[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 in plant location of legal requirements for Pharmaceutical industry.
- 2. Explain process automation with respect to small and large volume parenterals in manufacturing.
- 3. Discuss in detail the advancements in film coating and sugar coating for tablets.
- 4. Explain in detail the stability aspects and evaluation of stability of packaging materials.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

- 5. Explain briefly on dispatching of records and production control.
- 6. Write a note on Form Fill Seal Technology (FFS).
- 7. Explain the concept of QTTP, CQA and CPP.
- 8. Explain briefly about granulation and pelletization equipments.
- 9. Write a note on QbD for drug substances and drug products.
- 10. Give a brief account on flexible packaging.
- 11. Outline the flow chart for manufacturing of hard gelatin capsule.
- 12. Write a note on air and personnel control in sterile preparation area.
- 13. Write a note on standards and regulatory requirements in QbD.
- 14. Write a note on transit worthiness of package.



