

GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM - SEMESTER-2 EXAMINATION – SUMMER-2019

Subject Code: MPL202T**Date: 29/05/2019****Subject Name: Pharmacological and Toxicological Screening Methods-II****Time: 10:30 AM TO 01:30 PM****Total Marks: 80****Instructions:**

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- | | | | |
|-------------|-----|--|-----------|
| Q.1 | (a) | Describe briefly dermal irritation and dermal toxicity studies. | 06 |
| | (b) | Write origin, concepts and importance of safety pharmacology. | 05 |
| | (c) | Explain significance of toxicity study for drugs undergoing saturation kinetics. | 05 |
| Q.2 | (a) | Write species used, list of observations and report content of the following test as per OECD guidelines:
i) Acute eye irritation ii) Skin sensitization | 06 |
| | (b) | Describe inhalational toxicity studies for aerosols. | 05 |
| | (c) | Explain in detail acute toxicity study. | 05 |
| Q.3 | (a) | Explain in detail OECD guideline 407. | 06 |
| | (b) | Write a note on ICH guideline. | 05 |
| | (c) | Describe concept and importance of GLP in drug development. | 05 |
| Q.4 | (a) | Describe briefly Schedule Y for conducting toxicity studies. | 06 |
| | (b) | Explain female reproductive toxicity studies. | 05 |
| | (c) | What are roles and responsibilities of EPA? | 05 |
| Q.5 | (a) | Explain importance and application of toxicokinetic studies. | 06 |
| | (b) | Write a note on Chromosomal aberration study. | 05 |
| | (c) | Define IND and enlist various studies needed for IND submission. | 05 |
| Q. 6 | (a) | Explain following terminologies :
i) Dose progression factor ii)) RCC iii) RPD | 06 |
| | (b) | Describe detailed protocol for carcinogenicity studies for new drug molecule. | 05 |
| | (c) | Write a note on HERG Assay. | 05 |
| Q.7 | (a) | Enlist CNS assessment as per safety pharmacological studies and explain any one in detail. | 06 |
| | (b) | Explain test procedure and clinical observations of prenatal developmental toxicity study. | 05 |
| | (c) | Describe alternative methods to animal toxicity studies. | 05 |
