# C.U.SHAH UNIVERSITY
## Winter Examination-2018

**Subject Name:** Quality Management System

**Subject Code:** MQA102T          **Branch**: M. Pharm (QA)

**Semester:** 1          **Date: 28**/11/2018          **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.
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| **Q-I** | **Explain briefly the following:** | **(20)** |

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|---|---|---|---|---|
| a. | Drug Stability | b. | Risk assessment | |
| c. | Internal Customer | d | Risk ranking | |
| e. | Quality management | f. | Line clearance | |
| g. | Primary packaging | h. | Dimensions of quality | |
| i. | Vendor | j. | Benchmarking | |

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|---|---|---|
| **Q-II** | **Long Answer (Any two)** | **(20)** |
| a. | Discuss in detail six sigma. | (10) |
| b. | Write a brief note on ICH guidelines for stability testing of drug substances and drug products. | (10) |
| c. | Describe the concept and advantages of Statistical control charts. | (10) |
| **Q-III** | **Short  Answer (Any seven)** | **(35)** |
| a. | Describe strategic planning and implementation. | (5) |
| b. | Explain briefly McKinsey 7s model. | (5) |
| c. | Describe the concept of IPQC. | (5) |
| d. | Explain briefly total quality management. | (5) |
| e. | Write a note on risk management tools. | (5) |
| f. | Describe secondary packaging. | (5) |
| g. | Write a note on Corrective and Preventive action (CAPA). | (5) |
| h. | Give a note on risk ranking and filtering according to ICH Q9 guidelines. | (5) |
| i. | Write types of bench marking. | (5) |