

**Duration: 3 hrs**

**Total marks: 75 Marks**

**N.B. : 1. All questions are compulsory  
2. Figures to right indicate full marks**

- Q. I Choose the appropriate option for the following MCQs and write it down 20**
- 1 EPA is:**
- a** Environmental protection agency
  - b** European pharmaceutical agency
  - c** Environmental pharmaceutical agenda
  - d** Energy preservation agency
- 2 GLP studies are carried out for following products except:**
- a** Pharmaceutical products
  - b** Synthetic polypropylene products
  - c** Veterinary drugs
  - d** Food additives
- 3 Any substance can be teratogenic if given to the right species, at the right state of development as per:**
- a** Karnofsky's Law
  - b** Frank Starling's Law
  - c** Berger's Law
  - d** Darwin's Law
- 4 Subacute inhalation toxicity studies are always performed in:**
- a** Dynamic Inhalation Chambers
  - b** Static Exhalation Chambers
  - c** Saturated Gas Chambers
  - d** Rota rod Apparatus
- 5 A type of genetic damage is:**
- a** Nucleotide excision repair
  - b** Oxidative stress
  - c** Necrosis
  - d** Carcinogenesis
- 6 A toxic substance produced by a biological system is specially referred to as a:**
- a** Xenobiotic
  - b** Xenobiotic
  - c** Toxin
  - d** Poison

- 7 The OECD Guideline entitled " Acute Oral Toxicity- Up & Down Procedure" aims to estimate:
- a Dose Progression Factor
  - b Volume of Distribution
  - c Bioaccumulation Potential
  - d Median Lethal Dose -LD 50
- 8 According to the OECD Test Guideline " Acute Eye Irritation", experimental animals are:
- a Pre-treated with a Systemic Vasodilator
  - b Mydriatic Drug
  - c Topical Anaesthetic Agent
  - d Skeletal Muscle Relaxant
- 9 Reproductive toxicity studies should allow exposure of mature adults at all stages of development from conception to:
- a Death
  - b Pregnancy
  - c Sexual maturity
  - d Lactation
- 10 Teratology studies deal with:
- a Effects on pre- and postnatal development
  - b Fertility and early embryonic development
  - c Effects on embryo-fetal development
  - d Juvenile toxicity
- 11 A metaphase-arresting substance used in genotoxicity studies is:
- a Colchicine
  - b Toluene
  - c Theophylline
  - d Histidine
- 12 The disadvantage of Rat as an experimental animal for Reproductive Toxicity Study is:
- a Unsuitable for Dopamine Agonists
  - b Lack of Kinetic and Toxicity Data
  - c Susceptibility to Antibiotics
  - d Long Foetal Period

- 13 An IND with no immediate plan to market the product is:
- a Commercial IND
  - b Abbreviated IND
  - c Research IND
  - d Emergency use IND
- 14 In the cardiovascular system a core battery test is:
- a Irwin test
  - b Plethysmography
  - c Functional observatory battery
  - d hERG study
- 15 One of the standard techniques used to investigate Cardiovascular system is:
- a Open Field Observations In Vitro Studies
  - b Electrophysiological Effects
  - c Home cage Observations
  - d Neuromuscular measurements
- 16 Safety Pharmacology Studies are not necessary for:
- a Pharmaceuticals for Dermal Application
  - b Parenterals
  - c Sublingual products
  - d Oral suspensions
- 17 Which one of the following is a proven human teratogen?
- a Ceftriaxone
  - b Tetracycline
  - c Amphotericin B
  - d Tacrolimus
- 18 Alternative methods (alternative toxicology tests) are methods able to do everything except:
- a Reduce the number of animals necessary in a test.
  - b Refine toxicology procedures to make them less painful or stressful to laboratory animal
  - c Replace animals with non-animal (in vitro, ex-vivo or in silico systems
  - d Provide more accurate clinical data which can be used for humans.
- 19 Which one of the following is a Toxicokinetic Parameter?
- a Volume of Distribution
  - b Dose Response Curve
  - c Receptor Binding of Toxicant
  - d Median Lethal Dose

- 20 The study of disposition of toxicants in the body is known as:
- Toxicokinetics
  - Toxicodynamics
  - Toxicology
  - Toxicobolomics

**Q. II Answer any TWO of the following:**

**20**

- Describe reproductive toxicology studies in detail with examples of male and female toxicity studies.
- Write a short note on Acute Oral Toxicity and Acute Dermal Toxicity based on OECD TG 401 and 402 and respectively.
- Discuss in detail the ICH Guideline for Safety Pharmacology Studies.

**Q. III Answer any SEVEN of the following:**

**35**

- What are the "EPA 6-pack" studies? Give details.
- Write a short note on the Ames test.
- Give detailed description of the HERG assay.
- Give a detailed account on: OECD Principles of Good Laboratory Practices.
- Write a note on skin sensitization studies.
- Compare and contrast Acute Toxicity and Chronic Toxicity studies.
- Explain teratogenicity studies (segment II) in detail.
- Write a note on: Importance and Applications of Toxicokinetic Studies.
- Briefly describe toxicokinetic evaluation in preclinical studies.

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