

Time: 2 Hours

Marks: 40

Q1. Answer the following question

8M

1. Write a note on morphine poisoning.
2. What is Schedule Y and what are the toxicity data required as per Schedule Y for application of Phase I clinical trial?
3. Define chronic toxicity and mention the OECD guidelines to be followed for its testing.
4. Explain carcinogenesis.

Q2. Answer the following question (Any 2)

8M

1. Explain the factors influencing toxicity.
2. Explain the steps involved in the management of toxicity.
3. Explain how a free radical elicits its toxicity.

Q3. Answer the following question (Any 2)

8M

1. Explain in detail the symptoms of alcohol poisoning and how they can be managed.
2. Write a note on hematotoxicity.
3. What are the clinical consequences of a cardiotoxin.

Q4. Answer the following question (Any 2)

8M

1. Write a note on hepatotoxicity.
2. Explain acute toxicity study and OECD guideline 425 in detail.
3. Write a note on long term toxicity testing studies.

Q5. Answer the following question (Any 2)

8M

1. Write a note on ICH guidelines.
2. Explain animal toxicity studies as per Schedule Y.
3. Define risk and hazard. Explain the concept of risk assessment and management.
