QP CODE: 114333 **Reg. No:……**

First Semester M.Pharm Degree Supplementary Examinations August 2024

M. Pharm Pharmaceutical Regulatory Affairs

Paper - IV – Drug Regulations and Intellectual Property Rights (MRA 104T)

(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. Describe the regulatory requirements and approval procedures for Food and Nutraceuticals in India.
2. Explain in detail about Indian Pharmacopoeial standards and BIS standards.
3. Explain the organization, responsibilities and registration procedure for drugs under CDCSO.

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

4. Enlist the guidelines for approval of medical devices in India.
5. DPCO.
6. State licensing authority of CDSCO.
7. List out the categories of research on stem cell as per ICMR Guidelines.
8. Describe in short about CPCSEA Guidelines.
9. List out the regulatory requirements for carrying out BA/BE studies in India.
10. Define stability studies and explain the stability requirements as per WHO.
11. Enlist the permitable and objectionable advertisements as per Drugs and Magic Remedy Act.
12. Differentiate between IPR and Regulatory affairs.

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