



**MCK-014-003801**      Seat No. \_\_\_\_\_

**M. P. M. (Sem. VIII) (CBCS) Examination**

**May / June - 2018**

**Pharmaceutical Technology - II**

**Faculty Code : 014**

**Subject Code : 003801**

Time : **3 Hours**]

[Total Marks : **80**

- Instructions :**
- (1) Answer and tie both the sections separately.
  - (2) Figure to the right indicates marks.
  - (3) Answer any three (3) questions from each section.
  - (4) Que. One (1) and Que. Five (5) are compulsory.
  - (5) Draw neat and clean diagrams as required.

**SECTION - I**

- 1** Answer any **Seven** out of given ten questions :      **7×2=14**
- (a) Define GMP and Enlist its objectives.
  - (b) What do you mean by class 100 room?
  - (c) Enlist the main components of shampoo with its examples.
  - (d) Define displacement value. Describe its importance in suppository manufacturing.
  - (e) Enlist the excipients used for Nail polish along with its use.
  - (f) Define: Terminal Sterilization.
  - (g) Comment: Ophthalmic product should be used within one month after opening the cap.
  - (h) Explain Product Recall.
  - (i) Comment: Large volume Parenteral are given by IM route.
  - (j) Give a brief idea on comparison of GMPs of different countries.

- 2 Answer the following :
- (a) Define Aerosol and Explain in detail about its components. 7
- (b) Discuss the evaluation techniques for sterile dosage formulations. 6
- 3 Answer the following :
- (a) Write a note on Layout of a pharmaceutical pilot plant. 7
- (b) Write a note on Batch Packaging Record. 6
- 4 Answer the following :
- (a) Write a brief account on Validation of tablet manufacturing process. 7
- (b) Write in brief on formulation of ophthalmic dosage form. 6

## SECTION – II

- 5 Answer any **Two** out of given Three questions : 2×7=14
- (a) Write a note on FFS Technology.
- (b) Explain in detail about the Manufacturing techniques and evaluation parameters for aerosol formulations.
- (c) Give prototype sample of site master file and discuss each component of it in detail.
- 6 Answer the following :
- (a) Write a short note on suppository and Gels. 7
- (b) Describe "Water for Injection" and its preparation and quality control measures. 6
- 7 Answer the following :
- (a) Write a note on manufacturing of sterile product by aseptic process using flow plan. 7
- (b) Describe the design of aseptic area and importance of laminar flow bench. 6
- 8 Answer the following :
- (a) Write a brief account on lipsticks with its Characteristic, excipients, Manufacturing process and Evaluation parameters. 7
- (b) Discuss the self inspection and Quality audit proposed by FDA regarding maintenance of pharma. Mfg. unit. 6