

M.Sc. TOXICOLOGY
SEMESTER III EXAMINATION - 2022
PAPER-MTX 302
REGULATORY AND METHODS OF TOXICOLOGY

Time: Three Hours

Maximum Marks: 75

- 1. Briefly answer the following (in not more than half a page) [1.5 x 10 = 15]**
- i. The OECD 420 Oral Toxicity Method is also known as
 - ii. Phase IV clinical trial is also known as
 - iii. CDSCO stands for
 - iv. First pass effect
 - v. IEC stands for
 - vi. Up and down procedure falls under the Acute Toxicity Guideline of OECD
 - vii. Market surveillance falls under Phase of Clinical Trail
 - viii. Why are liver extracts used in Ames test?
 - ix. Auxotrophic strain
 - x. Harlequin
- 2. Write short notes on any three (3) of the following: [5 x 3 = 15]**
- A. Regulations related to transport, storage and disposal of hazardous chemicals
 - B. Regulation of Clinical Trail of Drugs
 - C. Importance of OECD
 - D. Schedule Y
 - E. Safety Pharmacology
- 3. Attempt any three of the following: [5 x 3 = 15]**
- A. Management of poisoning
 - B. Role of NDMA in disaster management
 - C. ICMR guidelines on clinical trails
 - D. Role of ICH guidelines on genotoxicity testing
 - E. Preclinical safety evaluation of biotechnology-derived pharmaceuticals
- 4. Write short notes on any three (3) of the following: [5 x 3 = 15]**
- A. Acute, chronic, sub-chronic toxicity testing
 - B. Basics of toxicokinetics procedures.
 - C. Different cell lines used in toxicological studies
 - D. Any two mammalian models used for toxicity testing
 - E. Importance of in vitro and in vivo testing of chemicals
- 5. Attempt any three of the following: [5 x 3 = 15]**
- A. Difference between neutral electrophoresis & alkaline electrophoresis stain in COMET assay.
 - B. Sister chromatid exchange assay
 - C. Carcinogenicity bioassay
 - D. Explain in detail about the micronucleus assay, types and its application
 - E. How we can determine the activity of mutagenic agent through AMES test?