

QP CODE: 211333

Reg. No:.....

**Second Semester M. Pharm Degree Regular/Supplementary Examinations
November 2025**

M.Pharm (Regulatory Affairs)

**Paper - I – Regulatory Aspects of Drugs & Cosmetics (MRA 201T)
(Common for 2019 and 2024 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 the regulatory requirements for registration of drugs and post approval requirements in WHO through prequalification programs
2. Discuss the organization, pharmaceutical laws, and regulations of Pharmaceutical and Medical Devices Agency (PMDA)
3. Explain in detail about the federal register and code of Federal Regulations (CFR)

Short Notes

(9x5=45)

4. Drug Master File (DMF) in US
5. Compliance of European Pharmacopoeia
6. Regulatory pre-requisites related to marketing authorization requirements for drugs in UAE
7. Procedure of certificate of pharmaceutical product in South Africa
8. Post Approval requirements in Singapore
9. Certification of Pharmaceutical Product
10. Legislations for distribution and sale of cosmetics in Australia
11. Regulatory Committee in APEC and PANDRH
12. ASEAN Common Technical Document (ACTD)
