

[Time: 3 Hours]

[Max. Marks: 75]

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. Write a note on CPCSEA guidelines.
2. Discuss in detail cGMP guidelines according to CDER USFDA.
3. List out the Quality control tests for parenterals according to Indian pharmacopoeia. Explain sterility testing methods.
4. Write a note on Electronic Common Technical Documentation (eCTD).

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

5. What are the objectives of GMP?
6. Distinguish between Quality control and quality assurance department.
7. Write a note on Good Warehousing Practice.
8. Explain the quality control test for Ophthalmic products.
9. Discuss the significance of In process quality control Tests.
10. Explain the procedure to maintain, retention and retrieval of Master Formula Record.
11. Distinguish between contamination, cross contamination and Mix ups.
12. How expiry date calculation is done as per ICH guidelines?
13. Discuss reprocessing and recovery procedures in formulation of dosage forms.
14. Write a note on concepts of trade marks.

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