GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Medical and Allied Sciences

Bachelor of Pharmacy
Semester End Examination - May 2024

Duration : 180 Minutes
Max Marks : 75

Sem VIII - BPET8005 - 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)	List the International Non-proprietary Names for drugs	K1	(2)
2)	Classify the Preclinical phase.	K2	(2)
3)	What is the Daily defined doses.	K1	(2)
4)	Illustrate the Targeted clinical investigations.	K2	(2)
5)	What Management of adverse drug reactions.	K1	(2)
6)	Explain the Individual case safety reports.	K2	(2)
7)	Define the importance of safety monitoring of medicine	K1	(2)
8)	Explain the safety data generation.	K2	(2)
9)	List the non-proprietary names for drugs	K1	(2)
10)	Explain the post approval expedited reporting.	K2	(2)
11)	Apply your knowledge the vaccination failure in Pharmacovigilance	K3	(5)
	OR		
	Apply your knowledge in vaccine safety surveillance	K3	(5)
12)	Simplify the ICH Guidelines for Pharmacovigilance.	K4	(5)
13)	Apply your knowledge in Good clinical practice in pharmacovigilance studies	K3	(5)
14)	Simplify Effective communication in Pharmacovigilance.	K4	(5)
15)	Apply your knowledge in Post approval expedited reporting Pharmacovigilance planning	K3	(5)

16)	Distinguish the Cross sectional study and case control studyCross sectional study and case control study	K4	(5)
	OR		
	Distinguish the Sentinel sites and drug event monitoring	K4	(5)
17)	Analyze the CIOMS Working Groups.	K4	(5)
18)	Elaborate the role of CDSCO with pharmacovigilance in India.	K6	(10)
19)	Explain Safety data generation, Preclinical phase, Clinical phase and Post approval Phase (PMS).	K5	(10)
	OR		
	Explain Effective communication in Pharmacovigilance Communication in Drug Safety Crisis management and Communicating with Regulatory Agencies.	K5	(10)