

**BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI  
(END SEMESTER EXAMINATION)**

**CLASS: M.Pharm  
BRANCH: PHARMACY**

**SEMESTER: II  
SESSION: SP-2022**

**SUBJECT: Pharmacological and Toxicological Screening Methods-II (MPL202T)**

**TIME: 3.00 Hours**

**FULL MARK: 75**

**INSTRUCTIONS:**

1. The missing data, if any, may be assumed suitably.
  2. Before attempting the question paper, be sure that you have got the correct question paper.
  3. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.
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| 1a. Describe major specialized areas of toxicology  | [7] |
| 1b. Discuss alternatives to animal toxicity testing with the example of bovine corneal opacity and permeability test.   | [8] |
| 2a. Explain the structure and roles of ICH  | [7] |
| 2b. Write a short note on the method of fixed-dose oral toxicity study of a new chemical entity.  | [8] |
| 3a. Describe screening tests in animals for reproductive toxicity of Segment-1 fertility & General reproductive performance segment and Segment-2 (Teratogenesis segment).                    | [7] |
| 3b. write detail about Genotoxicity & Carcinogenicity study   | [8] |
| 4a. Explain types & Categories of IND and write required information needed for IND applications  | [7] |
| 4b. Write detail information of Nonclinical & Clinical Components required in IND application for Clinical Investigation and safety & Annual reports in IND Application Reporting             | [8] |
| 5a. Illustrate lead optimization in the drug discovery process  | [7] |
| 5b. Explain the procedure of the skin sensitization test following guinea pig maximization test.  | [8] |
| 6a. Write Importance of safety pharmacology & write general consideration in selection & design of safety pharmacology studies  | [7] |
| 6b. Explain detail about Tier-1 & Tier-2 safety pharmacology  | [8] |
| 7a. Write objective, General Principle and the parameters to be measured in Toxicokinetic   | [7] |
| 7b. List down different reconstituted human epidermis models used in <i>in vitro</i> research. Demonstrate the experimental method for the most sensitive reconstituted human epidermis model | [8] |