Roll No. | | | | | | | | | | | | | Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy (Pharmacology) (2017 Batch) (Sem.–2)

# CLINICAL RESEARCH & PHARMACOVIGILANCE

Subject Code : MPL-204T

M.Code : 74946

Time : 3 Hrs. Max. Marks: 75

**INSTRUCTIONS TO CANDIDATES :**

1. **Attempt any FIVE questions out of SIX questions.**
2. **Each question carries FIFTEEN marks.**

1. Write an extensive note on adverse drug reactions with suitable examples and/or flow charts. 15

2. a. Discuss history, scope and significance of pharmacovigilance. 7

   b. Elaborate on roles and responsibilities of contract research organization. 8

3. a. Write a note on ICH-GCP guidelines for clinical trials. 9

   b. Discuss the concept of informed consent in clinical trial with suitable examples. 6

4. Give a detailed account on various components of clinical trials. 15

5. Write short notes on the following :

   a. Pharmacoepidemiology 5

   b. Phase 0 clinical trial 5

   c. Schedule Y 5

6. Discuss the following with suitable examples :

   a. Case report forms 5

   b. Clinical trial monitoring 6

   c. Sterile and aseptic area layout 4

**NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.**