GALGOTIAS UNIVERSITY

ADMISSION NUMBER

School of Medical and Allied Sciences

Master of Pharmacy in Pharmacology
Semester End Examination - Jun 2024

Duration : 180 Minutes
Max Marks : 75

Sem II - MPL202T - Pharmacological and Toxicological Screening Methods-II

General Instructions
Answer to the specific question asked
Draw neat, labelled diagrams wherever necessary
Approved data hand books are allowed subject to verification by the Invigilator

1)	Explain the origin and evolution of safety pharmacology.	K2(2)
2)	Explain the key aspects evaluated in reproductive toxicology studies.	K2(2)
3)	What is the impact of IND on the progression of a drug through clinical trials.	K1(2)
4)	Explain teratogenicity and explain its significance in regulatory toxicology.	K2(2)
5)	What is an industry standpoint, why is IND status important for drug development?	K1(2)
6)	Explain acute toxicity and explain its relevance in regulatory toxicology studies.	K2(2)
7)	What and why obtaining IND status is crucial in the drug development continuum.	K1(2)
8)	Explain the importance of conducting studies through inhalational route according to OECD guidelines.	K2(2)
9)	What is the difference between Acute and chronic toxicity.	K1(2)
10)	What is the difference between ICH and EPA Guidelines.	K1(2)
11)	Organize the differenence between general, mechanistic, regulatory, and descriptive types of toxicology, providing examples for each.	K3(5)
	OR	
	Organize the defination of toxicology and explain its primary objectives.	K3(5)
12)	Organize the importance of IND studies in the context of regulatory approval and the pharmaceutical industry.	K3(5)
13)	Analyze the defination of saturation kinetics in the context of	K4(5)

toxicokinetic studies. Discuss its importance and provide examples of situations where saturation kinetics play a crucial role in understanding the toxicity of a substance.

14) Organize a defination on IND (Investigational New Drug) and discuss its significance in the drug development process. K3(5)

15) Analyze a discussion on the key objectives and methodologies of acute, sub-acute, and chronic toxicity studies, highlighting the specific considerations for studies conducted through oral, dermal, and inhalational routes as per OECD guidelines. K4(5)

16) Simplify examine the importance and applications of toxicokinetic studies in the field of drug development and toxicology. K4(5)

OR

Simplify discuss on Tier 1 safety pharmacology studies, focusing on Cardiovascular (CVS), Central Nervous System (CNS), and Respiratory safety pharmacology. Highlight their relevance in ensuring drug safety. K4(5)

17) Analyze the description of Tier 2 safety pharmacology studies, emphasizing Gastrointestinal (GI), Renal, and other relevant studies. Discuss their role in providing a comprehensive safety profile of a new drug. K4(5)

18) Discuss about OECD guidelines for conducting acute oral toxicity studies. Highlight key parameters and endpoints. K6(10)

19) Determine recent advancements in non-animal testing methods for toxicity assessment. K5(10)

OR

Determine the role of Safety Pharmacology in assessing Central Nervous System (CNS) safety (Tier 1 - CNS). Discuss the key studies conducted in this tier and their relevance in predicting potential neurological adverse effects. K5(10)