M.PHARM. (PHARMACEUTICAL REGULATORY AFFAIRS) SEM. – I
(CBCS – 2019 COURSE) : WINTER – 2021
SUBJECT : CLINICAL RESEARCH REGULATIONS

Day : Wednesday
Date : 17-11-2021

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

W-20733-2021

N.B.
1) Attempt any **FIVE** questions out of **SIX.**
2) Figures to the right indicate **FULL** marks.

Q.1 **a)** Describe in details various aspects of ethics to be considered during clinical trials. **(10)**

b) Discuss the composition, roles and responsibilities of ethics committee. **(05)**

Q.2 **a)** Discuss salient features of good clinical practices as given in ICH guidelines. **(10)**

b) Add a note on general biostatics principles applied in clinical research. **(05)**

Q.3 **a)** Give an account of the various phases of clinical trials. **(07)**

b) Add a note on clinical evaluation of medical devices. **(08)**

Q.4 **a)** Write a note on 21 CFR Part 312 : IND application. **(07)**

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

Q.5 **a)** Discuss in detail key considerations for clinical studies in geriatric and paediatric populations as per ICH guidelines. **(07)**

b) Write about good pharmacovigilance practices in detail. **(08)**

Q.6 Write notes on the following: **(15)**
a) Declaration of Helsinki
b) Requirements of Schedule Y
c) USFDA Med Watch

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