivo test for chromosomal damage
- E. tests of the effects on central nervous system function

A change in excipients of an oral formulation can influence the following properties of a new chemical entity:

- A. Acute adverse drug reactions
- B. Half-life
- C. Oral bioavailability
- D. Physical stability
- E. Volume of distribution

In relation to drug metabolism:

- A. Conjugation to form a glucuronide is irreversible
- B. CYP 2D6 is the commonest cytochrome P450 pathway for drug metabolism
- C. CYP 3A4 exhibits clinically significant polymorphism
- D. Drugs may induce their own metabolism
- E. Neonatal liver is deficient in its ability to conjugate drugs with glucuronic acid

Regarding 'parallel group' clinical trial designs:

- A. No estimate of within subject variability on drug effect is possible
- B. A subject may receive the top dose as his/her first dose
- C. Results generally have a lower variance compared with cross-over studies
- D. 'Carry-over' effects from one period to the next must be accounted for
- E. The t-test may be used as a statistical analysis of the difference in the mean of the treatment effects

In a clinical trial, a SAE should be reported if a subject:

- A. Becomes pregnant
- B. Is hospitalised following a road traffic accident
- C. Is hospitalised for a myocardial infarction
- D. Is hospitalised for a planned hip replacement
- E. Takes an unintentional overdose

The following documents must be made available to the independent ethics committee (IEC) for review prior to trial approval:

- A. Case Report Form
- B. Investigators' Brochure
- C. Participant recruitment procedures
- D. Patient information sheet and informed consent form(s)
- E. Trial protocol

With respect to basic statistical concepts:

- A. Statistical tests should always be performed at the 5% level of significance
- B. The median is less affected by outliers than the mean
- C. The smaller the standard deviation (SD), the smaller the variability in the study population
- D. The standard error of the mean (SEM) is a better measurement of the variability in the general population than the standard deviation (SD)
- E. The standard error of the mean (SEM) is a measure of the precision of the mean

The Centralised procedure for approval of medicines in the EU:

- A. Cannot be used for the registration of generic medicines
- B. If approved, the approval applies to all member states
- C. Is mandatory for medicinal products indicated for orphan indications
- D. Is mandatory for medicinal products intended for the treatment of HIV/AIDS
- E. May be used for products other than those for which it is compulsory

The following apply to an Advisory Board meeting being held in the United Kingdom:

- A. A formal agreement should be in place with each member in advance of the meeting
- B. All arrangements are covered by the scope of the ABPI Code of Practice for the Pharmaceutical Industry
- C. All members should be paid the same
- D. It may be promotional
- E. The honoraria paid are exempt from the requirements for annual disclosure

The following are considered during Health Technology Assessments in the UK:

- A. Applicability to global populations
- B. Clinical efficacy
- C. Currency fluctuations
- D. Incremental cost effectiveness ratios
- E. Patient group feedback