

[Time: 3 Hours]

[Max. Marks: 75]

Drug Regulations and Intellectual Property Rights**Q.P. CODE: 5111**

Your answers should be specific to the questions asked.

Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any Three)**3 X 10 = 30 Marks**

1. Explain the procedure for patenting an invention.
2. Elaborate the consequences of GATT.
3. Describe the types of trademarks.
4. Explain the role of TGA and ANVISA in controlling drug regulations.

SHORT ESSAY (Answer any Nine)**9 X 5 = 45 Marks**

5. Explain the benefits of patent system.
6. Explain different types of inventions for which patents can be secured.
7. Explain the features of the TRIPS agreement.
8. What are the functions of WIPO?
9. Describe the types of intellectual property rights.
10. Explain the importance of copyright.
11. Describe objectives, responsibilities, scope, and functions of USFDA.
12. Explain the role of MCC.
13. Describe the regulatory requirements for contract research organization.
14. Explain the regulations for biosimilars.

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