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:

a Toxicokinetics

b Toxicodynamics

c Toxicology

d Toxicobolomics

Q. II **Answer any TWO of the following:** **20**

a Describe reproductive toxicology studies in detail with examples of male and female toxicity studies.

b Write a short note on Acute Oral Toxicity and Acute Dermal Toxicity based on OECD TG 401 and 402 and respectively.

c Discuss in detail the ICH Guideline for Safety Pharmacology Studies.

Q. III **Answer any SEVEN of the following:** **35**

1 What are the "EPA 6-pack" studies? Give details.

2 Write a short note on the Ames test.

3 Give detailed description of the HERG assay.

4 Give a detailed account on: OECD Principles of Good Laboratory Practices.

5 Write a note on skin sensitization studies.

6 Compare and contrast Acute Toxicity and Chronic Toxicity studies.

7 Explain teratogenicity studies (segment II) in detail.

8 Write a note on: Importance and Applications of Toxicokinetic Studies.

9 Briefly describe toxicokinetic evaluation in preclinical studies.

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