Enrollment No: _____ Exam Seat No: _____

C.U.SHAH UNIVERSITY

Winter Examination-2019

Subject Name: Regulatory Affairs
Subject Code: MPH104T **Branch: M.Pharm (Pharmaceutics)**
Semester : 1 **Date : 05/12/2019** **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-I Explain briefly the following terms: **[2X10]=20**

a) Documentation **[2]**
b) Objectives of Drug Master File **[2]**
c) Generic Drug **[2]**
d) Aim of MHRA **[2]**
e) Process Validation **[2]**
f) Master formula record **[2]**
g) Medicine Control Agency **[2]**
h) Investigator brochure **[2]**
i) Clinical trials **[2]**
j) Pharmacovigilance **[2]**

Q-II Attempt any two: **[2X10]=20**

a) Describe rules and guidance for Pharmaceutical manufacturers and distributors as per "the Orange Guide". **[10]**
b) Discuss in detail NDA approval process. **[10]**
c) Explain the different modules of CTD. **[10]**

Q-III Attempt any seven: **[7X5]=35**

a) Describe the outsourcing of BA and BE. **[5]**
b) Explain litigation under the HATCH-WAXMAN Act. **[5]**
c) Explain the guidelines of ICH-S. **[5]**
d) Write the guidelines of TGA for listed medicines. **[5]**
e) Write a note on ANDA. **[5]**
f) Explain regulation for medical devices. **[5]**
g) Describe general guidelines for dossier preparation for ROW market. **[5]**
h) Write a note on HIPAA. **[5]**
i) Explain pharmacovigilance safety monitoring in clinical trials. **[5]**