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

# C.U.SHAH UNIVERSITY

## Summer Examination-2018

**Subject Name:** Audits and Regulatory Compliance

**Subject Code:** MQA203T **Branch**: M. Pharm.

**Semester:** 2 **Date:** 27/04/2018 **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.

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**Q-I Explain the following:** **(20)**

- a. Describe in brief First-Party audit. b. Describe in brief field work.
  c. Explain the term Audit plan. d Explain the term Reference Standards.
  e. Explain the term Quality audit. f. Explain the term CAPA.
  g. Describe briefly second party plan. h. Describe briefly ion exchange resin.
  i. Write the objective of auditing. j. Explain the term water for injection.

**Q-II Long Answer (Answer 2 out of 3)** **(20)**

a. Explain in detail the auditing procedure. (10)
b. Discuss the major areas of audit in the microbiological laboratory. (10)
c. Describe in detail HVAC system. (10)

**Q-III Short Answer (Answer 7 out of 9)** **(35)**

a. Describe the purpose of FDA audit. (5)
b. Write a note on compliance management. (5)
c. Discuss the audit checklist for production area in pharmaceutical industry. (5)
d. What are the main elements that should be considered in the design of reverse osmosis system? (5)
e. Describe briefly the various parameters for auditing water for injection as per USP and why? (5)
f. Write a note on Effluent Treatment Plant. (5)
g. Describe the importance of audit in pharmaceutical industry. (5)
h. Write the approach for excipient vendor qualification. (5)
i. Write a note on vendor audit. (5)