GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Medical and Allied Sciences

Bachelor of Pharmacy
Semester End Examination - May 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 IRB	K1 (2)
2)	Explain supplemental NDA.	K2 (2)
3)	What is protocol template?	K1 (2)
4)	Illustrate DCGI	K2 (2)
5)	What is NDA?	K1 (2)
6)	Infer reference biological agent.	K2 (2)
7)	Define sponsors for clinical trials.	K1 (2)
8)	Infer ADRs.	K2 (2)
9)	Recall lead identification.	K1 (2)
10)	Infer CTD	K2 (2)
11)	Construct a note on post-market drug safety monitoring.	K3 (5)
	OR	
	Construct a note on Innovator drug product.	K3 (5)
12)	Assume table of contents of Federal Register.	K4 (5)
13)	Construct a note on GCP obligations with respect to sponsors.	K3 (5)
14)	Categorize the Metadata fields and values of federal register.	K4 (5)
15)	Construct a note on GCP obligations with respect to investigators.	K3 (5)
16)	Analyze the DCGI timelines for the IND approval process.	K4 (5)
	OR	
	Analyze the types of drug applications submitted to SLA.	K4 (5)
17)	Simplify the contents of purple book.	K4 (5)
18)	Discuss the CFR in pharmaceuticals.	K6 (10)
19)	Coclude the regulatory approval process of generic drug product.	K5 (10)
	OR	
	Conclude a note on generic drug product development.	K5 (10)