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

Total No. of Pages : 1

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

# CLINICAL RESEARCH & PHARMACOVIGILANCE

Subject Code : MPL-204T

Paper ID : [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.**

Q1. Briefly describe the ICH-GCP guidelines for good clinical practices.

Q2. Write short notes on following :

a) Comparison of advantages and disadvantages of RCT and Non RCT.

b) Role and responsibilities of clinical trial investigator.

Q3. Define and classify adverse drug reactions. Describe the methods for detecting and reporting ADRs.

Q4. Describe the legal and regulatory requirements for establishing Pharmacovigilance centre in hospitals. Briefly elaborate the WHO international drug monitoring program.

Q5. Briefly describe the following :

a) Methods of pharmacoeconomic analysis.

b) Applications of Pharmacoeconomics.

Q6. Describe the methods and guidelines for ADR reporting and monitoring.