Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY

Winter Examination-2019

Subject Name: Quality Control and Quality Assurance
Subject Code: MQA103T **Branch: M.Pharm (QA)**
Semester: 1 **Date : 04/12/2019** **Time : 02:30 To 05:30** **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 IPR
b) Penicillin can be manufacture with Paracetamol in same plant-Comment
c) Format for Batch Manufacturing Record
d) Classify types of DMF
e) Enlist Finished Product QC test for Shampoo
f) What is Geographical Indication in IPR
g) Calibration of pH metre
h) Give validation parameter
i) Describe Out of Specification
j) Give expiry date calculation

Attempt the following questions:

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

A	Define and differentiate Quality Control and Quality Assurance. Write scope of QA and QC in Pharmaceutical Company. Enlist and explain in brief IPQC tests Tablet.	**10**
B	Enlist the ICH Q series Guidelines and Discuss ICH guideline Q3B (R2) and Q2 (R1)	**10**
C	Explain importance of Documentation in Quality Control Department. Discuss the case study of Change Control procedure.	**10**

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

A	Draw the flow chart for Establishing Acceptance Criterion For a Degradation Product in a New Drug Product as per ICH Q6 A guidelines.	**5**
B	Write in brief Batch Manufacturing Record.	**5**
C	Discuss need for protection of Patent rights in Pharma.	**5**
D	Discuss the scope of GLP guidelines	**5**
E	Define Quality Audit. Write about the Quality Audit Plan.	**5**
F	Write SOP for Double beam Spectrophotometre	**5**
G	Draw triangle of CTD and discuss Module 5	**5**
H	Write the protocol to conduct non clinical testing.	**5**
I	Give the organization and personnel responsibilities as per cGMP.	**5**