

Time: Three Hours

Max. Marks: 75 Marks

Quality Control and Quality Assurance

Q.P. CODE: 5103

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 the cGMP guidelines as per schedule M, of the Drugs and Cosmetics Act.
2. Explain functions of quality control and quality assurance, in a pharmaceutical manufacturing setup.
3. Enlist quality control tests for Hard Gelatin Capsules. Explain any four.
4. What is Master batch record? Explain its contents and its regulatory significance.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

5. List the contents of the protocol intended for a non clinical study?
6. How will you ensure change control in pharmaceutical production?
7. Explain the principles of Good Warehousing Practice.
8. With a diagram explain the layout of tablet manufacturing unit.
9. What are purchase specifications? How it is related to maintenance of stores?
10. Describe quality control tests for suppositories, as mandated by IP.
11. Summarize contents of Common Technical documentation?
12. Describe checklist of quality audit report.
13. How will you handle materials recovered from the market after a product recall?
14. List the elements of IPR applicable to pharmaceuticals.

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