

[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. What is cost of quality? Explain the various models of cost of quality.
2. Explain the principles of six sigma.
3. What is HACCP? How does it help in drug manufacturing?
4. With the help of a flow chart explain the quality process bench marking?

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

5. What is competitive analysis? Explain.
6. Write a note on OSHAS guidelines.
7. Explain the process of NABL accreditation of a chemical testing lab.
8. What is OOS? How a OOS in quality control is handled as per USFDA guidelines?
9. What is self inspection? What is its importance in quality assurance and how self inspection is executed?
10. What are market complains? How are they evaluated?
11. What is stress testing? Why and how is it done?
12. How risk ranking is done? Explain in brief.
13. Enlist and explain attribute control charts.
14. List the indices used for process capability.

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