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JBU-103-T

Seat No. _____

Master of Pharmacy (Sem. I) Examination

January - 2020

MRA - 103T : Clinical Research Regulations

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

1 Answer the following questions : **20**

(1) Discuss in brief Appendix I of schedule Y.

(2) Which types of study covered under safety guideline?

(3) What is clause 4 of ISO 14155 : 2011 ?

(4) Justify comment : Coma patient cannot be enrolled in clinical trial.

(5) Give name of various regulatory bodies in India that are involved in the regulation of pharmaceuticals.

(6) Write functions of CDSCO.

(7) Write various general considerations of clinical trials.

(8) What is CFR 21 Part 312?

(9) What is Belmont report?

(10) Enlist different phases of clinical trials. What is phase 0 studies?

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

(1) Enlist various efficacy guidelines and discuss in detail about any one efficacy guideline.

(2) What is ICH GCP? Enlist different section of ICH GCP and discuss principles of ICH GCP as per E6 (R2) guideline.

(3) What is post marketing surveillance studies? Discuss different methods of post marketing surveillance study.

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

(1) Explain about Cohort study design of clinical trials.

(2) Discuss factorial design of clinical trials.

(3) Discuss on financial disclosure by clinical investigator as per USFDA.

(4) Discuss various safety guidelines that concern with carcinogenicity studies.

(5) Write an informative note on : Principles of declaration of Helsinki

(6) Give difference between Indian GCP & ICH GCP.

(7) Discuss : Pharmacovigilance for medicinal products for human use.

(8) Discuss : Application for approval of a generic drug product as per USFDA.

(9) Discuss : Choice of control groups and related issues in clinical trials.
