

DEPARTMENT OF PHARMACEUTICAL SCIENCES & TECHNOLOGY

BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI
(Internal Assessment I)

CLASS: BPHARM
BRANCH: PHARMACY

SEMESTER: VI
SESSION: SP/2025

SUBJECT: BP606T PHARMACEUTICAL QUALITY ASSURANCE

TIME: 2.00 Hour

FULL MARK: 30

PART I

A. Objective type questions (Answer all questions) (5 x 02 = 10 marks)

1. Write the various parameters of quality.
2. Differentiate between QA & QC
3. What do you mean by ICH? Write its significance.
4. What is ISO 9001-2008?
5. What is ISO 14030 and ISO 14040?

PART II

B. Long Answers (Answer any one out of two) (01x10=10 marks)

1. What do you mean by TQM? Write its significance in the pharmaceutical industry.
2. What is GLP? Write a note on different aspects of GLP.

PART III

C. Short Answers (Answer any two out of three) (02x05=10 marks)

1. What do you mean by QA? Summarise the role QA in the pharmaceutical industry
2. Explain the various aspects of QbD
3. Give a brief description of different aspects of GMP.

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