

Time: 3 Hours

Marks:75

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

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- 1 Which of the following is an acute toxicity symptom?
 - a Carcinogenesis
 - b Ptosis
 - c Mutation
 - d Hepatotoxicity
- 2 EPA is:
 - a Environmental protection agency
 - b European pharmaceutical agency
 - c Environmental pharmaceutical agenda
 - d Energy preservation agency
- 3 GLP studies are carried out for following products except:
 - a Pharmaceutical products
 - b Synthetic polypropylene products
 - c Veterinary drugs
 - d Food additives
- 4 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
- 5 Subacute inhalation toxicity studies are always performed in:
 - a Dynamic Inhalation Chambers
 - b Static Exhalation Chambers
 - c Saturated Gas Chambers
 - d Rota rod Apparatus
- 6 According to OECD Test Guideline " Acute Eye Irritation", experimental animals are pre-treated with:
 - a Systemic Vasodilator
 - b Mydriatic Drug
 - c Topical Anaesthetic Agent
 - d Skeletal Muscle Relaxant
- 7 The OECD Guideline *In-vitro* Skin Irritation Study is based on the use of:
 - a Local Lymph Node Assay
 - b Tail Flick Method in Rats
 - c Reconstructed Human Epidermis
 - d Guinea Pig Skin Permeation

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- 8 Acute toxicity studies are directly useful:
- a In determining genotoxicity
 - b In determining labelling instructions
 - c For carcinogenesis
 - d For pharmacokinetic studies
- 9 A metaphase arresting substance used in genotoxicity studies is:
- a Colchicine
 - b Toluene
 - c Theophylline
 - d Histidine
- 10 In the OECD Guideline entitled "*In-Vitro* Mammalian Cell Micronucleus Test" Cytochalasin B acts as:
- a Cyclin Dependent Kinase
 - b Actin Polymerisation Inhibitor
 - c Reverse Transcriptase
 - d Colony stimulating factor
- 11 The Reproductive Toxicity Study of Fertility and Early Embryonic Development to Implantation, include the Assessment of:
- a Pre- and postnatal death of offspring
 - b Pre-implantation Stages of Embryo
 - c Functional deficits in offspring
 - d Number of Live offspring at Birth
- 12 15. An IND with no immediate plan to market the product is a/an:
- a Commercial IND
 - b Abbreviated IND
 - c Research IND
 - d Emergency use IND
- 13 One of the following is proven human teratogen
- a Ceftriaxone
 - b Tetracycline
 - c Amphotericin B
 - d Tacrolimus
- 14 A compound and its major metabolites that are expected to achieve systemic exposure in humans should be evaluated in:
- a Epidemiological studies
 - b Toxicological studies
 - c Organoleptic studies
 - d Safety pharmacology studies

- 15 The inhibition of HERG Current causes a fatal tachyarrhythmias called:
- a Torsade de Pointes
 - b Angina Pectoris
 - c Atrial Fibrillation
 - d AV Node Bradycardia
- 16 Necropsy means:
- a Examination of Kidney
 - b Surgical examination of dead body
 - c Neurological examination
 - d Surgical examination of nerves.
- 17 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
- 18 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
- 19 The objective of which studies is to characterize the profile of a substance in a mammalian species (primarily rodents) following prolonged and repeated exposure?
- a Repeat toxicity tests
 - b Chronic Toxicity studies
 - c Subchronic toxicity studies
 - d Subacute toxicity studies
- 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 TWO) from the following:

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- a Explain dermal toxicity studies as per OECD guidelines
- b Describe in details male reproductive toxicity studies
- c Write note on HERG Assay. Discuss in detail the Core Battery Tests (Tier2) in Safety Pharmacology Studies

Q. III Answer (any SEVEN) from the following:

- a Explain Acute Oral Toxicity studies.
- b Give principles and importance of GLP in new drug development.
- c Discuss the study design, conduct and evaluation of ocular toxicity study
- d Write a note inhalation studies as per OECD guidelines.
- e Write note on i) Ames test ii) Micronucleus test
- f Explain in details teratogenicity studies.
- g Explain the types of IND. Write the details of IND application form.
- h Define toxicokinetics. Explain importance & application of toxicokinetic studies.
- i Write a note on saturation kinetics.
