

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

**CLASS: MPHARM.
BRANCH: PHARMACY**

**SEMESTER: I
SESSION: MO24**

SUBJECT: MQA102T QUALITY MANAGEMENT SYSTEM

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. Discuss the importance of Vision and Mission statements and their significance for a company. | [7] |
| 1b. Discuss the factors affecting customer perception with suitable examples. | [8] |
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| 2a. Explain the Six System Inspection Model. | [7] |
| 2b. Writes notes on the significance of investigating and determining the root cause in the pharmaceutical industry. | [8] |
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| 3a. Discuss the advantages of Statistical Process Control. | [7] |
| 3b. Discuss Westgard rules. | [8] |
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| 4a. Write notes on the concept of self-inspection. | [7] |
| 4b. Summarise the ICH Guidelines for the stability study of drug substances and drug products | [8] |
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| 5a. Justify the role of CFR-21 part 11 in the pharmaceutical industry | [7] |
| 5b. What is QMS? Discuss the role of TQM in the quality management of pharmaceutical products | [8] |
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| 6a. Discuss the WHO GMP requirements | [7] |
| 6b. Explain the salient features of ISO 9001:2008 in pharmaceutical quality management | [8] |
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| 7a. What do you mean by benchmarking? Discuss the reasons for benchmarking and types of benchmarking | [7] |
| 7b. Explain the benchmarking process and its limitations. | [8] |

:::10/12/2024:::M