GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Biomedical Science

Master of Science Clinical Research
Mid Term Examination - May 2024

Duration : 90 Minutes
Max Marks : 50

Sem II - Q1PN203T - Pharmacovigilance

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 what is passive surveillance	K2	(2)
2)	Define ADE, ADR and Side effect.	K1	(3)
3)	Explain the seriousness criterias of ADR	K2	(4)
4)	Explain the different pharmacovigilance methods.	K2	(6)
5)	Illustrate what is drug utilization studies	K3	(6)
6)	Analyze the need and scope of Pharmacovigilance	K3	(9)
7)	Analyze the reasons of different drug withdrawal from Market with example.	K4	(8)
8)	Analyze the methods of Active surveullance	K4	(12)
	OR		
	What is expedited reporting. Discuss the Process of expedited reporting.	K4	(12)