GALGOTIAS UNIVERSITY

ADMISSION NUMBER

School of Biomedical Science

Bachelor of Science Honours in Healthcare and Clinical Research
Semester End Examination - Jun 2024

Duration : 180 Minutes
Max Marks : 100

Sem II - Q1UF201T - Regulatory Affairs-I

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)	Define the Adverse Event.	K1(2)
2)	Explain the ICMR and indian GCP.	K2(4)
3)	Explain the bioavailability (BA) Trials.	K2(6)
4)	Illustrate the responsibilities of USFDA.	K3(9)
5)	Illustrate the documents retrieval and archival process.	K3(9)
6)	Examine the EMEA.	K5(10)
7)	Analyze the importance of Phase IV Clinical Trial.	K4(12)
8)	Examine the European medicine agency (EMEA) guidelines.	K5(15)
9)	Examine the thalidomide disaster and Kafauvers Harris amendment act.	K5(15)
10)	Elaborate the phase III and phase 4 clinical research.	K6(18)