

QP CODE: 114333

Reg. No:.....

First Semester M.Pharm Degree Regular Examinations June 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. Write in detail about Narcotics Drugs and Psychotropic Substances Act.
2. Describe in detail regulatory requirements and approval procedure for Drugs in India.
3. Explain in detail about ICMR DBT guidelines for Stem Cell Research.

Short Notes

(9x5=45)

4. Indian Patent Scenario.
5. Discuss in brief about Copyrights and Industrial Designs.
6. BCS Classification of Drugs.
7. Explain regulatory requirements of Bioequivalence studies.
8. BIS Standards.
9. Explain organization and Responsibilities of CDSCO.
10. Prevention of Cruelty to Animals Act.
11. ICH stability requirements of Pharmaceuticals.
12. Ethical Guidelines for human participants.
