



[Time: 3 Hours]

[Max. Marks: 75]

Scale up and Technology Transfer

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. Draw the flow chart of technology transfer in pharmaceutical industry and discuss in detail scale up process for liquid orals.
2. Explain cleaning validation. Discuss factors influencing cleaning validation.
3. Discuss installation, operational and performance qualifications for rapid mixer granulator.
4. List out environmental pollution and discuss control over environmental pollution.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

5. Write a note on common problems encountered during technology transfer.
6. Explain development phase of technology transfer from R & D to production for capsules.
7. What are the responsibilities of validation team during validation process?
8. Give the objectives and importance of validation master plan.
9. Discuss the operational and performance qualifications for cone blender.
10. Write the installation and operational qualifications for autoclave.
11. Explain the process validation for tablet coating.
12. Explain the process validation for liquid filling and sealing.
13. Describe the general methods of preventing hazards in an industry.
14. Define the term safety and discuss the elements of safety programme.

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