Your Roll No.....

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M.Sc TOXICOLOGY SEMESTER III EXAMINATION, MAY 2023

Paper:Pre-clinical Toxicology for Drug Development

Paper Code: MTX-DCE – 302

Time: 1.5 hours **Maximum marks: 37**

Question 1. Choose the best response for the following multiple choice questions [7 marks]

a) In Segment II Female Reproductive Studies, dams must be examined for all EXCEPT:
   i. Effect on body weight
   ii. Skeletal abnormalities
   iii. signs of intoxication
   iv. ovaries and uterine contents

b) In Segment III Female Reproductive Studies, F2 generation must be monitored till:
   i. Weaning ii. Pairing iii. Parturition iv. Lactation

c) In dermal photo-toxicity studies, light exposure should be
   i. Visible light at 10 lux
   ii. UV at 10 J/cm²
   iii. IR at 10 J/cm²
   iv. Visible light at 10 J/cm²

d) For injectable test substances, the injection sites should be evaluated:
   i. Gross examination
   ii. Microscopic examination
   iii. Reversibility
   iv. a & b
   v) a, b & c

e) In slit-lamp examination, changes in the following structures are detected EXCEPT:
   i. Conjunctiva ii. Cornea iii. Iris iv. Aqueous humour

f) During inhalation experiments, test substance of particle size of the following size must be used:
   i. 2.5 micron ii. 4 micron iii. 10 micron iv. 25 micron

g) *In vitro* cytogenetic assay should be performed in:
   i. CHO cells ii. Human lymphocytes iii. Either i or ii iv. Both i and ii

Question 2. Answer ANY THREE of the following questions: [5x3=15 marks]

a) Describe the steps involved in estimations of Maximum Recommended Safe Starting Dose in humans.
b) What is MABEL? How is it different from MRSD calculation? Describe the background that forced the scientific community to propose this method.
c) Write a note on 'Male fertility study'.
d) When are carcinogenicity studies required to be conducted? Outline the protocol of a carcinogenicity study.
e) Describe Dose ranging studies as prescribed in New Drugs & Clinical Trial Rules 2019 of India.

Question 3. Answer ANY THREE of the following questions: [5x3=15 marks]

A) Discuss the basis of selection of animal models for toxicity studies.
B) Evaluate rat as an animal model for toxicity studies.
C) Create a check-list for clinical signs to be noted during routine examination of animals included in clinical studies.
D) Describe the *in vitro* toxicity studies conducted to eliminate toxic molecules in early drug discovery stage.
E) Enumerate the toxicity data required for the conduct of Phase I clinical trial.