

[Time: 3 Hours]**[Max. Marks: 75]****Quality Management System****Q.P. CODE: 5102**

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 the significance of mission and vision statements in an industry.
2. Explain the concept of pharmaceutical quality management as per ICH Q10.
3. Explain the management of risk as per ICH Q9 guidelines.
4. With the help of a flow chart, explain the benchmarking of a quality process.

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

5. Write a note on cost optimizing strategies.
6. Explain the features of NABL accreditation.
7. Explain the scope of ISO 9001:2015
8. What is annual product reviews. Why is it compiled?
9. Explain returns and recalls.
10. What are OOS and OOT? Explain.
11. What are control charts? Give their applications.
12. Explain how SPC helps in measuring quality.
13. Explain the stability testing condition for a new drug as per ICH guidelines.
14. Explain briefly the role of HACCP in risk management.

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