

QP CODE: 212333

Reg. No:.....

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

**M.Pharm (Regulatory Affairs)
Paper - II – Regulatory Aspects of Herbal and Biologicals (MRA 202T)
(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. Describe the data requirements for pre-clinical studies including pharmacodynamics and toxicological studies
2. Explain the regulatory requirements and post approval requirements for biologics in Europe
3. Differentiate between generic drug and biosimilars. Give an account of regulatory aspects of development and approval process of biologics and biosimilars as per US

Short Notes

(9x5=45)

4. Post market data for similar biologics
5. International Haemovigilance Network
6. Indian regulatory guidelines for herbal medicine
7. Pharmacovigilance role in biosimilars
8. Vaccine marketing authorization requirements as per EMA in EU
9. Safety study of herbal products
10. Regulatory requirements for blood components in India
11. Safety and advertising requirements for biologics in EU
12. Directive 2004/24/EC of the Europe Union
