

Total No. of Questions : 4]

SEAT No. :

P3995

[Total No. of Pages : 1

[5246]-223

M. Pharmacy (Semester - I & II)

SAFETY PHARMACOLOGY

(2013 Pattern) (Credit System)

Time : 3 Hours]

[Max. Marks : 50

Instructions to the candidates:

- 1) *Question number one is compulsory.*
- 2) *Figures to the right indicate full marks.*
- 3) *Draw well labeled diagrams whenever necessary.*

Q1) Discuss the importance and principles of safety pharmacology. **[10]**

Q2) Solve the following (Any 3) **[15]**

- a) Explain OECD guidelines for acute oral toxicity.
- b) Explain Risk-benefit assessment in clinical trials.
- c) Write in detail about data collection during pharmacovigilance.
- d) Write in detail about guinea pig sensitization assays for testing dermatological products.

Q3) Write short notes (Any 3) **[15]**

- a) Product safety update reports
- b) Regulatory requirements for safety pharmacology
- c) Analysis of safety Pharmacological data
- d) Post-marketing surveillance

Q4) Discuss in detail Ames test for mutagenicity. **[10]**

OR

Explain in detail the various applications of in vitro techniques in drug safety assessment.

