

Exam Date & Time: 15-Jul-2022 (10:00 AM - 01:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examination.

Pharmacological and Toxicological Screening Methods II [PHA-MPL202T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

- 1) To setup a testing facility as per the principles of GLP, elaborate the organizational structure, individual roles, and documentation requirements. (10)
- 2) Discuss the grouping, species used, and parameters evaluated in chronic toxicity testing by oral route. (10)
- 3) Draw the 3-segment protocol followed in reproductive studies and explain the teratogenicity studies. (4+6) (10)
- 4) A new chemical entity developed to treat psychosis has come to your lab for safety pharmacological testing. As a principal investigator design various core battery test which will be used to assess the behaviour and CNS safety of the drug. (10)
- 5) What are the emerging technologies for non-animal toxicity testing and describe any two? (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

- 6) Discuss the different types of IND filing with examples. (5)
- 7) What are the applications of toxicokinetics? (5)
- 8) What is the importance of regulatory toxicity guidelines with respect to toxicity assessment of chemicals? (5)
- 9) Explain a test to assess both clastogenicity and aneuploidy. (5)
- 10) A new chemical entity (NCE) intended to be used as a sedative and hypnotic was tested for sub-acute toxicity in rodents. This compound at a dose of 200 and 400 mg/kg caused lethargy and decreased food consumption from day 14 to 28. In these groups, 6 out of 10 rats showed decreased RBC, WBC, Hb, platelet count, plasma protein and elevated levels of serum transaminases. What are the target organs that might be affected by the NCE? How can histology of various organs confirm the toxicity to the target organs? (5)

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