Enrollment No: _____ **Exam Seat No:**_____

C. U. SHAH UNIVERSITY

Summer Examination-2017

Subject Name: Fundamental of Formulation & Product Development
Subject Code: 5PS01FPD2 **Branch:** M.Pharm (Pharmaceutics)

Semester: 1 **Date: 24/03/2017** **Time: 10:30 To 01:30** **Marks:** 70

Instructions:

(1) Use of Programmable calculator and 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.

SECTION – I

Q-1 **Define the following terms** **(07)**

a. Consolidation
b. Spherical crystallization
c. Solid dispersion
d. Polymorphism
e. Compression
f. Sink condition
g. Biowaiver

Q-2 **Attempt all questions** **(14)**

1. Discuss preformulation study of parenteral dosage form with considering pharmaceutical factor. **(7)**

2. What is compatibility study? How are accelerated testing is carried out for drug – excipients compatibility study for oral solid? **(7)**

OR

Q-2 **Attempt all questions**

1. Short note on application of DSC & TG Analysis. **(7)**

2. Explain factor affecting crystal habit & its application. **(7)**

Q-3 **Attempt all questions** **(14)**

1. Advantages & disadvantages of different techniques to improve solubility of API. **(7)**

2. Describe the different method of preparation of beta-cyclodextrin inclusion complex. **(7)**

OR

Q-3 **1.** Enlist different chemical degradation pathway for various pharmaceutical Ingredients. **(7)**

2. Write a note on Photo stability testing **(7)**

SECTION – II

Q-4 **Define the following terms:** **(07)**

a. Co-processed excipients.
b. Lyophilisation
c. Spray dried diluents
d. First order reaction
e. Pseudo-zero order reaction
f. Kinetics
g. Super disintegrates

Q-5 **Attempt all questions** **(14)**

1. How bracketing & matrixing design for stability testing is carried out? **(7)**
2. Write a note on modified dissolution testing for TDDS **(7)**

OR

Q-5 **1.** Discuss Comparison of dissolution profile by model independent methods. **(7)**
2. Explain major hurdles and challenges associated with herbal product development **(7)**

Q-6 **Attempt all questions** **(14)**

1. Write a note on applications of biomaterials in pharmaceutical formulations **(7)**
2. Write a brief note on techniques to estimate log P value **(7)**

OR

Q-6 **Attempt all Questions**

1. Write a detailed account on polymeric excipients for controlled release applications **(7)**
2. Write the importance of Documentation and records in GMP. **(7)**