

M. PHARMA.
THEORY EXAMINATION (SEM-II) 2016-17
TOXICOLOGICAL SCREENING METHODS

Time : 3 Hours

Max. Marks : 70

Note : Be precise in your answer. In case of numerical problem assume data wherever not provided.

SECTION- A

1. Attempt all parts of this Section **7×2=14**

- (a) What do you mean by mechanistic toxicology?
- (b) Classify toxicity study of any drug molecule.
- (c) Give a short note on the report handling in OECD Test Guideline on Acute Dermal Toxicity.
- (d) What are the teratogenicity test parameters?
- (e) What do you mean by genotoxicity?
- (f) Give a short note on comet assay.
- (g) Enlist the importance of IND.

SECTION- B

2. Attempt any three parts of the following **3×7=21**

- (a) Give short notes on the followings.
 - (i) Schedule -Y
 - (ii) OECD Principles of good laboratory practice (GLP)
- (b) Discuss the inhalational toxicity studies as per OECD guidelines.
- (c) Give short notes on the followings.
 - (i) Male reproductive toxicity studies
 - (ii) Chromosomal aberrations studies
- (d) Write down the industrial prospects of IND.
- (e) Define toxicokinetics. Give a detailed account on the toxicokinetic evaluation in preclinical studies.

SECTION- C

3. Attempt all questions in this section. **5×7=35**

- (a) Describe the regulatory guidelines for conducting toxicity studies under OECD or ICH.
- (b) Answer **any one** of the following questions
 - (i) Describe the principle, methodology and grading of acute eye irritation toxicity study under OECD guidelines.
 - (ii) Write down the test procedure and report in OECD Test Guideline for chronic Toxicity Studies.
- (c) Describe the principle, methodology and reporting of female reproductive toxicity study under OECD guidelines.
- (d) Write down the concepts and importance of safety pharmacology for CVS and respiratory system?
- (e) Write down the importance and applications of toxicokinetic studies.