School of Basic and Applied Sciences

BioScience

ETE - Jun 2023

Time : 3 Hours **Marks : 50**

Sem II - MBACNT2006 - ICH GCP and ICMR Guidelines

Your answer should be specific to the question asked

Draw neat labeled diagrams wherever necessary

1.	Describe adverse drug reaction (ADR).	K1 CO1	(2)
2.	Define inform consent process.	K2 CO5	(2)
3.	Define monitoring in clinical research.	K1 CO3	(2)
4.	Define SAE.	K2 CO2	(2)
5.	Define Inspection in clinical trials.	K2 CO4	(2)
6.	Demonstrate the term blinding and case report form in clinical research.	K4 CO6	(6)
7.	Evaluate the 13 principles of ICH Good Clinical Practice.	K3 CO1	(5)
8.	Demonstrate the Investigational Brochure (IB).	K3 CO2	(5)
9.	Evaluate the Components of ICF in clinical trials.	K4 CO4	(8)
10.	Express the roles and responsibilities of Investigator in clinical trial.	K4 CO5	(8)
11.	Express the general principle of ICMR.	K3 CO3	(8)