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

CLASS: M.PHARM **SEMESTER: 1ST**
BRANCH: PHARMACY **SESSION: MO 22**

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.	What do you mean by quality? Explain the role of QA & QC with respect to quality of drugs	[7]
1b.	Explain in detail about the various components of GLP with respect to quality of drug.	[8]
2a.	What do you mean by IPQC? Explain its role in manufacturing of pharmaceuticals	[7]
2b.	Explain the role of CPCSEA guidelines with respect to animal experimentation in drug discovery process	[8]
3a.	Justify the role of Good Manufacturing Practice in pharmaceutical industry	[7]
3b.	Discuss the role ICH guideline with respect to QSEM	[8]
4a.	Compare the role of trade mark, copy rights and patents	[7]
4b.	What is IPR? Describe the role of IPR in drug development	[8]
5a.	Expain briefly location and sanitation requirement of pharmaceutical plant.	[7]
5b.	Discuss the role of CBER and CDER.	[8]
6a.	Elaborate about significance of batch manufacturing records and Standard operating procedure.	[7]
6b.	Describe about CTD and eCTD.	[8]
7a.	Explain stages of drug development and CDER review division.	[7]
7b.	Describe in detail quality documentation in pharmaceutical industry.	[8]

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