



Pharmaceutical Technology and Validation

(Revised Scheme 4)

Q.P. CODE: 9362

Your answers should be specific to the questions asked.

Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any TWO)

2 X 20 = 40 Marks

1. What are the objectives of IVIVC? Describe different levels of correlation for IVIVC.
2. Explain the procedure for determining the solubility of an API. Describe different techniques of increasing the solubility of a sparingly soluble drug. Compare their merits and demerits.
3. Explain the different approaches to CLV and fixing their acceptance criteria.

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. List and explain the ICH guidelines associated with stability testing.
5. What is polymorphism? What is its significance in dissolution? Name the methods to identify polymorphs.
6. Bracketing and Matrixing in stability studies
7. How will you perform HEPA filter leak test (DOP), give its significance.
8. Criteria for granting biowaivers and their significance
9. Qualification of Sterilization Tunnel

SHORT NOTES

2 X 5 = 10 Marks

10. BACPAC
11. How will you sample particulate matters in clean rooms?

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