Duration: 3 hrs **Total marks: 75**

Marks

N.B. : 1. All questions are compulsory

2. Figures to right indicate full marks

Q. I	**Choose appropriate option for following multiple choice based questions.**	**20**
1	The branch of Toxicology which studies molecular and cellular mechanisms of toxicity is	
a	Mechanistic Toxicology	
b	Preclinical Toxicology	
c	Clinical Toxicology	
d	Cytotoxicology	
2	OECD guidelines are periodically reviewed in the light of scientific progress or	
a	Changing countries as OECD members	
b	Changing timelines	
c	Changing assessment practices	
d	Changing chemicals undergoing evaluation	
3	Principles of GLP apply to	
a	Clinical Studies	
b	Hospital studies	
c	Chemical methods of analysis	
d	Non-clinical health studies	
4	Which of the following is an acute toxicity symptom ?	
a	Carcinogenesis	
b	Hypothermia	
c	Mutation	
d	Hepatotoxicity	
5	Karber's method for determination of LD50 is also known as	
a	Arithmetic method	
b	Graphical method	
c	Fixed dose procedure	
d	Up and down method	
6	Toxicity studies which are carried out throughout the total lifespan of the test animal are	
a	Acute toxicity studies	
b	Subacute toxicity studies	
c	Subchronic toxicity studies	
d	Chronic toxicity studies	

7	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	
8	The degree of eye irritation/corrosion is evaluated by scoring	
a	Ptosis	
b	Lesions of cornea and iris	
c	Vision tests	
d	Excessive lacrimation	
9	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	
10	Studies for adverse effects on peri- and postnatal devopment are taken up in	
a	Segment I	
b	Segment II	
c	Segment III	
d	Segment IV	
11	A type of genetic damage is	
a	Nucleotide excision repair	
b	Oxidative stress	
c	Necrosis	
d	Carcinogenesis	
12	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	
13	The bacterial reverse utation test is	
a	Ames Test	
b	In vitro micronucleus test	
c	In vivo micronucleus test	
d	Chromosomal aberration test	

14	One of the standard techniques used to investigate Cardiovascular system is	
a	Open Field Observations	
b	In Vitro Studies for Electrophysiological Effects	
c	Home cage Observations	
d	Neuromuscular measurements	
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	
16	In the cardiovascular system a core battery test is	
a	hERG study	
b	Irwin test	
c	Plethysmography	
d	Functional observational battery	
17	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	
18	A toxic substance produced by biological system is specially referred to as a	
a	Xenobiotic	
b	Toxicant	
c	Toxin	
d	Poison	
19	If you could summarize toxicokinetics to a five year old, what would you say?	
a	It is what the body does to the toxin	
b	It is what the toxin does to the body	
c	It is the way to calculate a toxin's lethal dose	
d	It is the study of non-poisonous compounds	
20	An advantage of in vitro toxicity tests is	
a	Interactions between tissues and organs can be tested	
b	Controlled testing conditions	
c	Chronic effects can be tested	
d	More reliable than in vivo tests	

Q. II	**Answer any <u>TWO</u> from the following:**	**20**
a	Write a short note on (i) Ames test and (ii) *In vivo* micronucleus assay	
b	Write a note on alternative methods to animal toxicity testing	
c	**Explain** Tier1 studies of Safety Pharmacology in details	

Q. III	Answer any <u>SEVEN</u> from the following:	35
a	Discuss the OECD principles of Good laboratory practices (GLP) in detail	
b	Give the general principles of toxicokinetic studies	
c	What do you mean by Test item? Discuss the characterization for specific test items	
d	Discuss in details the Tier 2 tests in Safety Pharmacology studies	
e	Give an account of Female Reproductive Studies (segment I and segment III)	
f	Discuss IND and give its importance	
g	Explain Teratogenicity studies	
h	Explain Eye Irritation Studies in depth	
i	Give applications and importance of Toxicokinetic Studies	

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