

FACULTY OF PHARMACY

**M. Pharmacy (Pharmacology) II-Semester (PCI) (Suppl.) Examination,
February 2019**

Subject: Pharmacological and Toxicological Screening Methods - II

Time: 3 Hrs

Max. Marks: 75

Note: Answer any five questions. All questions carry equal marks.

1. Explain the regulatory requirements of ICH for the new drug safety assessment. 15
2. Explain the OECD guidelines for the conduct of acute, sub-acute and chronic toxicity studies. 15
3. Write short notes on:
 - a) Genotoxicity studies 8
 - b) Carcinogenicity studies 7
4. Define IND. Elucidate the importance and industry perspectives of IND enabling studies. 15
5. Define safety pharmacology. Describe in detail the Tier1 and Tier2 safety pharmacology studies. 15
6. What is Toxicokinetics? Discuss its importance and applications in preclinical toxicity testing of drugs. 15
7. Discuss the study design and importance of reproductive toxicity testing. 15
8. Describe how skin sensitization studies are conducted. 15
