

Note: (a) All questions are compulsory.

(b) The candidate is allowed to make Suitable numeric assumptions wherever required for solving problems

(c) Use of calculator is not allowed

Q. No	Question	Marks															
Q1	Devise a protocol and suggest following procedures in a clinical study design issues such as minimizing variation, blinding and selection of endpoints.	10															
Q2	Observational studies are those in which groups of individuals are monitored or outcomes are measured without manipulation or intervention to affect the result. Discuss in detail and the advantages and disadvantages of Case control and cohort study.	10															
Q3	In process quality control test is necessary to insure the safety of finished pharmaceutical product. Demonstrate the methods to evaluate capping, abrasion or excessive breakage of tablet during mechanical shocks of handling in manufacture, packing and shipping.	5															
Q4	A 45-year-old male patient participating in a clinical trial for a new antihypertensive drug develops severe dizziness, skin rash, and low blood pressure two days after starting the investigational medication. The investigator stops the drug and provides supportive treatment. The patient recovers within three days. a) Identify the adverse event reported in the case. [1 mark] b) Explain whether the event should be considered an Adverse Drug Reaction (ADR) or not. Give reason. [2 mark] c) Mention any two important details that must be included while reporting this clinical trial case. [2 mark]	5															
Q5	A medicinal chemist synthesized a series of compounds to study the relationship between chemical structure and antibacterial activity. The lipophilicity (log P) and biological activity of four compounds were recorded as follows: <table border="1"> <thead> <tr> <th>Compound</th><th>log P</th><th>Antibacterial Activity (%)</th></tr> </thead> <tbody> <tr> <td>A</td><td>1.2</td><td>45</td></tr> <tr> <td>B</td><td>2.0</td><td>68</td></tr> <tr> <td>C</td><td>2.8</td><td>85</td></tr> <tr> <td>D</td><td>4.5</td><td>40</td></tr> </tbody> </table> a) Define QSAR. [1 mark] b) Identify the compound showing maximum antibacterial activity. [1 mark] c) Explain the relationship between lipophilicity (log P) and biological activity from the data. [1 mark] d) Predict why Compound D shows lower activity despite higher log P value. [1 mark] e) Mention any one application of QSAR in drug design. [1 mark]	Compound	log P	Antibacterial Activity (%)	A	1.2	45	B	2.0	68	C	2.8	85	D	4.5	40	5
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