Total No. of printed pages = 2 MPL 202 T 23/08/22 Roll No. of candidate BINACHOWDHURY CENTRAL LIBRA KGIMT & SIPS) perk Hatty wapara, 2022 M.Pharm. 2nd Semester End-Term Examination PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - II Time - Three hours Full Marks - 75 The figures in the margin indicate full marks for the questions. Group A $(5 \times 2 = 10)$ Attempt the following: 1. (a) Descriptive Toxicology (b) ICH Schedule Y (e) IND (d) HERG Assay (e) Group B $(9 \times 5 = 45)$ Answer any nine of the following: 2. Briefly explain the salient points of OECD guidelines. (a) Write about teratogenecity studies. (b) Write about OECD principles of GLP.

Write a note on chromosomal aberrations studies.

What are the different types of Toxicology studies?

What are the objectives and importance of safety Pharmacology studies?

Turn over

Write a note AMES test.

(c)

(d)

(e)

(f)

(g)

- (h) Write a note on EPA regulatory guidelines for conducting toxicity studies.
- (i) Discuss the importance of saturation kinetics in toxicokinetic studies.
- (j) Write a note on in vivo carcinogenicity studies.
- (k) Write a brief note on acute oral toxicity studies as per OECD guidelines.

Group C

3. Answer any two questions

 $(2 \times 10 = 20)$

- (a) Explain in details about male reproductive toxicity studies.
- (b) Describe in detail about dermal toxicity studies as per OECD guidelines.
- (c) List out and discuss the studies needed for IND submission.

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