

Enrollment No: \_\_\_\_\_

Exam Seat No: \_\_\_\_\_

# C.U.SHAH UNIVERSITY

## Winter Examination-2022

**Subject Name: Industrial Pharmacy II- Theory**

**Subject Code: BP702T**

**Branch: B.Pharm**

**Semester: 7**

**Date: 22/11/2022**

**Time: 11:00 To 02:00**

**Marks: 75**

**Instructions:**

- (1) Use of Programmable calculator & any other electronic instrument is prohibited.
- (2) Instructions written on main answer book are strictly to be obeyed.
- (3) Draw neat diagrams and figures (if necessary) at right places.
- (4) Assume suitable data if needed.

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- Q-I Answer the following in brief: (20)**
1. Pilot Plant 02
  2. Platform technology 02
  3. QRM 02
  4. QA and QC Activity in pilot plant operation 02
  5. NDA 02
  6. ANDA 02
  7. PAT 02
  8. Six Sigma 02
  9. CDSCO 02
  10. COPP 02
- Q-II Attempt any two: (20)**
1. Discuss scale up and post approval changes for modified release oral solid formulation. 10
  2. What do you mean by technology transfer from R & D to Production? Explain along with steps involved in it. 10
  3. Detailed note on QbD. 10
- Q-III Attempt any seven: (35)**
1. Explain the procedure for pilot plant scale up for tablet? 5
  2. Write a note on SUPAC guideline. 5
  3. Write importance of technology transfer in pharmacy 5
  4. Write a note on Investigator's Brochure. 5
  5. Discuss general consideration of Investigational New Drug (IND) application. 5
  6. Give a detail account on regulatory requirement for drug approval. 5
  7. Describe Clinical Trial Protocol. 5
  8. Write a note on CDSCO. 5
  9. Write a note on ISO 14000 and PDCA cycle 5

