CTS PhD103 *Your Roll No.* **……**

Ph.D. Course Work (October, 2023)
CTS PhD 103-Elective Paper: Clinical Research
REGULATORY AND ETHICAL ASPECTS IN CLINICAL RESEARCH

Time: Three Hours ***Maximum Marks: 75***

(Write your Roll No. at the top immediately on receipt of this question paper)
Answer ALL questions. All parts of a question must be answered in continuation. Start answering each question on a new page. Cite examples and draw labeled diagrams.

Q1. Short Answer Type; attempt any 10 (not more than half a page) 10×1.5=15

i. Define CFR.
ii. TGA
iii. CIOMS
iv. Therapeutic equivalence
v. CTRI
vi. NDA
vii. ANVISA
viii. NDCT 2019
ix. DTAB
x. IRB
xi. DCC
xii. CIOMS
xiii. Schedule X
xiv. Schedule H
xv. DOH

Q.2. Short note type; <u>Attempt any 04</u> (not more than two pages) 4×5=20

1. Discuss ICH guidelines.
2. Discuss the process of filing an NDA.
3. Discuss the ethical issues in clinical trials.
4. Discuss GCP guidelines.
5. Discuss the fraud and misconduct in clinical research.
6. Discuss Indian regulatory guidelines for BA/BE studies.

Q.3. Long note type <u>Attempt any 02</u> (no limit of pages) 2×20=40

1. Compare the regulation of drugs in the USA and JAPAN in detail.
2. Discuss CTD and eCTD and its documentation process.
3. Discuss the compensation process for trial-related injuries as per the Indian regulatory system.
4. What is the quorum of the ethics committee for CR. What are the changes as per the NDCT rule regarding the ethics committee?
5. Discuss ethical principles as per the declaration of Helsinki. what is the impact on the ethical conduct of clinical trials?

****