

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. Explain the contents of a Batch Manufacturing Record? How is it developed?
2. How are ICH guidelines organized by scope? List the Q series guidelines of ICH?
3. Enlist quality control tests for parenterals. Explain any three.
4. Compare and control the roles and responsibilities of QA & QC departments.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

5. List the responsibilities of QAU in a GLP study?
6. Explain the concept of FIFO, and its significance.
7. Explain the protocol for conduct of non-clinical testing.
8. Discuss about drug industry location, design and construction.
9. Explain the QC tests prescribed for ophthalmic products?
10. Describe quality audit plan and reporting.
11. Explain in detail about aseptic process control.
12. Explain the CTD Triangle and its modules.
13. Explain IPQC, tests mandated for tablet production.
14. Describe personal training as per WHO.

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