Printed Pages: 01 **Sub Code: MPL-202T**

Paper Id: | 2 | 9 | 8 | 2 | 0 | 9 | **Roll No.** | | | | | | | | | | |

M. PHARM.
(SEM. II) THEORY EXAMINATION 2017-18
PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II

Time: 3 Hours ***Total Marks: 75***

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. 10 x 2 = 20

a. What is the objective of Globally Harmonized System (GHS) for the classification of a chemical?
b. What is Form 44?
c. Name any two OCED test guidelines for oral toxicity studies.
d. What do you mean by Satellite group?
e. Name two clastogens used as a positive controls in *in-vitro* mammalian chromosomal aberration test.
f. Write the principle of Perinatal Study (Segment III).
g. What is IND? Discuss its types.
h. What is HERG assay?
i. What is the basic difference between pharmacokinetics and toxicokinetics?
j. Write a short note on Dried Blood Spot bioanalysis.

SECTION B

2. Attempt any *two* parts of the following: 2 x 10 = 20

a. Discuss the OECD principles of Good laboratory practice (GLP) in detail.
b. Describe Guinea-pig maximisation test method in detail.
c. Write a short note on the following:
   (i) Ames test
   (ii) *in-vivo* micronucleus assay

SECTION C

3. Attempt any *five* parts of the following: 7 x 5 = 35

a. Discuss the role of OECD, ICH, and Schedule Y in toxicity studies.
b. What do you mean by Test item? Discuss the characterization for specific test items.
c. Write the objectives and principle of combined chronic toxicity\carcinogenicity studies (OECD TG 453).
d. Explain teratogenicity studies (segment II) as per schedule Y in detail.
e. Write a descriptive note on safety pharmacology core battery of tests by ICH guidelines S7A and S7B.
f. Discuss the role of toxicokinetic evaluation in the drug development process
g. Write a note on alternative methods to animal toxicity testing.