Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY

Summer Examination-2019

Subject Name : Audits and Regulatory Compliance

Subject Code : MQA203T **Branch: M.Pharm (QA)**

Semester : 2 **Date : 30/04/2019** **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) Describe the term CAPA.
b) Explain in brief general areas of packaging materials.
c) Explain the term: Quality system approach
d) Explain the term: administration
e) Explain the term: information gathering.
f) Give note on First party audit.
g) Explain in short: field work.
h) What do you mean by water for injection? Explain in short.
i) Discuss in short: Second party audit.
j) Define and explain in short: Dry granulation.

Attempt the following questions:

Q-2		**Attempt any two of following :**	**(20)**
	A	Write a detailed note on HVAC system.	**10**
	B	Write a detailed note on planning process.	**10**
	C	Share your knowledge about sterile production and packaging.	**10**
Q-3		**Attempt any Seven of following :**	**(35)**
	A	Write a note on general areas in the building of raw materials.	**5**
	B	Give a note on ETP.	**5**
	C	What do you mean by deficiency? Classify them.	**5**
	D	Write a note on cGMP regulations.	**5**
	E	Share your knowledge on vendor audit	**5**
	F	Write a note on warehouse and weighing.	**5**
	G	Discuss the purpose of FDA audit.	**5**
	H	What do you mean by compliance management? Write a note on it.	**5**
	I	Give importance of audit in pharmaceutical industry.	**5**