GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Biomedical Science

Master of Science in Healthcare and Clinical Research
Mid Term Examination - Nov 2023

Duration : 90 Minutes
Max Marks : 50

Sem I - Q1PM103T - ICH GCP and ICMR Guidelines

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)	Define the Adverse Event.	K2	(2)
2)	Illustrate the Adverse drug reaction.	K1	(3)
3)	Demonstrate the five vriterias of SAE.	K2	(4)
4)	Describe the drug regulations in clinical trials.	K2	(6)
5)	Apply the different phases of trials including phase 0.	K3	(6)
6)	Utilise the ICH GCP Principles.	K3	(9)
7)	Conclusion of serious adverse event and the steps are used after SAE.	K4	(8)
8)	Distinguish the unethical clinical trial happened in past.	K4	(12)
	OR		
	Distinguish the role and responsibilities of ethics committee members.	K4	(12)