

Time: 3 Hours

Marks: 70

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

(2) Figures to the right indicate full marks.

(3) Draw neat labeled diagram wherever necessary.

1. a) What are the steps involved in Qualification of a Mixing Equipment. Illustrate with a suitable example. (04)

b) i) Explain the importance of vendor audit with reference to raw material control. (02)

ii) Write a note on ABC concept used in Inventory management. (02)

OR

b) Write a note on Sales Forecasting. (04)

c) Explain any two in vitro methods used to study mucoadhesive strength. (03)

d) Define Osmosis. State the equation explaining release kinetics for an Osmotic system. (02)

e) Write briefly on Quality control standards of 'Purity'. (02)

2. a) Enlist the methods used for Microencapsulation and explain in detail any one method. (04)

OR

a) Enlist the techniques used for phase separation in Coacervation phase separation method and elaborate on any one technique using suitable example of core and coat material.

b) Draw a neat layout scheme for manufacturing of Tablets. (04)

c) Write a note on cleaning and sanitation aspects in a pharmaceutical industry as per cGMP. (03)

3 a) Enlist different floating gastro retentive systems. Explain the design of any one of them. (04)

b) Define F value and Z value. How will you validate Steam sterilization cycle. (04)

c) State the importance of documentation and enlist the methods used for the retrieval of documents. (03)

- 4. a) Discuss briefly site selection and environmental factor to be considered in designing a pharmaceutical facility. (04)
- b) Write a note on sampling and sampling plans. (03)
- c) State the advantages of drug targeting. Define Active targeting. (02)
- d) State the advantages of buccal bioadhesive drug delivery systems. (02)

OR

- d) Colon targeting is a novel approach for drug delivery, Justify. (02)
- 5. a) Discuss the role of Quality Assurance in control of packaging and labeling of the finished product. (04)
- b) Discuss any 2 theories explaining mucoadhesion. (03)
- c) State any four applications of Microencapsulation. (02)
- d) Discuss the essential qualification requirement for the Personnel working in the production department. (02)

- 6. a) State the limitations of the Elementary Osmotic pump. Draw a labeled diagram and explain Push pull osmotic system. (04)
- b) Prepare a Batch Manufacturing Record for an Oro-Dispersible tablet. (04)

OR

- b) Discuss scale-up requirements for liquid orals. (04)
- c) Discuss prodrug based approach for Colon targeted drug delivery system. (03)

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