

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

**CLASS: BPHARM
BRANCH: PHARMACY**

**SEMESTER: VITH
SESSION: SP/25**

SUBJECT: BP606T PHARMACEUTICAL 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 handbook/Graph paper etc. to be supplied to the candidates in the examination hall.
4. This question paper consists of (03) three parts. Read the part wise instructions before attempting the questions.

PART-I

Objective types of questions (Instruction: Answer all questions)

Q1. (10 x 2 = 20 Marks)

C01

- A. Write the various parameters of quality.
- B. Differentiate between QA & QC
- C. What do you mean by ICH? Write its significance.
- D. Write the storage conditions of raw materials
- E. Classify packaging used in pharmaceutical product
- F. Write the significance of GLP
- G. Mention the types of complaints in pharmaceutical industry
- H. Classify recall observed in pharmaceutical system
- I. What do you mean by SOP & process of SOP?
- J. How will you Maintain the pH Meter?

PART-II

Short Answers

(Instruction: Answer seven out of nine questions)

(7 x 5 = 35 Marks)

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| Q2. Define & differentiate between QA & QC | C02 |
| Q3. Explain the major components of quality control in pharmaceuticals. | C03 |
| Q4. Justify the role of various QA activities in pharmaceutical industry. | C04 |
| Q5. Write the role of QbD in quality management | C02 |
| Q6. Describe about the different areas found in pharmaceutical industry premises. | C02 |
| Q7. Explain the SOP of complaint handling in industry | C03 |
| Q8. Justify the role of MFR in pharmaceutical production | C05 |
| Q9. Describe the various analytical validation parameters | C04 |
| Q10. Write the process of calibration for UV-Visible spectrophotometer? | C04 |

PART-III

Long Answers

(Instruction: Answer two out of three questions)

(2 x 10 = 20 marks)

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| Q11. What do you mean by TQM? Explain the key elements of TQM & Edwards Deming's quality concept. Justify the role of TQM in managing quality | C05 |
| Q12. Why is GMP required in pharmaceutical products? Explain various parameters in GMP required for API | C05 |
| Q13. Explain about quality control tests for glasses used as packaging material | C05 |