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

CLASS: M. Pharm. **SEMESTER: 1st**
BRANCH: PHARMACY **SESSION: MO 2023**

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.

1a.	Explain the Dimensions of Quality with respect to Pharmaceuticals.	[7]
1b.	Write notes on the various aspects involved in Customer focus.	[8]
2a.	Discuss in detail concept of Total Quality Management (TQM) and explain how TQM contributes to continuous improvement process.	[7]
2b.	Explain in brief objectives and principles governing ISO 9000 and 14000 family.	[8]
3a.	Explain Six System Inspection model taking pharmaceutical industry as an example.	[7]
3b.	Discuss the importance of Root Cause Analysis (RCA) quoting an imaginary situation.	[8]
4a.	Describe importance of ICH Q8 in pharmaceutical product development.	[7]
4b.	Explain in detail Quality Risk management (QRM) as part of integrated quality management.	[8]
5a.	Discuss the importance of statistical process control in pharmaceutical quality assurance taking Shewhart Control Chart as an example.	[7]
5b.	Explain Westgard rules.	[8]
6a.	Write notes on regulatory compliance through quality management.	[7]
6b.	Explain Benchmarking with respect to Pharmaceutical Industry.	[8]
7a.	Explain ICH Q10 in brief elaborating regulatory applicability and implementation of ICH Q10 throughout product lifecycle.	[7]
7b.	Discuss in detail functions of National Accreditation Board for Testing and Calibration Laboratories (NABL) and the process of registration for NABL accreditation.	[8]

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