

MPHARM
(SEM II) THEORY EXAMINATION 2017-18
TOXICOLOGICAL SCREENING METHODS

Time: 3 Hours**Total Marks: 70**

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.
2. Any special paper specific instruction.

SECTION A

1. Attempt *all* questions in brief. 2 x 7 = 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* of the following: 7 x 3 = 21

- a. Give short notes on the followings.
 - i. Schedule -Y
 - ii. OECD
- 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 any *one* part of the following:** **7 x 1 = 7**
- (a) Describe the regulatory guidelines for conducting toxicity studies under OECD or ICH.
 - (b) Narrate the principles of GLP.
4. **Attempt any *one* part of the following:** **7 x 1 = 7**
- (a) Describe the principle, methodology and grading of acute eye irritation toxicity study under OECD guideline
 - (b) Write down the test procedure and report in OECD Test Guideline for chronic Toxicity Studies
5. **Attempt any *one* part of the following:** **7 x 1 = 7**
- (a) Describe the principle, methodology and reporting of female reproductive toxicity study under OECD guidelines.
 - (b) Discuss invivo carcinogenicity studies in animals
6. **Attempt any *one* part of the following:** **7 x 1 = 7**
- (a) Write down the concepts and importance of safety pharmacology for cardiovascular system?
 - (b) Write down the concepts and importance of safety pharmacology for respiratory system?
7. **Attempt any *one* part of the following:** **7 x 1 = 7**
- (a) Write down the importance and applications of toxicokinetic studies
 - (b) Write short notes on “Alternatives to animal toxicity testing”