



[Time: 3 Hours]

[Max. Marks: 75]

Scale Up and Technology Transfer -II

Q.P. CODE: 5142

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 equipment qualification of Rapid Mixer Granulator in detail.
2. Explain pilot plant design of parenteral dosage forms in detail.
3. Define pollution. Enlist different types of pollutions. Explain the methods to control environmental pollution.
4. Describe analytical method of validation.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

5. Explain types of process validation.
6. Explain the reasons and preventive measures for electrical hazards in pharmaceutical industry.
7. Explain the importance of technology transfer in pharmaceutical industry.
8. Describe validation report in cleaning validation.
9. Explain equipment qualifications of fluidized bed dryer.
10. Describe validation of liquid filling and sealing in pharmaceutical industry.
11. Enlist various members of validation team. Explain their responsibilities in validation.
12. Draw a neat pilot plant layout of tablet dosage forms.
13. Explain the importance of vendors in equipment qualifications.
14. Explain the importance of Validation Master Plan.

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