Roll No. | | | | | | | | | | | | |

Total No. of Pages : 01

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M.Pharmacy (Pharmacology) (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. a) Outline the requirements for a sterile product manufacturing plant. Indicate various areas with the help of an illustration. (7.5)

   b) Describe the constitution of IRB. Mention the functions of IRB. (7.5)

2. a) Write a note on cross sectional observation studies. (7.5)

   b) Comment on the responsibilities of study coordinator of a clinical trial. (7.5)

3. a) What is an investigator brochure? Outline the contents of this brochure and mention the purpose of each entry in the form. (7.5)

   b) What is ADR? Give five examples of ADRs. How are ADRs detected and reported? Outline the format used for this purpose. (7.5)

4. Outline the importance of safety monitoring in clinical trials. Give a detailed account of safety monitoring in clinical trials. (15)

5. Give a detailed account of passive and active surveillance in pharmacovigilance. Outline the steps involved in each. (15)

6. Write notes on (**any three**) : (5 × 3 = 15)

   a) Pharmacoeconomics

   b) Responsibilities of a CRO

   c) Pharmacovigilance in hospitals

   d) International classification of diseases

**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.**