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

CLASS: M. PHARM. **SEMESTER: I**
BRANCH: PHARMACY **SESSION: MO24**

SUBJECT: MQA103T QUALITY CONTROL & QUALITY ASSURANCE

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.	Discuss the importance of 21CFR Part 210 and 211 for the Pharmaceutical Industry.	[7]
1b.	Compare Schedule M with other cGMP guidelines.	[8]
2a.	Explain the three-tier documentation with respect to the pharmaceutical industry.	[7]
2b.	Write notes on the concept of regulated and non-regulated markets.	[8]
3a.	Describe the concept and importance of CTD and eCTD	[7]
3b.	Write notes on electronic data handling.	[8]
4a.	Discuss the importance of Intellectual Property Rights (IPR).	[7]
4b.	Explain about the sanitation of manufacturing premises, mix-ups & cross-contamination	[8]
5a.	Write quality parameters. Justify the role of quality control in the pharmaceutical industry	[7]
5b.	What do you mean by QSEM in ICH? Explain its role in the development of quality in pharmaceutical products.	[8]
6a.	Discuss about salient features of GMP in the manufacturing of pharmaceutical products	[7]
6b.	Justify the role of GLP in quality management	[8]
7a.	What do you mean by IPQC? Justify the role of IPQC in quality management.	[7]
7b.	Explain the IPQC parameters for semi-solid dosage forms and highlight the troubleshooting parameters for Tablets.	[8]

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