

[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. List the parts of a patent specification and briefly explain the importance of each part.
2. Discuss in detail the GATT agreements in pharmaceutical industry.
3. Explain in detail USFDA Guidelines for the GMP Conditions.
4. Define Trademark. Examine the significance of non-conventional marks as trademarks. What are the absolute and relative grounds on which registration can be refused? Explain.

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

5. What is the test for ascertaining infringement by equivalence?
6. Are gene sequences patentable in India? Explain with examples.
7. How are the TRIPS agreement affect the Marketing of Imported medicines?
8. Write a note on assignment of trade mark.
9. Explain the regulatory requirements for contract research
10. What are the Regulatory guidelines for TGA?
11. Explain in detail ISO9000.
12. Write note on rectification of register under the Trademarks Act.
13. Write the regulations for bio similar products.
14. Explain the guidelines for laboratory note book.
