QP CODE: 212333 **Reg. No:……**

Second Semester M. Pharm Degree Regular Examinations November 2024

M.Pharm (Regulatory Affairs)

Paper - II – Regulatory Aspects of Herbal and Biologicals (MRA 202T)

(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. Explain 510(k) requirements for biologicals/biosimilars by US FDA
2. Describe the data requirements for clinical trial application in Europe
3. Elaborate on US FDA requirements for vaccine product safety and potency testing

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

4. Indian regulatory guidelines for herbal product quality
5. Plasma Master File
6. Role of international society for blood transfusion
7. TSE/BSE evaluation in EU
8. Differentiate between generic drugs and biosimilars
9. Marketing authorisation of blood and blood products in India.
10. Role of Office of Alternative Medicine (OAM) in US
11. General information on vaccine regulatory submission in India
12. Regulatory approval of biologics in EU.

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