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

CLASS: M. PHARM **SEMESTER : I**
BRANCH: PHARMACY **SESSION : MO/19**

SUBJECT: MQA102T QUALITY MANAGEMENT SYSTEM

TIME: 3:00 HOURS **FULL MARKS: 75**

INSTRUCTIONS:
1. The question paper contains 7 questions each of 15 marks and total 105 marks.
2. Candidates may attempt any 5 questions maximum of 75 marks.
3. The missing data, if any, may be assumed suitably.
***4*. Before attempting the question paper, be sure that you have got the correct question paper.**
5. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.

Q.1(a)	Discuss the WHO GMP requirements.	[7]
Q.1(b)	Explain the salient features of ISO 9001:2008 in pharmaceutical quality management.	[8]
Q.2(a)	Define benchmarking. Discuss the benchmarking process.	[7]
Q.2(b)	Discuss the advantages and limitation of benchmarking.	[8]
Q.3(a)	What do you mean by dimensions of quality? Give a note on strategic planning and implementation.	[7]
Q.3(b)	What do you mean by cost of quality? Explain various aspects of customer satisfaction.	[8]
Q.4(a)	Highlight the various parameters of ISO 14001:2004.	[7]
Q.4(b)	Discuss the concept of Risk Control and its components as per ICH Q9.	[8]
Q.5(a)	The Deming philosophy is an important framework for implementing quality and productivity. Describe Deming's 14 points of management.	[7]
Q.5(b)	Justify the statement "A control chart is one of the primary techniques of statistical process control (SPC)".	[8]
Q.6(a)	Discuss the principles of Quality risk management as per ICH Q9.	[7]
Q.6(b)	Justify the Elements of Pharmaceutical Development as per ICH Q8(R2).	[8]
Q.7(a)	Discuss the importance of Concept of self-inspection for quality management of any company.	[7]
Q.7(b)	Discuss the importance of the concept of batch review and batch release in Pharmaceutical Industry.	[8]

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