



[Time: 3 Hours]

[Max. Marks: 75]

Advanced Pharmaceutical Technology - II

Q.P. CODE: 5165

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 optimization. Classify and explain Factorial designs.
2. Explain Pharmaceutical packaging materials, containers and closures.
3. Explain WHO stability guidelines.
4. Give the detailed account of quality by design tools.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

5. Brief note on photo stability test with a suitable example.
6. Enumerate the basic principle of stability testing as per ICH guidelines.
7. Enlist the elements of the quality by design.
8. Discuss the parameters of optimization techniques.
9. Explain accelerated stability testing protocol.
10. Write short note on Shrink and Stretch films.
11. Explain design of experiments (DOE) in optimization.
12. Write short note on pharmacopoeial specification in packaging technology.
13. Explain the interaction between pharmaceutical container and product packing.
14. Discuss the risk assessment in quality by design.

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