M. PHARM. (PHARMACOLOGY) SEM – II (CBCS – 2019 COURSE) : Winter-2021
SUBJECT : CLINICAL RESEARCH & PHARMACOVIGILANCE

Day : Thursday
Date : 02-12-2021

Time : 02:00 PM-05:00 PM
Max. Marks : 75

W-20798-2021

N. B. :

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

SECTION – I

Q. 1 Discuss the components for preparation of protocol of a clinical trial. **(08)**

Q. 2 Classify adverse drug reactions (ADRs) with suitable examples. Discuss reporting of ADRs and management strategies for ADRs. **(15)**

Q. 3 Discuss different types of clinical trial studies with examples. **(15)**

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

a) ICH – GCP Guidelines

b) Institutional Review Board

c) Ethical principles governing informed consent process

SECTION – II

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

Q. 6 With suitable examples, elaborate on vaccine safety surveillance and describe Indian guidelines related to it. **(15)**

Q. 7 Describe importance of Pharmaco Economics in Indian context with suitable examples. **(15)**

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

a) WHO International Drug monitoring

b) Vigiflow

c) Safety Pharmacology

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