

School of Basic and Applied Sciences

BioScience
ETE - Jun 2023

Time : 3 Hours

Marks : 50

Sem II - MBACRT2003 - Pharmacovigilance

Your answer should be specific to the question asked

Draw neat labeled diagrams wherever necessary

- | | | |
|-----|--|------------|
| 1. | What do you mean by Causality assessment? | K2 CO2 (2) |
| 2. | What do you mean by Seriousness criteria? | K1 CO1 (2) |
| 3. | What do you mean by risk benefit balance of drug? | K2 CO5 (2) |
| 4. | Differentiate active and passive surveillance. | K2 CO4 (2) |
| 5. | List the limitation of spontaneous reporting system. | K1 CO3 (2) |
| 6. | Analyse the evolution of Pharmacovigilance program in India. | K4 CO6 (6) |
| 7. | Describe the evolution of pharmacovigilance with the emphasis of thalidomide tragedy. | K3 CO1 (5) |
| 8. | Illustrate the UMC classification of ADR. | K4 CO2 (5) |
| 9. | Discuss the different method of active surveillance. | K4 CO5 (8) |
| 10. | What do you mean by Pharmacovigilance planning. Discuss the different safety specification. | K4 CO4 (8) |
| 11. | Discuss what is spontaneous reporting system. Explain the different sources of spontaneous report. | K3 CO3 (8) |