

Roll No.

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Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy (Pharmaceutical Quality Assurance) (2017 & Onwards)
(Sem.-1)**QUALITY MANAGEMENT SYSTEMS**

Subject Code : MQA-102T

Paper ID : [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.

1.
 - a) What is meant by 'quality'? Discuss the strategies for building a quality product and the advantages of such a product.
 - b) Enumerate the factors influencing customer delight and discuss the steps taken by the management to achieve it.
2.
 - a) Mention the aims of ISO 9001 : 2015. Give a brief account of ISO 9001 : 2015 with respect to customer satisfaction.
 - b) Write a note on NABL certification.
3.
 - a) Discuss the essential parts of quality management systems with respect to production.
 - b) Differentiate between OOS and OOT with suitable examples.
4.
 - a) Discuss risk management tools with examples.
 - b) Outline the method of stability testing of drug products.
5.
 - a) What is process capability? Explain the procedure to evaluate it.
 - b) Write a note on control charts and their utility.
6.
 - a) Discuss the advantages and limitations of benchmarking.
 - b) Briefly discuss the different types of benchmarking and the situations where they are applied.