GALGOTIAS UNIVERSITY

ADMISSION NUMBER

School of Medical and Allied Sciences

Bachelor of Pharmacy
Semester End Examination - Aug 2024

Duration : 180 Minutes
Max Marks : 75

Sem VIII - BPET8004 - Pharmaceutical Regulatory Science

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)	Recall IEC.	K1(2)
2)	Explain target validation.	K2(2)
3)	What are the different types of clical trials?	K1(2)
4)	Illustrate custom clearence.	K2(2)
5)	What is informed consent?	K1(2)
6)	Infer ASEAN.	K2(2)
7)	Define drug.	K1(2)
8)	Infer ACTD	K2(2)
9)	Recall GCP.	K1(2)
10)	Infer pharmacokinetic.	K2(2)
11)	Construct a note on GCP obligations with respect to sponsors.	K3(5)
	OR	
	Construct a note on GCP obligations with respect to investigators.	K3(5)
12)	Categorize the Metadata fields and values of federal register.	K4(5)
13)	Construct a note on Innovator drug product.	K3(5)
14)	Compare ACTD with ICH-CTD.	K4(5)
15)	Construct a note on post-market drug safety monitoring.	K3(5)
16)	Analyze the types of drug applications submitted to CDSCO.	K4(5)
	OR	
	Analyze the types of drug applications submitted to SLA.	K4(5)
17)	Examine the role significance of Federal register.	K4(5)
18)	Discuss various internetional drug regulatory agencies.	K6(10)
19)	Conclude the procedure to export medicine from India.	K5(10)
	OR	
	Conclude a note on management of clinical trials.	K5(10)