Question Paper

Exam Date & Time: 15-May-2024 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations

Pharmacological and Toxicological Screening Methods II [PHA-MPL202T -S1]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

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

1)	For a non-clinical study to be performed as per GLP, list the various personnel that are involved and their respective roles. What are the details to be included in the final study report? (7+3)	(10)
2)	A pharmaceutical company is conducting acute oral toxicity testing for a new chemical compound as per OECD Test Guideline 425. The compound is intended for therapeutic use in humans. Design a study protocol for assessing the acute oral toxicity of the compound in accordance with OECD 425 guidelines. Provide details on the experimental procedure, including dosing, observation period, and criteria for classification of toxicity levels. Additionally, discuss the ethical considerations and welfare of the test subjects involved in the study.	(10)
3)	Elaborate any two segments of female reproductive toxicity studies in animals and explain its significance.	(10)
4)	A new generation anti-histaminic drug was recalled from the market due to the cardiovascular safety concerns. Describe the intended tests need to be performed according to ICH recommendations.	(10)
5)	Explain the importance of alternative methods to animal testing and discuss two emerging technologies with merits and demerits.	(10)

SECTION - B

Answer all the questions.

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

6)	How is the gastrointestinal injury potential of a drug assessed?	(5)
7)	What are the applications of toxicokinetic studies?	(5)
8)	Write a short note on an *in vitro* genotoxicity test that is used to detect chromosomal abnormalities such as polyploidy.	(5)
9)	How are adverse drug reactions classified? Discuss any one type with a suitable example.	(5)
10)	A pharmaceutical company is developing a topical formulation of a drug intended for dermatological application. They need to evaluate the potential skin irritancy of the formulation following OECD Test Guideline 404. Design an *in vivo* study protocol for conducting a skin irritancy test. Provide details on the selection of the animal model, application of the topical formulation, observation period, scoring system for skin reactions, and statistical analysis methods.	(5)

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