

MASTER OF SCIENCE (BIOINFORMATICS) (CBCS-2019 COURSE)
M. Sc. (Bioinformatics) Sem-III : WINTER :- 2021
SUBJECT: INTRODUCTION TO CLINICAL TRIALS &
PHARMACOVIGILANCE

Day : Friday
Date 4/2/2022

W-21180-2021

Time : 02:00 PM-03:30 PM
Max. Marks: 30

N.B.

- 1) All questions are **COMPULSORY**.
 - 2) Figures to the **RIGHT** indicate **FULL** marks.
 - 3) Answer to both the sections should be written in **SAME** answer book.
-

SECTION – I

Q.1 Attempt **ANY FIVE** of the following : **(05)**

- a) Explain the term Addiction.
- b) Explain the term Tachyphylaxis.
- c) Define Phase 2 trial with types.
- d) Explain Clinical Pharmacology.
- e) Explain exclusion criteria in clinical trials.
- f) What are the types of animal species in preclinical studies.
- g) Give importance of clinical studies in clinical research.

Q.2 Attempt **ANY TWO** of the following : **(10)**

- a) Explain drug development process.
- b) Explain ANDA in detail.
- c) Write a note on Clinical trials Designs.

SECTION – II

Q.3 Attempt **ANY FIVE** of the following : **(05)**

- a) Explain serious adverse reactions.
- b) Explain sulfanilamide disaster.
- c) Explain role of WHO.
- d) Write a note on Phase 5 clinical trials.
- e) What is role of Drug Safety associate in clinical trials?
- f) Name the regulatory bodies in USA, UK, Japan and India.
- g) What are types of Pharmacovigilance?

Q.4 Attempt **ANY TWO** of the following : **(10)**

- a) Write a note on Informed Consent.
- b) Write about privacy and confidentiality in Pharmacovigilance.
- c) What are major legal agreements in clinical trials?
