



K. R. MANGALAM UNIVERSITY
SOHNA ROAD, GURGAON
HARYANA,
INDIA

Reappear End Term Examination -Dec, 2024

Course Title: Clinical Research and Pharmacovigilance

Course Code: MPL204T

Programme: M. Pharm (Pharmacology) Sem II

Max. Marks: 75

Time: 3hr

Note: Attempt FIVE out of Seven questions.

Question 1, 3, 4 and 7 have 3parts of 5 marks each, question 2, 5, 6 is of 15 Marks.

Section -A (5 Questions X 15 =75)

1	Explain the terms a) Randomized control and non-randomized control study b) Placebo double blind study, good clinical practices c) Full form of ICH, hemovigilance, ADR, IEC, principle of Helsinki	CO2
2	Elucidate the term Pharmacoeconomics and Pharmacogenomics?	CO3
3	a) Write in brief about role and constitution of institutional Review Board (IRB)? b) Explain Role and Responsibilities in Pharmacovigilance? c) Explain role of Pharmacogenomic in current trend?	CO1
4	a) Write about passive and active surveillance? b) Elaborate each point of Vigiflow, Argus? c) Explain 13 point of ICH guidelines?	CO3
5	What are the steps of designing a clinical trial of drug with the purpose of drug repositioning?	CO4
6	Explain Significance of ADR monitoring and WHO drug monitoring programme?	CO2
7	a) Explain in brief the mechanism for managing ADR? b) Explain the clinical trials documentation? c) Write in brief the protocol for different clinical trials?	CO1