

Time: Three Hours

Max. Marks: 100 Marks

Quality Assurance
(Revised Scheme 4)
Q.P. CODE: 9361

Your answers should be specific to the questions asked.
Draw neat, labeled diagrams wherever necessary. Answer any ten questions.

LONG ESSAY (Answer any TEN)

10 X 10 = 100 Marks

1. Discuss the concept of TQM. Add a note on ICH-E6 guidelines.
2. Discuss the concept of QSEM series of ICH guidelines.
3. Discuss the responsibilities, training requirements for personnel working in sterile manufacturing area.
4. Discuss cGMP guidelines for construction, maintenance and sanitation of Pharmaceutical unit.
5. Write a master formula for sodium chloride 0.9% injection.
6. Write standard operating procedure (SOP) for cleaning and disinfection of sterile manufacturing area.
7. Discuss in detail Good warehousing practices and cold chain management.
8. Describe the procedure for handling of returned goods reprocessing.
9. Write an explanatory note on European guidelines for contract manufacturing.
10. Write introductory note on scope, importance and concept of IPR.
11. Explain the in-process quality controls for non sterile dosage forms.
12. Explain the scope and importance of intellectual property rights.

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