School of Medical and Allied Sciences

Pharmacy

ETE - May 2023

Time : 3 Hours **Marks : 75**

Sem VIII - BP805ET - Pharmacovigilance

Your answer should be specific to the question asked

Draw neat labeled diagrams wherever necessary

1.	Define WHO international drug monitoring programme.	K1 CO1 (2)
2.	Demonstrate the basic drug information resources.	K2 CO1 (2)
3.	What is drug safety department in industry.	K1 CO2 (2)
4.	Explain pharmacovigilance establishing in a hospital	K2 CO2 (2)
5.	Define vaccine in pharmacovigilance.	K1 CO3 (2)
6.	Explain the cross sectional study.	K2 CO3 (2)
7.	What are the individual case safety reports.	K1 CO4 (2)
8.	Illustrate the safety data generation.	K2 CO4 (2)
9.	List of drugs avoid in pregnancy.	K1 CO5 (2)
10.	Explain the drug safety evaluation.	K2 CO5 (2)
11.	Identify the adverse events following immunization. OR Choose the method of Passive and Active surveillance pharmacovigilance.	K3 CO1 (5)
12.	Categorize the severity and seriousness assessment.	K4 CO1 (5)
13.	Develop drug dictionaries and coding in pharmacovigilance.	K3 CO2 (5)
14.	Simplify the contract Research Organisations (CROs).	K4 CO2 (5)
15.	Apply your knowledge in vaccine safety surveillance.	K3 CO3 (5)
16.	Compare the method of Passive and Active surveillance pharmacovigilance. OR Compare the Sentinel sites and drug event monitoring	K4 CO3 (5)
17.	Discuss Pharmacovigilance planning.	K6 CO5 (5)
18.	Compare the periodic safety update reports and post approval expedited report	K5 CO4 (10)
19.	Discuss the role of CDSCO with pharmacovigilance in India. OR Elaborate the Indian and global pharmacovigilance requirements.	K6 CO5 (10)