DBW-014-1101003 Seat No. _____

Master of Pharmacy (Sem. I) Examination

July - 2022

Clinical Research Regulations : MRA-103T

Faculty Code : 014
Subject Code : 1101003

Time : **3** Hours] [Total Marks : **75**

1 Answer the following questions : **20**

(1) Enumerate steps involved in developing a new drug.

(2) Define GCP.

(3) What is EMA and PSUR ?

(4) What is ANDA 505(j) of the FD & C Act ?

(5) Enlist the responsibilities of Investigator in ethical conduct of clinical research.

(6) Write down the principles of Belmont Report.

(7) What is CFR 21 Part 50 and CFR 21 Part 314 ?

(8) Describe in brief the techniques used to avoid bias in clinical trials.

(9) Describe in brief about the Nazi's trial.

(10) ICH E8 and E10 guideline are given for _____ and _____ respectively.

2 Answer the following questions : (Any **Two**) **20**

(1) Enumerate different chapters covered by ICH GCP. Describe the detail about the principles of ICH GCP. Write a detailed note on Indian GCP.

(2) Explain in brief Clinical Research regulations in India.

(3) Explain in detail about Clinical Investigation and Evaluation of Medical Devices & IVDs.

3 Answer the following questions : (Any **Seven**) **35**

(1) Explain NDA 505(b)(1) of the FD & C Act.

(2) What is NDA ? Explain regulatory guidelines of NDA as per USFDA.

(3) Write a brief note on ICH-E11.

(4) Explain objectives and regulatory guidelines of PSUR.

(5) Explain different phase of clinical studies.

(6) Write a note on ethics of randomized clinical trials.

(7) Explain in brief ICMR Ethical Guidelines for Biomedical Research.

(8) Write a note on FDA Med Watch.

(9) Explain Application for approval of a generic drug product in USA.
