

Roll No

PY - 805 (B)**B.Pharmacy VIII Semester**

Examination, June 2015

Clinical Research**Elective - II****Time : Three Hours****Maximum Marks : 70**

Note : i) Solve any five questions out of the following.
ii) All questions carry equal marks.

1. Define clinical pharmacy and clinical research.
Describe the activities of clinical pharmacist in hospital.
4, 10
2. a) Explain the role of laboratory tests for hormones in
evaluation of disease states. 7
b) Describe clinical pharmacokinetic models. 7
3. Write in brief about following terminologies / abbreviation
used in clinical pharmacy. 2×7
 - i) IRB
 - ii) CRF
 - iii) Bias
 - iv) Cohort

- v) Orphan drugs
- vi) Randomization
- vii) Serious adverse drug reaction

4. Enlist the principles of ICH-GCP guideline and give a detailed
account of schedule Y. 4, 10
5. Elaborate on various phases of clinical trials. 14
6. Give different designs of clinical trials and discuss randomized
controlled clinical trial. 7, 7
7. Write short notes on any four of the following: 3.5×4
 - a) Contract Research Organizations in India
 - b) Therapeutic drug monitoring
 - c) Patient case history format
 - d) Documentation of adverse drug reaction
 - e) Drug information resources.
