Q.P. Code : 717102

(3 Hours) **[Total Marks :70**

N.B. : (1) **All** questions are **compulsory**.
(2) **Draw** neat **diagrams** wherever **necessary**.

1. (a) Define Process validation. Explain the different types of validation. 4
(b) What is the importance of the vendor audit and inventory control in the material management. 4

OR

(b) Write a note on Elements of cost control in production management.
(c) Enlist the invitro methods to assess the mucoadhesive strength. Explain any one method. 3
(d) Differentiate between osmosis and diffusion. 2
(e) What is meant by Standards of Purity. 2

2. (a) Give the various techniques of Phase Separation Coacervation for microencapsulation. Explain any one method. 4
(b) With reference to Schedule M, discuss on Warehousing. 4

OR

(b) Draw a neat layout scheme for Tablet manufacturing area.
(c) Briefly discuss on Building and Premises of pharmaceutical industry on basis of cGMP. 3

3. (a) State advantages and disadvantages of Transdermal drug delivery system. What is meant by Iontophoresis and Sonophoresis. 4
(b) Define F value. Describe the steps for validating steam sterilization method. 4
(c) State the need and importance of Documentation. 3

4. (a) Describe the environmental factors to be considered in designing a pharmaceutical facility. 4
(b) Write a note on Q.C. Charts. 3
(c) Define Passive and active targeting. 2
(d) Discuss on bioadhesive polymers used in drug delivery. 2

OR

(d) Discuss on physiology of colon.

TURN OVER

5. (a) How Quality Assurance excise control on Packaging. 4
(b) Define mucoadhesion. State factors influencing mucoadhesion. 3
(c) State the need of microencapsulation. 2
(d) With reference to cGMP, discuss on Personnel training. 2

6. (a) Describe in detail the design and release kinetics of Elementary Osmotic Pump. 4
(b) Prepare a SOP for Hot Air Oven. 4

OR

(b) Discuss on Scale up studies done in manufacture of suspension.
(c) Explain on prodrug approach in Colonic drug delivery system. 3
