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

Day : Friday
Date 25-Mar-2022 **M-20733-2022**

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

N.B.:

1) **Q. No. 1 and Q. No.5** are **COMPULSORY.** Out of remaining questions answer **ANY TWO** from each section.
2) Answers to both sections should be written in **SEPARATE** answer books.
3) Figures to the right indicate **FULL** marks.

SECTION-I

Q.1 Write a note on pediatric clinical trials. **(08)**

Q.2 Discuss the general biostatistics principles to be considered during clinical trials. **(15)**

Q.3 Discuss in details the process of Informed Consent in clinical trials. **(15)**

Q.4 Write notes on **ANY TWO** of the following: **(15)**

a) Role of placebo in clinical trials

b) Medical Device Clinical Evaluation

c) Ethics in clinical research

SECTION-II

Q.5 Discuss the principles of Geriatric clinical trials. **(07)**

Q.6 Write a detailed note on IRB, its role, functions and composition. **(15)**

Q.7 Write about ICMR guidelines for Biomedical research in India. **(15)**

Q.8 Write notes on **ANY TWO** of the following: **(15)**

a) Med Watch

b) Phases of clinical trials

c) BA-BE study requirements in USA

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