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

Total No. of Questions : 06

M.Pharmacy (Regulatory Affairs) (Sem.-1)

GOOD REGULATORY PRACTICES

Subject Code : MRA 101T

M.Code : 79180

Date of Examination : 21-01-23

Time : 3 Hrs. **Max. Marks : 75**

INSTRUCTIONS TO CANDIDATES :

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

1. a) Write a note on EC principles of GMP.

   b) Write a note on US cGMP guidelines.

2. a) Give principles and requirements of GALP.

   b) Explain software evaluation checklist in detail.

3. Discuss the USFDA GLP regulations.

4. What do you understand by GDP? Give principle and discuss the legal GDP requirements in detail.

5. a) Comment on concept of quality. Explain total quality management in quality management system.

   b) Describe out of specifications concept of quality management system.

6. a) Give in detail ICH guidelines with respect to quality safety and efficacy of drug substances and products.

   b) Give types of validation with special emphasis on cleaning validation.

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