Time:3 Hours **Marks:75**

Q. I **Choose appropriate option for following multiple choice-based questions and write down the correct answer** **20**

1 Which of the following is an acute toxicity symptom?
a Carcinogenesis
b Hypothermia
c Mutation
d Hepatotoxicity

2 Dose that produces side effects in 10% of exposed, relative to control is called
a LD50
b LED10
c LOAEL
d NOAEL

3 Toxicity studies which are carried out throughout the total lifespan of the test animal are
a Acute toxicity studies
b Subacute toxicity studies
c Sub-chronic toxicity studies
d Chronic toxicity studies

4 A quality system concerned with non-clinical health and environmental safety studies is
a Good Laboratory Practice
b Good Clinical Practice
c Good Health Practice
d Good Safety Practice

5 A study that allows selection of the appropriate starting concentration for the main study is
a Preclinical study
b Limit test
c Dose selection study
d Sighting study

6 Which of the following option conveys the purpose of ICH S5(R2) guidelines on Reproductive toxicology?
a They are non-clinical safety studies for the conduct of human clinical trials and marketing authorisation for pharmaceuticals
b They detect reproductive toxicity for medicinal products including toxic effects on male fertility
c They detect preclinical safety evaluation of biotechnology - derived pharmaceuticals
d They guide for assessing systemic exposure in toxicology studies

7 United States Environment Protection Agency Test Guidelines for Pesticides are issued as per which of the following Act?

a Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
b Prevention of Cruelty to Animals Act
c Wildlife Protection Act
d Federal Pollution Control Act

8 The OECD Guideline entitled " Acute Oral Toxicity- Up & Down Procedure" aims to estimate a

a Dose Progression Factor
b Volume of Distribution
c Bioaccumulation Potential
d Median Lethal Dose -LD 50

9 Which of following statement is incorrect about the data derived from toxicological studies:

a they provide pharmacokinetic data that can be used to define the test measurement intervals
b they provide acute toxicity data that can be used to select the appropriate high dose
c they provide toxicology/pathology findings that can be used to help define the mechanism of the functional changes measured in safety pharmacology studies.
d they provide clinical data on the proper usage of drugs.

10 General principles of teratology include all the following except:

a Teratogenic agents act via specific pathways
b The final manifestations of abnormal development are death, malformation, growth retardation and functional disorder**.**
c Susceptibility of the conceptus to teratogenic agents varies with the developmental stage at the time of exposure.
d Recommendations related to contraception and pregnancy testing in clinical trials.

11 The ICH Guideline entitled "Detection of Toxicity to Reproduction for Medicinal Products and Toxicity to Male Fertility" is:

a S-5 R (2)
b E-3 R (1)
c S-11 R (2)
d E-15 R (2)

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 Studies that evaluate adverse pharmacodynamic effects of a substance observed in clinical studies are:
a Cell Based Assays
b Safety Pharmacology Studies
c Toxicokinetic Studies
d Preclinical Efficacy Studies

14 Safety pharmacology studies
a Define the pharmacokinetics of the drugs
b define the dose-response relationship of the adverse effect observed
c Are done to determine the pharmacodynamics of the drug
d They determine the acute toxicity of the drug

15 Before a potential pharmaceutical compound can be given to humans:
a An NDA must be filed with the FDA
b Acute Toxicity studies on 4 species must be conducted
c A 2-year Dog Carcinogenicity study must be completed
d An IND must be filled with the FDA

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 Toxicokinetic Parameter ?
a Volume of Distribution
b Dose Response Curve
c Receptor Binding of Toxicant
d Median Lethal Dose

18 Drugs which are extensively metabolized like phenytoin exhibit
a Zero order kinetics
b First order kinetics
c Linear pharmacokinetics
d Nonlinear pharmacokinetics

19 Which one of the following is an alternative to In-vivo Animal Toxicity Studies?
a Strychnine Induced Convulsions in Rats
b Carcinogenicity Study in Mice
c Physiological Based Toxicokinetic Modelling
d Histamine Bioassay using Guinea Pig Trachea

20 Which of the following represents application of Toxicokinetic studies?

a identification of multiple types of calcium channels

b investigation of a wider angle of electrophysiological cell properties.

c measurement of cell membrane conductance.

d drug development stages especially in preclinical stage.

Q.II **Answer (any <u>TWO)</u> from the following:** **20**

a Write a short note on Acute Dermal Toxicity and Inhalational studies as per OECD guideline.

b Give an account of Female Reproductive Studies (seg I and seg III)

c Write a descriptive note on safety pharmacology.

Q.III **Answer (any <u>SEVEN)</u> from the following:** **35**

a Enlist various OECD Guideline for Oral Toxicity Studies. Describe Any One OECD Test Guideline for Oral Toxicity Studies.

b Write a short note on EPA studies.

c Write a note on skin sensitization studies.

d What do you mean by Test item? Discuss the characterization for specific test item.

e Write a short note on the following:

(a) Ames test

(b) In vivo micronucleus assay

f Give an account of Male Reproductive Toxicity Studies.

g Write a short note on IND studies.

h Write a note on Importance and Application of Toxicokinetic Studies.

i Give an account of toxicokinetic evaluation in preclinical studies.

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