

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) Elaborate on the validation of mixing process with a suitable example. 4
- (b) Classify types of inventories and explain ABC Concept of inventory management. 4

OR

Explain EOQ in materials management.

- (c) Which are the methods used in evaluating mucoadhesive drug delivery systems? 3
- (d) State the principle of osmotic drug delivery. 2
- (e) What is meant by standards of purity? 2

- 2 (a) Discuss the multiorifice centrifugal process of microencapsulation. 4

OR

Explain coacervation phase separation as a method for manufacture of microcapsules?

- (b) Illustrate layout for manufacture of film coated tablets. 4
- (c) Give the salient features of Schedule M of Drugs and Cosmetics Act. 3

- 3 (a) Briefly explain the advantages, applications and formulation of Microemulsions. 4

(b) How is the validation of steam sterilization conducted? 4

(c) Justify the need for documentation and state why it is significant. 3

- 4 (a) What are the considerations in designing a pharmaceutical manufacturing facility? 4

(b) What techniques are used in statistical quality control? Explain any one. 3

(c) Give four examples of targeted drug delivery systems. 2

(d) What is the role of bioadhesive polymers in formulations for colonic use? 2

OR

Justify use of NDDS in colon targeting of drugs .

- 5 (a) Write a note on the need for raw material control in Quality Assurance. 4
- (b) Discuss any two theories of mucoadhesion . 3
- (c) Explain advantages and applications of microencapsulation with suitable examples. 2
- (d) What are the eligibility criteria for personnel working in Pharmaceutical industry? 2
- 6 (a) With the help of a neat diagram, explain the working of an elementary osmotic pump. 4
- (b) Give the flowchart to explain steps involved in scale up of a tablet prepared by Dry granulation. 4

OR

Prepare a BMR for manufacture of a semi solid formulation.

- (c) State approaches used for drug targeting to colon and elaborate on any one. 3