

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

CLASS: M. Pharm.  
BRANCH: PHARMACY

SEMESTER: I  
SESSION: MO/22

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. | Define Quality Assurance and discuss the development process of Quality Control.                | [7] |
| 1b. | Discuss the Dimensions of Quality from Process Viewpoint.                                       | [8] |
| 2a. | Discuss Cost of Poor Quality (COPQ) with its categories?  | [7] |
| 2b. | Discuss any two models of Cost of Quality.  | [8] |
| 3a. | Discuss the importance of Westgard rules in SPC.  | [7] |
| 3b. | Describe Shewhart Control Chart with an example.  | [8] |
| 4a. | Discuss the significance of Customer satisfaction and customer delight in QMS.                  | [7] |
| 4b. | Write your views on importance of the Concept of internal and external customers.               | [8] |
| 5a. | Discuss the role of management in commitment to quality as per quality as a strategic decision. | [7] |
| 5b. | Discuss Corrective and preventive actions (CAPA) as a part of Quality System.                   | [8] |
| 6a. | Explain Six System Inspection Model.  | [7] |
| 6b. | Explain the ICH guidelines for stability testing of drug substances.                            | [8] |
| 7a. | Define TQM and discuss the key element of TQM approach.   | [7] |
| 7b. | Discuss the Principles of Six sigma.  | [8] |

::::22/11/2022::::E