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MPHARM (SEM II) THEORY EXAMINATION 2023-24 TOXICOLOGICAL SCREENING METHODS

TIME: 3 HRS M.MARKS: 75

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1.	Attempt all questions in brief. $10 \times 2 = 20$
a.	Explain sub acute toxicity study
b.	Define IND
c.	Mention the importance of safety pharmacology.
d.	Define Ames test
e.	What are the applications of toxicokinetic studies
f.	What are roles and responsibilities of EPA?
g.	Explain acute toxicity study
h.	Why do we conduct male reproductive toxicity studies?
i.	What are the various steps in drug development?
į.	What do you mean by HERG assay?

SECTION B

2.	Attempt any <i>two</i> parts of the following: $2 \times 10 = 3$	20
a.	Write species used, list of observations and report content of the following test as per OECI	2
	guidelines: i) Acute eye irritation ii) Dermal irritation	
b.	Mention the significance of IND in industrial perspective and enlist various studies needed fo	r
	IND submission	
c.	Discuss the oral toxicity studies as per OECD guidelines	

SECTION C

3.	Attempt any <i>five</i> parts of the following: $7 \times 5 = 35$				
a.	Narrate the various features of good laboratory practice (GLP)				
b.	Discuss in details the various alternatives to animal experimentation				
c.	Explain the various steps of In vivo carcinogenicity studies				
d.	Give in detail about genotoxicity and explain chromosomal aberration studies				
e.	What are the evaluation parameters in preclinical studies. Suggest the importance and applications of toxicokinetic studies				
f.	Explain test procedure and clinical observations of prenatal developmental toxicity				
	study				
g.	Enlist CVS assessment as per safety pharmacological studies and explain any one in detail.				