GALGOTIAS UNIVERSITY

ADMISSION NUMBER

School of Biomedical Science

Master of Science Clinical Research
Semester End Examination - Jun 2024

Duration : 180 Minutes
Max Marks : 100

Sem II - Q1PK207B - Drug Discovery and Development

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 IMRDA-Composition.	K1(2)
2)	Explain QSEM in ICH.	K2(4)
3)	Explain the Phase 2 Clinical trial in clinical research.	K2(6)
4)	Illustrate the IND review process in clinical research.	K3(9)
5)	Illustrate the the steps involved in new drug discovery.	K3(9)
6)	Examine theFollow-up Studies for Safety Pharmacology Core Battery in S7A.	K5(10)
7)	Analyze the new drug application process.	K4(12)
8)	Examine the guide lines of (E2A) in Clinical Safety Studies.	K5(15)
9)	Examine the guide lines of (S7A) in Preclinical evaluation.	K5(15)
10)	Elaborate the Sponsor responsibilities for maintaining the integrity clinical research data.	K6(18)