M.Sc. TOXICOLOGY
SEMESTER III EXAMINATION – 2022-23
PAPER-MTX 302
REGULATORY TOXICOLOGY

Time: Three Hours **Maximum Marks: 75**

1. Briefly answer any 10 of the following (in not more than half a page) [1.5 x 10 = 15]

i. Full form of GPMT is .....
ii. In which test FCA is used and its full form is .....
iii. Arrange according to their appearance in a dose-response curve- LD_{50}, NOEL, NOAEL, LOAEL (ascending order):
iv. If a vaccine needs to be developed within 3 months' time, which study would be performed:
v. Identify NOAEL and LOAEL- 14 mg/kg bw/day and 20 mg/kg bw/day:
vi. Name the two methods used in Ames assay:
vii. Define C_{max} and T_{max}
viii. Define Point of departure (POD)
ix. Stimulation index and EC3 value
x. 1ppb = _____µg/L
xi. Differentiate between Toxicokinetics and Toxicodynamic
xii. The most rapid exposure to a chemical would occur through which route of administration (oral, subcutaneous, inhalation, intramuscular) and why?
xiii. Differentiate between local and systemic effects with examples
xiv. Mention any 3 haematological estimations, which are measured in repeated dose toxicity studies.
xv. For how many days the male and female animals (w.r.t rats) are dosed in 'Two Generation Reproduction Toxicity' study and why?

2. Write shot notes on any three (3) of the following: [5 x 3 = 15]

A. Adverse outcome pathway in skin sensitization. Different events of skin sensitization and OECD guidelines (only name and number) associated with them.
B. OECD guidelines associated with reproduction and post-natal development (number and names). Elaborate principle, significance, results of any one of them.
C. Difference between sensitization and irritation. Difference between GPMT and Buhler test.
D. What is Ames test (with principle)? Which strains are used and what is the endpoint? Is it a qualitative or a quantitative test?
E. What is *in vivo* micronucleus test? State its principle, significance, endpoint. Is it a qualitative or a quantitative test?

3. Attempt any three of the following: [5 x 3 = 15]

A. Role of ICH guidelines on genotoxicity testing or Preclinical safety evaluation of biotechnology-derived pharmaceuticals
B. Differentiate between serious adverse effects and side effects? Explain with an example for each type of effects.

C. What is EURL ECVAM? Mention the steps involved in the validation process under EURL, along with validated toxicological test methods.

D. Define the principle of 3Rs. What are alternative method of testing which can be employed instead of animal testing? Mention an example of *in chemico* method of testing.

E. Mention briefly about Schedule Y. Which regulatory authority oversee the clinical trials and amendments under schedule Y in India? Mention the recent amendments of the Act.

4. Write shot notes on any three (3) of the following: **[5 x 3 = 15]**

A. Acute, chronic, sub-chronic toxicity testing

B. LD_{50}, NOEL, NOEC, LOAEL along with units

C. Basics of toxicokinetics procedure

D. Importance of *in vitro* and *in vivo* testing of chemicals

E. Define various routes of administration

5. Attempt any three of the following: **[5 x 3 = 15]**

A. Sister chromatid exchange assay

B. Threshold of Toxicological Concern (TTC) with cutoff values

C. Margin of safety and Margin of exposure (with formulae and units)

D. Elaborate the 4 major steps involved in risk assessment

E. Basic principles of Toxicokinetics. Mention the various parameters which can be derived from such studies