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

CLASS: M.Pharm **SEMESTER: Ist**
BRANCH: PHARMACY **SESSION: MO 25**

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.	Mention the quality parameters. Differentiate between QC &QA	[7]
1b.	Explain the role of QC in quality management	[8]
2a.	Describe in detail about GLP	[7]
2b.	Discuss the various aspects of CPCSEA guidelines	[8]
3a.	What do you mean by IPQC? Justify the role of IPQC in quality management.	[7]
3b.	Explain the troubleshooting parameters for capsules as per IPQC. Write a note on ICH.	[8]
4a.	Discuss the importance of Intellectual Property Rights (IPR).	[7]
4b.	Justify the role of sanitation, mix-ups and cross-contamination in the pharmaceutical industry	[8]
5a.	Compare GMP and cGMP.	[7]
5b.	Describe the specific requirements for the manufacturing of oral solid dosage forms forms, emphasising tablets and capsules as per GMP.	[8]
6a.	Describe the standard operating procedure (SOP) in the pharmaceutical industry	[7]
6b.	State the specific requirement for plant and equipment as per GMP.	[8]
7a.	Discuss the three-tier documentation, policy, work instruction and records in the pharmaceutical industries.	[7]
7b.	Write a note on DMF, CTD and eCTD.	[8]

::::::21/11/2025::::::M