

# Question Paper

Exam Date & Time: 05-May-2018 (02:00 PM - 05:00 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES  
END SEMESTER THEORY EXAMINATIONS- MAY 2018  
PROGRAM: MPHARM SEMESTER 2 (PHARMACOLOGY)

DATE: 05/05/2018

TIME: 2:00 PM - 5:00 PM

### Pharmacological and Toxicological Screening Methods II [PHA-MPL202T]

Marks: 50

Duration: 180 mins.

**a**

**Answer all the questions.**

**Answer the following (5 marks x 8 = 40 marks)**

- 1) Briefly discuss the types of audits that are performed by quality assurance unit for GLP compliance (5)
- 2) Discuss various agencies that issue guidelines for the conduct of toxicity study in animals. (5)
- 3) Explain the parameters monitored in sub-acute toxicity studies as per OECD guidelines 407 (5)
- 4) Discuss the grading of skin reactions as per OECD guidelines 404 (5)
- 5) Explain the following terms in assessing reproductive toxicity still births, males of proven fertility, post implantation loss and teratogen. (5)
- 6) What is the purpose and rationale behind the gastric emptying assay? Describe the procedure and challenges. (5)
- 7) What do you understand by follow up studies in CNS safety Pharmacology? Name three different follow up tests? (5)
- 8) What is chromosomal Aberration test? Explain it with advantages and disadvantages. (5)

**b**

**Answer all the questions.**

**Answer the following with specific answers (2 marks x 5 = 10 marks)**

- 9) (2)

- A) LD<sub>50</sub> of a chemical, which was tested for oral acute toxicity, was found to be 250 mg/kg. Mention the warning signs and symbols that must be printed in the label for this test chemical as per Global Harmonized System of classification and labelling.
- B) Explain the duration of chronic toxicity studies as per S4 document of ICH guidelines. (2)
- C) What is 3Rs Philosophy? (2)
- D) Name only different follow-up studies used in CNS safety pharmacology (2)
- E) What is toxicokinetic? Mention its significance. (2)

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