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Total No. of Pages : 01

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**M.Pharmacy (Pharmaceutical Quality Assurance) (2017 & Onwards)  
(Sem.-1)****QUALITY MANAGEMENT SYSTEMS****Subject Code : MQA-102T****M.Code : 74700****Time : 3 Hrs.****Max. Marks: 75****INSTRUCTIONS TO CANDIDATES :**

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

**Q1. Elaborate upon the following :**

- a. Quality (5)
- b. Strategies of quality management (5)
- c. Factors affecting customer Perception (5)

**Q2. a. Discuss the principle of six sigma. (8)**

- b. Write a note on ISO 9001: 2008 (7)

**Q3. a. What do you understand by the concept of self inspection? (8)**

- b. What is the Vendor Qualification system? (7)

**Q4. a. ICH guidelines for accelerated stability studies. (9)**

- b. Write a note on quality by design. (6)

**Q5. a. Define SPC. What is the importance of SPC in pharmaceuticals? (10)**

- b. What are the advantageous of statistical control? (5)

**Q6. Discuss in detail the advantages and disadvantages of Benchmarking. (15)**

**NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.**

