

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

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

**C.U.SHAH UNIVERSITY****Winter Examination-2020****Subject Name: Modern Pharmaceutics****Subject Code: MPH103T****Branch: M.Pharm (Pharmaceutics)****Semester: 1****Date: 10/03/2021****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.

- Q-1 Define the following: (20)**
- |                            |   |
|----------------------------|---|
| a) Response surface method | 2 |
| b) Heckel plots            | 2 |
| c) Budget                  | 2 |
| d) Design space            | 2 |
| e) Variables               | 2 |
| f) Level                   | 2 |
| g) Calibration             | 2 |
| h) Validation Master Plan  | 2 |
| i) PQ phase                | 2 |
| j) Validation Protocol     | 2 |
- Attempt the following questions:**
- Q-2 Attempt any two of following : (20)**
- |   |    |
|---|----|
| A Explain any one method for optimization with example.                                     | 10 |
| B What is validation? Explain its scope and advantages to the pharmaceutical industry.      | 10 |
| C What is accelerated stability testing? How can it be correlated with real time stability? | 10 |
- Q-3 Attempt any Seven of following : (35)**
- |  |   |
|--|---|
| A Write a note on Design Space Determination.  | 5 |
| B Discuss the Benefits of Implementing Quality by Design for pharmaceutical industry.                                      | 5 |
| C Explain in detail IQ,OQ and PQ for Hot Air Oven.   | 5 |
| D Write the importance of inventory management and control in cGMP   | 5 |
| E Explain the terms 'Production Management' and discuss the performance evaluation technique use in production management. | 5 |
| F Describe the compression and consolidation in tablet compression.  | 5 |
| G Describe the Kawakita and Heckle equations in regard to compression.   | 5 |
| H Discuss the characterization of Self Micro Emulsion Drug Delivery System (SMEDDS).                                       | 5 |
| I What is compatibility study? How compatibility studies are carried out for drug- excipients?                             | 5 |

