[Time: 3 Hours] [Max. Marks: 75]

## Pharmaceutical Manufacturing Technology -II Q.P. CODE: 5164

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

- Explain factors influencing the design of pharmaceutical plant layout for tablets.
- Explain advanced sterile manufacturing technology.
- Discuss the in process quality control tests for sterile dosage forms in injectables and ointment.
- Discuss PAT standards and regulatory requirements.

## SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

- Explain the evaluation of stability of packaging materials.
- 6. Write short note on a) Bottle seals
  - b) Breakable seals
- Discuss the flow charts for large volume parenterals.
- 8. Explain the process automation involved in tablet granulation equipments.
- Explain about the current approach for pharmaceutical product development and limitations associated.
- Explain IPQC tests for hard gelatin capsules.
- 11. Explain the principle and procedure involved in marumerisers.
- Write a note on product package compatibility.
- Explain analytical QbD.
- Write short note on a) RLD.
  - h) GAMP

