



[Time: 3 Hours]

[Max. Marks: 75]

Quality Control and Quality Assurance -II

Q.P. CODE: 5151

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. Discuss in detail about the concept and evolution of quality control and quality assurance.
2. Write a note on USFDA guidelines for drug industry location, design, construction and plant layout.
3. Explain briefly about the three tier documentation, policy procedures and work instruction in pharmaceutical industry.
4. Describe the measurements of patent rights and patent enforcement according to patent regime and IPR.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

5. Explain the quality control tests for ophthalmic products.
6. Discuss about the processing of intermediates and bulk products.
7. Write about the sanitation of manufacturing premises.
8. Write the procedure involved in the control on animal house.
9. Explain the report preparation and documentation for non clinical laboratory study.
10. Write in detail about the quality control test for Containers.
11. Explain in brief quality audit plan in Pharmaceutical Industry.
12. Write a note on aseptic process control.
13. Write the procedure involved in the preparation of master formula record.
14. Discuss in brief process deviation and expiry date calculation.

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