



[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. Define Quality control and Quality Assurance? Explain the functions of Quality Control Quality Assurance department.
2. Discuss in detail cGMP guidelines according to WHO.
3. List out the Quality control tests for Tablets according to Indian pharmacopoeia. Explain any three.
4. Discuss the principles of maintenance, retention and retrieval of Standard operating procedures.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

5. Write a note on objectives of ICH Guidelines.
6. Write in detail contents of protocol for conduct of non clinical testing.
7. Discuss in detail location, design and plant lay out for Tablet dosage form manufacturing unit.
8. Explain the procedure for sampling of Raw materials and finished products.
9. List out and explain Quality control tests for suppositories.
10. What are the different GMP concepts of regulated and non regulated markets?
11. Discuss the procedure for Sanitation of manufacturing premises.
12. Write a note on handling and documentation of process Change controls.
13. Write a note handling of waste and scrap disposal in quality control laboratory.
14. Write a note on concepts of copyright and patent act.

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