**QP CODE: 112333** **Reg. No:……**

## First Semester M. Pharm Degree Regular Examinations June 2024

## M. Pharm Pharmaceutical Regulatory Affairs

### PAPER - II – Documentation and Regulatory Writing (MRA 102T)

# (2019 Scheme)

**Time: 3 Hours** **Total Marks: 75**

- ***Answer all questions to the point neatly and legibly • Do not leave any blank pages between answers • Indicate the question number correctly for the answer in the margin space***
- ***Answer all parts of a single question together • Leave sufficient space between answers***
- ***Draw table/diagrams/flow charts wherever necessary***

**Essays** **(3x10=30)**

1. Write in detail about Product Development Plan and Product Development Report
2. Describe in detail about modules of CTD
3. Explain in detail about Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions

**Short Notes** **(9x5=45)**

4. Product Life Cycle Management
5. Annual Report
6. Corrective and Preventive Action (CAPA)
7. Explain in detail about Global Harmonization Task Force (GHTF) study Groups
8. Types of Audits
9. SUGAM System of CDSCO
10. Non eCTD electronic submissions (NeeS)
11. Site Master File
12. Explain in detail about Asian CTD

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