GALGOTIAS UNIVERSITY

ADMISSION NUMBER

School of Biomedical Science

Master of Science Clinical Research
Semester End Examination - Jun 2024

Duration : 180 Minutes
Max Marks : 100

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)	What is is active surveillance?	K1(2)
2)	Explain the difference between seriousness criteria and severity criteria of ADR	K2(4)
3)	Explain the need and scope of post marketing surveillance	K2(6)
4)	Discuss the format of PSSR.	K3(9)
5)	What is Narajos' s scale. Discuss the advantage and disadvantages of Narajos's scale	K3(9)
6)	Discuss the methods of Passive surveillance	K5(10)
7)	What do you mean by expedited reporting. Discuss the Process of expedited reporting.	K4(12)
8)	Discuss the classification of ADR based on causality.	K5(15)
9)	Discuss the classification of ADR as per Upsala monotoring center.	K5(15)
10)	Elaborate different methods of Pharmacovigilance.	K6(18)