

**Time: 3 Hours**

**70 marks**

N. B: (1) All questions are compulsory.

(2) Figures to the right indicate full marks.

(3) Draw neat labelled diagram wherever necessary

1 a) Write in brief on Equipment Qualification. 04

b) Elaborate on any one sales forecasting technique. 04

**OR**

Explain concept of EOQ model of inventory control.

c) Describe a test to study mucoadhesive strength of polymers. (3)

d) Explain the basic principle of an Osmotic drug delivery system. (2)

e) Discuss Quality control standards of identity and potency. (2)

2 a) Write a note on Multiorifice centrifugal process for microencapsulation. (4)

**OR**

Describe Spray drying and Spray congealing process.

b) Give a layout plan for manufacturing of ophthalmic ointment. (4)

c) With reference to cGMP state the general requirements for a (3)

Pharmaceutical Plant.

3 a) Write a note on erodible ocular inserts. (4)

b) Give an outline for validation of steam sterilization process. (4)

c) Explain the importance of documentation in case of Pharmaceuticals. (3)

- 4 a) Discuss factors to be considered for selection of site for small scale Pharmaceutical Plant. (4)
- b) Write a short note on Quality Control Charts. (3)
- c) Explain the concept of Active and Passive Targeting. (2)
- d) Explain the use of bioadhesive polymers in nasal drug delivery. (2)

**OR**

Enlist the various limitations associated with colonic drug delivery.

- 5 a) Write on specifications of packaging and labelling material as components of Quality control. (4)
- b) Write a note on factors affecting mucoadhesive strength of polymers. (3)
- c) List out the core and coat material properties required for microencapsulation. (2)
- d) State the requirements for personnel working in pharmaceutical industry (2)
- 6 a) Discuss the design and release kinetics for an elementary osmotic pump. (4)
- b) Give a BMR for a terminally sterilized aqueous injection. (4)

**OR**

Discuss parameters to be considered for scale up of a suspension.

- c) Explain use of polysaccharides for colon specific drug release . (3)