F.Y. M. Pharma
Sem - II
23/08/2025

Duration: 3 Hours **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. **20Marks**

1 Which type of rats are preferably selected for toxicity studies?
a Nulliparous, nonpregnant female rats
b Female rats aged 8-10 weeks
c Male rats aged 8-10 weeks
d Female rats after the weaning period

2 In a multi-site study, the individual who acts on behalf of the Study Director at a participating site is known as the:
a Sponsor
b Director
c Principle Investigator
d QA head

3 What is the primary role of the Quality Assurance Unit (QAU) in a GLP-compliant test facility?
a Conducting the studies
b Reviewing final reports to confirm accuracy and completeness
c Interpreting study results
d Approving study personnel

4 The EPA's four-step risk assessment paradigm includes:
a Hazard identification, hazard characterization, exposure assessment, and risk characterization
b Chemical analysis, pathway analysis, risk management, and risk communication
c Effective dose determination, dose-response assessment, Protocol monitoring, and economic analysis
d Impurity testing, laboratory analysis, risk reduction, and public outreach

5 The duration of sub-acute toxicity studies is:
a 28 Days
b 90 Days
c Two years
d Six Months

6 Which toxicity study commonly uses buprenorphine (an anaesthetic) and meloxicam (an analgesic) for pain management in animals?
a Skin irritation test
b Eye irritation test
c Skin sensitization test
d Oral Toxicity test

7 The test substance is applied to the rabbit skin at the following sites:
a A 6 cm^2 area on the flank region
b A 6 cm^2 area on the back near the ear, secured with adhesive tape
c A 2 cm^2 area without adhesive tape
d Two separate 6 cm^2 areas on intact, unclouded skin

8 According to OECD guidelines, acute oral toxicity studies can be conducted using which of the following dosing scheme?
a 5 mg/kg, 50 mg/kg, 300 mg/kg, 2000 mg/kg in ascending doses on 3 animals
b 50mg/kg, 100mg/kg, 350mg/kg, 2000 mg/kg in ascending doses on 3 animals
c 5mg/kg, 500mg/kg, 300mg/kg, 2000 mg/kg in descending doses on 6 animals
d 10mg/kg, 100mg/kg, 300mg/kg, 2000 mg/kg in descending doses on 3 animals

9 Which of the following is an *in-vivo* Genetic Toxicology test?
a Chromosomal aberration test
b Gel Electrophoresis
c Ames Test
d Erythrocyte micronucleus test

10 In the OECD Guideline entitled "*In-Vitro* Mammalian Cell Micronucleus Test" Cytochalasin B acts as
a Cycling Dependent Kinase
b Actin Polymerisation Inhibitor
c Reverse Transcriptase
d Colony stimulating factor

11 Which of the following factors is most important in determining whether a substance will act as a teratogen?
a The species and stage of fetal development
b The colour of the substance
c The storage conditions of the drug
d The weight of the pregnant female

12 Which of the following is a limitation of the Ames test?
a It is used to screen potential chemical carcinogens
b It uses *Salmonella typhimurium*, which is not a perfect model for the human body
c It provides a quick and convenient assay.
d It is based on the principle of reverse mutation.

13 Which of the following is a standard technique used to investigate the cardiovascular system in safety pharmacology studies?
a Open Field Observations
b In Vitro Studies for Electrophysiological Effects
c Home cage Observations
d Neuromuscular measurements

14 Which one of the following is a proven human teratogen?
a Ceftriaxone
b Tetracycline
c Amphotericin B
d Tacrolimus

15 Inhibition of the hERG (human Ether-à-go-go-Related Gene) potassium current can lead to which potentially fatal tachyarrhythmia?
a Torsade de Pointes
b Angina Pectoris
c Atrial Fibrillation
d AV Node Bradycardia

16 Which of the following techniques is commonly used to assess respiratory function in safety pharmacology studies?
a Vital capacity densimeter
b Electrocardiography (ECG)
c Spirometry
d Blood pressure measurement

17 No Observed Adverse Effect Level (NOAEL) is:
a The maximum dose at which the toxicant shows no signs of toxicity
b The condition of experimental animals when no adverse effect can be observed
c A condition where adverse effects exist, but is not possible to observe
d The maximum dose of a chemical which causes death

18 Which one of the following is a Toxic kinetic parameter?
a Volume of Distribution
b Dose Response Curve
c Receptor Binding of Toxicant
d Median Lethal Dose

19 Which of the following represents application of Toxic kinetic 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

20 Which one of the following is an Alternative to In-vivo Animal Toxicity Studies?
a ADR Database
b Chronopharmacology studies
c *In vitro* stem cell-based assays
d Knockout transgenic murine models

Q.II Answer any TWO of the following: **20 Marks**
a Discuss acute and chronic Oral toxicity test in details.
b Define teratogen with example. Explain teratogenic studies (Segment II) in details.
c Discuss in detail the Core Battery Tests (Tier 1) in Safety Pharmacology Studies.

Q.III Answer any SEVEN of the following: **35 Marks**
a Explain OECD regulatory guidelines for conducting acute dermal toxicity studies.
b Give a detailed account on: Role of study director and Quality assurance programme in Good Laboratory Practices.
c Outline the study design, methodology, and assessment criteria for acute inhalation toxicity studies.
d Define toxicology. Give in details of its types.
e Write a short note on the Ames test and its significance in mutagenicity testing.
f Explain in details female reproductive (Segment III) studies.
g Explain HERG assay. Explain Tier 2- renal studies.
h Explain in details the evaluation and importance of toxic kinetic studies.
i Explain cell culture techniques as an alternative to animal experiments.
