

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.

Q-I Explain the following: (20)

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| 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)

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| 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)

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| 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) |

