

School of Biomedical Science

Department of Biomedical Science

Mid Term Examination

Exam Date: 30 Sep 2023

Time : 90 Minutes

Marks : 50

Sem III - MBACTT3004 - Clinical Trial Amended Rule

Your answer should be specific to the question asked

Draw neat labeled diagrams wherever necessary

- 1) Define the active pharmaceutical ingredient. K2 (2)
- 2) Illustrate the academic clinical trial. K1 (3)
- 3) Demonstrate the central licensing authority. K2 (4)
- 4) Describe the bioavailability and bioequivalence study. K2 (6)
- 5) Enlist the members name of ethics committee. K3 (6)
- 6) Utilise the SAE timeline and reporting procedure. K3 (9)
- 7) Conclusion of new drugs meaning as per NDCT 2019. K4 (8)

- 8) Distinguish the Constitution of Ethics Committee for clinical trial. K4 (12)

OR

- Distinguish the Proceedings of Ethics Committee for clinical trial. K4 (12)