MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)
M.Pharm. Sem-I : SUMMER : 2022
SUBJECT: CLINICAL RESEARCH REGULATIONS

Day : Thursday
Date 12-May-2022 **S-20733-2022**

Time : 10:00 AM-01:00 PM
Max. Marks: 75

N.B.
1) Attempt any **FIVE** questions out of **SIX.**
2) Figures to the right indicate **FULL** marks.
3) Answers to both section should be written in separate Answer book.

Section I

Q.1 **a)** Discuss the principles of ICH GCP. **(10)**

b) Write a note on the process of informed consent. **(05)**

Q.2 **a)** Discuss in detail Good Pharmacovigilance Practices. **(10)**

b) Write a note on functions of Institutional Review Board. **(05)**

Q.3 **a)** Elaborate the salient features of Schedule Y. **(07)**

b) Discuss in detail key considerations for clinical studies in paediatric population as per ICH guidelines. **(08)**

Q.4 **a)** Discuss present basic features of E7 ICH guidelines for studies in geriatric population. **(07)**

b) Give an account of the history of clinical research in the world. **(08)**

Section-II

Q.5 **a)** Write a note on 21 CFR Part 812 : Investigational Device Exemptions. **(07)**

b) Write a note on 21 CFR Part 320 : Bioavailability and Bioequivalence Requirements. **(08)**

OR

Q.6 Write notes on the following: **(15)**
a) Responsibilities of sponsor in a clinical trial
b) Composition and duties of Ethics Committee
c) Contents of an IND application in USA

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