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

Total No. of Questions : 06

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

DOCUMENTATION & REGULATORY WRITING

Subject Code : MRA 102T

M.Code : 79181

Date of Examination : 23-01-23

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. Discuss in detail about Product Development Report (PDR)
2. Discuss the compilation and review of dossier in detail.
3. Discuss in detail about Print pack specifications.
4. Discuss about overview and various modules of CTD.
5. Discuss GMP compliance audit in detail.
6. Discuss in detail about FDA inspection and enforcement.

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.