**QP CODE: 114333** **Reg. No:……**

# First Semester M.Pharm Degree Regular/Supplementary Examinations April 2025

## M. Pharm Pharmaceutical Regulatory Affairs

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

## (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 in detail about regulatory requirements for conducting bioequivalence studies in India
2. Describe in detail regulatory requirements and approval procedure for biologicals in India
3. Explain the regulatory requirements for import of drugs and cosmetics as per D & C Act 1940 and Rules 1945.

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

4. Write a brief procedure for obtaining patent in India
5. Discuss in brief about Bureau of Indian Standard
6. Write the functions of National Pharmaceutical Pricing Authority
7. Explain CPCSEA guidelines for conducting experiments in animals
8. Write the function and role of Drug Testing Advisory Board and Drugs Consultative Committee
9. Differentiate between Intellectual Property Rights and Regulatory Affairs
10. Indian Pharmacopoeia and its standards.
11. WHO stability requirements of Pharmaceuticals
12. Explain organization and Responsibilities of State Licensing Authority

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