QP CODE: 211333 **Reg. No:……**

Second Semester M. Pharm Degree Regular Examinations November 2024

M.Pharm (Regulatory Affairs)

Paper - I – Regulatory Aspects of Drugs & Cosmetics (MRA 201T)

(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. Differentiate between mutual recognition procedure and national procedure in EU. Add a note on compliance of European Pharmacopeia

2. Discuss the regulatory considerations for manufacture, packaging and labelling of pharmaceuticals in USA

3. Explain the drug regulatory approval process in Japan

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

4. Regulatory requirements for import and manufacture of cosmetics in Canada

5. Certificate of pharmaceutical product (COPP) for Kenya and Botswana

6. Guidelines for distribution and sale of cosmetics in GCC

7. Eudralex directives for human medicines

8. Post marketing surveillance in Japan

9. Marketing authorization procedure in Kazakhstan

10. Orange Book and Purple Book in US

11. Regulatory prerequisites related to marketing authorization requirements related to drugs in Commonwealth Independent States (CIS).

12. Explain Active Substance Master File (ASMF)

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