

FACULTY OF PHARMACY**M. Pharmacy (Pharmacology) II – Semester (PCI) (Suppl.) Examination,****January 2020****Subject: Pharmacological & Toxicological Screening Methods – II****Time: 3 Hrs****Max.Marks: 75****Note: Answer any five questions. All questions carry equal marks.**

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| 1 | Discuss the ICH guidelines for toxicity studies in detail. | 15 |
| 2 | a) Write abt varis studies required for IND submission. | 7 |
| | b) Write the role and responsibilities of | |
| | i) Sponsorer | 4 |
| | ii) Investigator in clinical research | 4 |
| 3 | Write a note on: | |
| | a) Teratogenecity studies | 8 |
| | b) In vivo carcinogenicity studies. | 7 |
| 4 | a) Describe the spermatogenesis | 7 |
| | b) Explain the possible toxicity effects on reproductive endocrinology. | 8 |
| 5 | a) Explain the principles of GLP (Good Laboratory Practice) as per OECD guidelines for toxicity studies. | 15 |
| 6 | Write a note on: | |
| | a) Chromosomal aberration test | 7 |
| | b) In vivo micronucleus test | 8 |
| 7 | a) Explain principles of toxicokinetics. | 8 |
| | b) Write a note on dermal toxicity testing. | 7 |
| 8 | a) Explain the varis factors influencing the toxicity evaluation studies with animal models. | 8 |
| | b) Write abt acute, sub -acute and chronic toxicity studies as per OECD guidelines. | 7 |
