

BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI
(END SEMESTER EXAMINATION)

CLASS: M.PHARM/PRE-PHD
BRANCH: PHARMACY

SEMESTER : II/NA
SESSION : SP/18

SUBJECT: MPH2033 PHARMACOLOGICAL & TOXICOLOGICAL SCREENING METHODS II
TIME: 3 HOURS

FULL MARKS: 60

INSTRUCTIONS:

1. The question paper contains 7 questions each of 12 marks and total 84 marks.
 2. Candidates may attempt any 5 questions maximum of 60 marks.
 3. The missing data, if any, may be assumed suitably.
 4. Before attempting the question paper, be sure that you have got the correct question paper.
 5. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.
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- Q.1(a) What is the importance of dose response relationship in toxicokinetics. Explain biotransformation in the light of toxicokinetics [6]
- Q.1(b) Enumerate with suitable examples the factors influencing toxicity. [6]
- Q.2(a) Classify different types of toxicity studies? Describe in detail about single dose and repeated dose toxicity studies with proper examples? [5]
- Q.2(b) Classify the types of Local toxicity studies? Summarize the test guidelines for acute systemic testing & short term repeated dose toxicity testing? Outline the carcinogenicity studies for any chemicals as per OECD guidelines? [7]
- Q.3(a) Analyse the conditions of Proto-oncogenes & Tumor suppressors in mutated cells? Identify the Pathways affected by carcinogenic mutations? Illustrate the mitogenic signals & involvement of cyclins in *in vivo* cancer studies? [6]
- Q.3(b) Define Reproductive toxicology including Endocrine Disruption? Identify some usual suspects for reproductive toxicity? Describe few of them with a key focus to consequences with DES-daughter? [6]
- Q.4(a) Summarize the risk category of drugs during pregnancy (A to X)? Identify the mechanisms of teratogenicity? List some proven human teratogens. Illustrate the Teratogenicity Test under the guidelines of FDA? [6]
- Q.4(b) Define Mutation? What are the major causes of Mutation? List some products with possible mutagens? Analyse the sentence "Bacteria can prevent cancer"& Illustrate with pictogram of Ames Test? [6]
- Q.5(a) Elaborate on the *in vitro* & *in vivo* Mammalian cell micronucleus tests with detailed procedure & principles involved? [6]
- Q.5(b) Outline the grading of (i) ocular lesion (ii) skin reactions according to OECD guidelines [6]
- Q.6(a) Summarize the initial considerations and principles of the *in vivo* acute eye irritation studies as per OECD. [6]
- Q.6(b) Design the testing and evaluation strategy for dermal irritation and represent it schematically. [6]
- Q.7(a) Define safety pharmacology and discuss the criteria in selection and design of safety pharmacology studies. What is it's importance. [6]
- Q.7(b) What does the safety pharmacology core test and follow up tests include? Schematically represent the safety pharmacology study approaches for a new chemical entity. [6]

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