

M.PHARM. (PHARMACOLOGY) SEM-II (CBCS-2019 COURSE): Winter-2021
SUBJECT : PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - II

Day : Tuesday
Date : 30-11-2021

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

W-20776-2021

N.B.

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

SECTION – I

- Q.1** Attempt **ANY FOUR** of the following : **(08)**
- a) What is IND and when it is carried out?
 - b) Write about OECD guideline-AOT-425?
 - c) Which guideline is used for toxicity testing of inhalational drugs?
 - d) Write the importance of Schedule Y.
 - e) Define chromosomal aberration study.
 - f) Write the guideline for dermal toxicity testing.
- Q.2** Discuss the principles and basic concepts of GLP. **(15)**
- Q.3** What are OECD acute oral toxicity studies? Describe it using AOT-423. **(15)**
- Q.4** Write short notes on **ANY TWO** of the following : **(15)**
- a) Teratogenicity tests
 - b) ICH guidelines
 - c) Female reproductive toxicity testing

SECTION – II

- Q.5** Attempt **ANY TWO** of the following : **(07)**
- a) Explain the scope of ICH S7A guidelines.
 - b) Enlist assessment parameters used in CNS safety pharmacology studies.
 - c) What are the phases of ventricular action potential?
- Q.6** Discuss the origin, concept and goals of safety pharmacology. Explain in detail the safety pharmacology core battery test for respiratory system. **(15)**
- Q.7** Explain in detail objective, parameters and principles of toxicokinetics. Discuss the setting of dose levels in order to produce adequate exposure in toxicokinetic studies. **(15)**
- Q.8** Write short notes on **ANY TWO** of the following : **(15)**
- a) HERG assay (in vitro IKr assay)
 - b) Factors that limit the interpretation of in vitro electrophysiology studies
 - c) Importance of Safety pharmacology
