

**FINAL YEAR B.PHARM. SEMESTER-VII (2011 COURSE) :
SUMMER - 2018**

SUBJECT : Dosage Form Design IV

Day : **Saturday**
Date : **28/04/2018**

S-2018-3978

Time : **02.00 PM TO 05.00 PM**
Max. Marks : **80**

N.B.:

- 1) **Q.No.1 and Q.No.5 are COMPULSORY.** Out of the remaining questions attempt **ANY TWO** questions from each section.
- 2) Answers to both the sections should be written in **SEPARATE** answer books.
- 3) Draw neat and labeled diagram **WHEREVER** necessary.
- 4) Figures to the right indicate **FULL** marks.

SECTION – I

- Q.1** Attempt **ANY FIVE** of the following: **(10)**
- a) Explain how CDDS are superior to sustained release formulations?
 - b) Draw neat diagram of ocusert system.
 - c) What are compudose subdermal implants?
 - d) Explain Brandt model in CDDS.
 - e) Give the significance of fillers in silicon elastomers.
 - f) What are Nitroder systems?
 - g) Draw a neat diagram of Alzet osmotic pump.
- Q.2** a) Classify activated modulated DDS and discuss iontophoretically activated DDS. **(08)**
- b) Discuss designing of matrix diffusion controlled DDS. **(07)**
- Q.3** a) Explain how hydrodynamic diffusion layer influences release profiles of drug. **(08)**
- b) Discuss mechanistic approach for release profiles of drug from membrane permeation DDS. **(07)**
- Q.4** Write notes on **ANY THREE:** **(15)**
- a) Penkinetic systems.
 - b) Dynamics of GIT and its influence on drug release.
 - c) Feedback regulated DDS.
 - d) Mechanism of drug release from matrix DDS.
 - e) Consideration of GI transit in oral DDS.

SECTION –II

- Q.5** Answer **ANY FIVE** of the following: **(10)**
- a) Differentiate between GMP and cGMP.
 - b) Define retrospective validation.
 - c) Explain instability due to moisture.
 - d) Differentiate between QA and QC.
 - e) Enumerate various IPQC tests in production of tablets.
 - f) State any two duties of coordinator in GLP.
 - g) State the importance of cleaning validation.
- Q.6** a) Discuss GMP in relation to building facilities. **(08)**
- b) Discuss various components of GLP. **(07)**
- Q.7** a) Discuss process validation. Give the procedure for validation of an autoclave. **(08)**
- b) Discuss documentation and its significance. **(07)**
- Q.8** Write notes on (**ANY THREE**): **(15)**
- a) ICH stability guidelines.
 - b) Mix up and cross contamination.
 - c) Concept of TQM.
 - d) Evaluation of preservatives.
 - e) Cleaning validation.