GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Biomedical Science

Master of Science in Healthcare and Clinical Research
Semester End Examination - Nov 2023

Duration : 180 Minutes
Max Marks : 100

Sem III - MBACTT3004 - Clinical Trial Amended Rule

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 Informed consent form.	K1	(2)
2)	Demonstrate the Licence to manufacture unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability and bioequivalence study under the Drugs and Cosmetics Rules, 1945.	K2	(4)
3)	Differentiate between institutional ethics committee and independent ethics committee.	K2	(6)
4)	Utilise the Permission to conduct clinical trial of a new drug or investigational new drug as part of discovery, research and manufacture in India.	K3	(9)
5)	Utilise the Grant of licence for import of new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis.	K3	(9)
6)	Evaluate the Grant of permission for import of new drugs for sale or distribution.	K5	(10)
7)	Distinguish the grant of permission to manufacture new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence study, or for examination, test and analysis	K4	(12)
8)	Interpret the ethics committee for biomedical and healthy research.	K5	(15)
9)	Interpret the Central licensing authority vs state licensing authority.	K5	(15)
10)	Elaborate the aim and primary objective of efficacy endpoints.	K6	(18)