SUPPLEMENTARY
MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)
M.Pharm. Sem-II PHARMACOLOGY :SUMMER- 2022
SUBJECT : CLINICAL RESEARCH & PHARMACOVIGILANCE

Day : Wednesday
Date : 21-09-2022

S-20798-2022

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 Discuss in detail key considerations for clinical studies in geriatric and pediatric populations as per ICH-GCP guidelines. **(08)**

Q.2 Explain various aspects of ethics to be considered during clinical trials. Add a note on ethics committee : composition, roles and responsibilities. **(15)**

Q.3 Write a detailed account of history of clinical trials. **(15)**

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

a) Requirements of schedule Y
b) Declaration of Helsinki
c) Phase 'O' trial

SECTION – II

Q.5 Present an outline of pharmacovigilance program in India. **(07)**

Q.6 Describe importance of Pharmacoeconomics in Indian context with suitable examples. **(15)**

Q.7 Describe any six regulatory terms in ADR and indicate their importance. **(15)**

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

a) Spontaneous reporting system
b) International Non-proprietary names of drugs
c) Assessment of severity and seriousness of ADRs

*****