

**BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI  
(END SEMESTER EXAMINATION)**

**CLASS: M.PHARM.  
BRANCH: PHARMACY**

**SEMESTER: I  
SESSION: MO25**

**SUBJECT: MQA102T QUALITY MANAGEMENT SYSTEMS**

**TIME: 3.00 Hours**

**FULL MARK: 75**

**INSTRUCTIONS:**

1. The missing data, if any, may be assumed suitably.
2. Before attempting the question paper, be sure that you have got the correct question paper.
3. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.
5. Answer any five questions.

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| 1a. What is QMS? Discuss the role of TQM in the quality management of pharmaceutical products.  | [7] |
| 1b. Explain the salient features of ISO 9001:2008 in Pharmaceutical Quality Management.   | [8] |
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| 2a. Give a detailed note on the significance of ICH Q8 in the pharmaceutical industry.  | [7] |
| 2b. Justify the role of ICH Q10 in the pharmaceutical industry.   | [8] |
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| 3a. Explain the requirement for WHO-GMP.  | [7] |
| 3b. Define and analyse the reasons for benchmarking. Describe the types of benchmarking.  | [8] |
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| 4a. Discuss the various aspects of the Benchmarking process and the limitations of benchmarking.  | [7] |
| 4b. Discuss the concept of IPQC.  | [8] |
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| 5a. Explain the McKinsey 7s Model.  | [7] |
| 5b. Describe the importance of customer satisfaction and customer delight with suitable examples.   | [8] |
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| 6a. Explain the Six System Inspection Model.  | [7] |
| 6b. Discuss Out of Specification (OOS) and Out of Trend (OOT) with respect to Pharmaceuticals.  | [8] |
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| 7a. Discuss estimating inherent or potential capability from a control chart analysis with suitable examples.   | [7] |
| 7b. Calculate the $\pm 1SD$ , $\pm 2SD$ , and $\pm 3SD$ of the weights (mg) of the following tablets: 100, 125, 115, 112, 118, 106, 109, 105, 117, 120. | [8] |

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