Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY

Summer Examination-2018

Subject Name : Pharmaceutical Manufacturing Technology
Subject Code : MQA204T **Branch: M.Pharm (QA)**
Semester : 2 **Date : 02/05/2018** **Time : 10:30 To 01:30** **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 **Attempt the following questions:** **(20)**

a) Enlist factors influencing the plant layout and plant location.
b) Give different types of container and closure linears.
c) Enlist the advantages of QbD.
d) What do you mean by process automation in pharmaceutical industry?
e) Define the terms: (1) CMA(2)CQA(3)CPP
f) What do you mean by PAT?
g) Give the applications of coating technology.
h) What is Lyophilization?
i) Give the manufacturing flowchart of Emulsion.
j) Enlist the different types of Glasses.

Attempt the following questions:

Q-2 **Attempt any two of following :** **(20)**

A Discuss in detail about QbD and PAT. **10**
B Give the manufacturing flowcharts and its in process-quality control tests of tablet and capsules. **10**
C Discuss in detail about Principal, process and equipments of Lyophilization technology: **10**

Q-3 **Attempt any Seven of following :** **(35)**

A Write a note on evaluation of stability of packaging materials. **5**
B Write a brief note on solid automation technology using spheronizers and merumerisers. **5**
C Write a brief note on calculation of standard cost and production planning in pharmaceutical industry developments. **5**
D Write a note on process automation in manufacturing of sterile semi-solids. **5**
E Describe in brief about various types of container and closure linear. **5**
F Write a note on Risk assessment and mitigation in QbD. **5**
G Describe in detail about Fluidized bed coating. **5**
H Write a note on Form Fill Seal Technology. **5**
I Write a note on aseptic process technology of SVP and LVP. **5**