

[Time: 3 Hours]**[Max. Marks: 75]****Pharmaceutical Formulation Development****Q.P. CODE: 5109**

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. Describe in detail the preformulation studies to be conducted for the development of a semi-solid dosage form.
2. Describe the importance of factorial design and models for the process development studies with relevant examples.
3. Explain in detail the various techniques of improving the drug solubility.
4. Define dissolution. Explain in detail the theories of dissolution.

SHORT ESSAY (Answer any Nine)**9 X 5 = 45 Marks**

5. Discuss the structure modifications of drug substances in view of preformulation studies.
6. Explain the formulation development of any solid dosage form.
7. Describe the importance of formulation additives with respect to liquid dosage form development.
8. Explain experimental method to determine the solubility of drug substances.
9. Describe the significance of accelerated stability studies.
10. Explain solution stability of drugs.
11. Describe ICH guideline for stability testing.
12. Explain data handling of dissolution studies of controlled release dosage forms.
13. List out the various dissolution testing apparatus. Explain any two official dissolution testing apparatus.
14. Mention the different techniques of Drug-excipient compatibility studies. Explain in detail any one.

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