

QP Code: 103332

Reg No:

**First Year M.Pharm Degree Examinations (Supplementary)- November 2012
(Pharmacy Practice)**

Paper III -Clinical Toxicology and Pharmacokinetics

Time: 3 hrs

Maximum Marks: 100

- *Answer all questions*
- *Draw diagrams wherever necessary*

Essays:

(2x20 =40)

1. Explain various phases of clinical research and describe the role of clinical trials in new drug development.
2. Explain the composition of institutional review board with roles and responsibility of its members in conduct of the protocol reviews.

Short Essays:

(6x10=60)

3. Describe the content of investigator's brochure and mention its importance in clinical trial.
4. Explain the role of sponsors in clinical trial as per ICH GCP guidelines.
5. Describe the non-renal routes of drug elimination from the body
6. Explain dosage adjustment in renal failure and pediatric patients
7. Explain the management of paracetamol and organophosphorus poisoning
8. Describe the significance of descriptive statistics and mention the formula to calculate mean, standard deviation, standard error mean and % coefficient of variation.
