Roll No:

MPHARM

(SEM II) THEORY EXAMINATION 2021-22 TOXICOLOGICAL SCREENING METHODS

Time: 3 Hours

Total Marks: 75

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

SECTION A

1.	Attempt all questions in brief.10 x 2 = 20)
a.	Define and classify toxicology.	
b.	What are the principles of Good Laboratory Practice?	
c.	Describe principle of acute inhalation toxicity studies.	
d.	Justify the use of topical anesthetics and systemic analgesic in acute eye irritation studies.	
e.	Compare micronucleus and chromosomal aberration test.	
f.	What do you understand by RICC and RPD cytotoxicity assessments?	
g.	Enumerate importance of INDA.	
h.	Demonstrate objectives of safety pharmacology studies.	1
i.	Compare half life of linear and nonlinear kinetics.	
j.	Enlist various alternative methods in toxicity testing.	

SECTION B

2. Attempt any *two* parts of the following:

	a.	Summarize tier-1 and tier-2 safety pharmacology studies.
	b.	Discuss the principle, procedure and observations of reproductive and developmental toxicity studies according to OECD guidelines.
	c.	Explain the OECD guidelines for carcinogenicity studies.

SECTION C

3. Attempt any *five* parts of the following:

a. Illustrate various studies of ICH Guidelines.
b. Explain guinea pig maximization test procedure for skin sensitization test.
c. Describe procedure and observations of acute oral toxicity – fixed dose procedure.
d. Summarize test procedure and observations in *in-vitro* micronucleus test.
e. Explain Ames test according to OECD guidelines.
f. Illustrate INDA review process.
g. Discuss toxicokinetic studies in preclinical stage.

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 $7 \ge 5 = 35$

 $2 \times 10 = 20$