



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. Explain in detail Good Laboratory Practices.
2. Describe the c-GMP guidelines according to schedule M with respect to organization personnel responsibilities training and hygiene.
3. Explain the quality control tests for parenteral products.
4. Elaborate on NABL certification and accreditation procedure.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

5. Write in brief patent regime and IPR.
6. Explain the brief maintenance of sterile areas in drug industry.
7. Write the quality control test for suppositories.
8. Write a note on batch formula record.
9. How to write a SOP?
10. Write a brief note on release of finished products.
11. Explain the quality control test for containers in Pharmaceutical Industry.
12. Write about Quality Assurance unit.
13. Explain the sanitation procedures in drug industry.
14. Explain CPCSEA guidelines in general.

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