GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Medical and Allied Sciences

Master of Pharmacy in Pharmaceutics
Mid Term Examination - Nov 2023

Duration : 90 Minutes
Max Marks : 30

Sem I - MPH104T - Regulatory Affair

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 gole of regulatory affairs .	K1	(2)
2)	Demonstrate the post marketing surveillance	K2	(2)
3)	Summarize the US registration for foreign drugs.	K2	(2)
4)	Explain drug master file.	K1	(2)
5)	Explain the ANDA process differ from NDA for generic drug approval?	K2	(2)
6)	Develop the importance of drug product performance testing, both in vitro and in vivo, during the drug development process?	K3	(5)
7)	Distinguish the Bioequivalence (BE), and why is it crucial in the assessment of generic drugs?	K4	(5)
	OR		
	Examine the differences in the approval process between NDA and ANDA applications?	K4	(5)
8)	Explain the How does the Code of Federal Regulations (CFR) relate to the pharmaceutical industry, and what are its key provisions?.	K5	(10)
	OR		
	Justify the pharmaceutical companies outsource Bioavailability (BA) and Bioequivalence (BE) studies to Contract Research Organizations (CROs), and what are the benefits of this practice	K5	(10)