

AY: 2021-22

Subject: Pharmacological & Toxicological Screening Methods (PTSM)-II

Year and Sem: M. Pharm. SEM-II

Duration: 3 hrs

Total marks: 80 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	Any substance can be teratogenic if given to the right species, at the right state of development as per the	
a	Frank Starling's Law	
b	Karnofsky's Law	
c	Berger's Law	
d	Darwin's Law	
2	Reproductive toxicity studies should allow exposure of mature adults and at all stages of development from conception to	
a	Death	
b	Pregnancy	
c	Sexual maturity	
d	Lactation	
3	Manifestation of abnormal development increase in degree from the no-effect to the totally _____ level as dosage increases.	
a	Lethal	
b	Safe	
c	Benign	
d	Harmful	
4	Susceptibility to a teratogen depends on the _____ and on the interaction with the environment	
a	Fetus	
b	Genotype	
c	Phenotype	
d	Person	
5	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	

6	Preclinical Investigations according to the Regulatory courses, facilitate which of the following processes:
a	Shipment of unapproved new drugs and biologics without prior FDA approval or notification if properly labelled.
b	Gathering facts about the safe and effective use of the product in humans to support approval.
c	Compiling requirements for an Investigational New Drug Application (IND) detailed under 21 CFR 312.
d	Keeping records for inspection purpose
7	New Drug Application (NDA) contains information on:
a	Only Pharmacological findings
b	Drug substance, i.e. mechanism of action, stability, impurities, etc.
c	Only toxicological findings
d	Drug data from clinical studies.
8	Chronic Toxicity studies in animals are also called as:
a	Single dose studies
b	Lifelong studies
c	Genotoxicity studies
d	Acute toxicity studies
9	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
10	Which of the following options is NOT a type of genetic damage
a	Base substitution
b	Frame shift mutation
c	Nucleotide excision repair
d	Structural chromosome aberrations
11	From the following options select limitation of Ames test.
a	Ames test is one of the test which screens for potential chemical carcinogens.
b	Salmonella typhimurium is a bacterium and thus not a perfect model of human body.
c	Ames test serves as quick and convenient assay.
d	Ames test is based on the Principle of back mutation or reverse mutation.
12	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 of 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
13	General principles of teratology includes all of 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.	
14	During which of the following situations do we need to file for an IND application?	
a	during conduction of Non clinical studies	
b	during conducting studies when drug is within its approved indication for use.	
c	during clinical studies where the new drug is to be administered to human subjects.	
d	during chemical analysis of the new chemical entity	
15	Generally, any parent compound and its major metabolites that achieve, or are expected to achieve systemic exposure in humans should be evaluated in;	
a	Safety pharmacology studies	
b	Pharmacological studies	
c	Toxicological studies	
d	Epidemiological studies	
16	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.	
17	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.	
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	A parameter assessed by the biostatistician during validation is:	
a	Reproducibility	
b	Sensitivity	
c	Predictivity	
d	Accuracy	
20	An organism's increased ability to metabolize and distribute the drug in the body is known as:	
a	Pharmacological tolerance	
b	Dispositional tolerance	
c	Voluntary tolerance	
d	Self resistance	

Q. II	Answer any ONE of the following:	12
a	Explain the in vitro Mammalian Chromosomal Aberration test in detail	
b	Describe various alternatives to Animal Toxicity Testing.	
Q. III	Answer any ONE of the following:	48
a	Write a descriptive note on safety pharmacology	
b	Describe reproductive toxicology studies in detail with examples of male and female toxicity studies	
c	Discuss the OECD principles of Good laboratory practices (GLP) in detail.	
d	Explain teratogenicity studies (segment II) in detail	
e	Discuss the role of toxicokinetic evaluation in the drug development process	