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

**CLASS: B.PHARM** **SEMESTER: VI**
**BRANCH: PHARMACY** **SESSION: SP23**

**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 hand book/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.**

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**PART-I**
**Objective types questions (Instruction: Answer all questions)**

Q1. (10 x 2 = 20 Marks)
CO1-3

A. Define quality control.
B. Explain TQC in brief.
C. Provide the role of ISO 9000 and ISO 9001.
D. Explain in short TPP.
E. Define the role of NABL in quality assurance and its role in short.
F. Define quality assurance.
G. Recall the names of at least four processes to dispose the pharmaceutical waste.
H. Sketch the quality document hierarchy
I. Which personnels are responsible for calibration of industrial instruments?
J. Which quality costs can be minimized if the pharmaceutical process is validated?

**PART-II**
**Short Answers**
**(Instruction: Answer seven out of nine questions)**

(7 x 5 = 35 Marks)

Q2. Illustrate the role and responsibilities of head of quality control department and identify the roles for joint responsibilities. CO2

Q3. Identify mandatory hygiene including personal hygiene to be maintained within the organization premises. CO2

Q4. Explain the risk assessment methodology used for QBD: CO2
   a. Fish bone risk assessment methodology
   b. Failure mode effect analysis
   c. Process analytical technology (PAT)

Q5. Define the following: CO1
   a. CMA
   b. CPP
   c. QTPP
   d. CQA
   e. Risk assessments

Q6. Discuss the evaluation of packaging materials. CO2

Q7. Discuss the effluent treatment process of pharmaceutical waste water CO1

Q8. Enumerate the components of batch manufacturing record. CO1

Q9. Define revalidation. Outline the possible reasons which lead to initiate revalidation. CO3

Q10. Write notes on calibration interval. CO3

**PTO**

**PART-III**
**Long Answers**
**(Instruction: Answer two out of three questions)**

(2 x 10 = 20 marks)

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| Q11. | | Explain in detail the ICH guidelines, their usage, and applications. | CO2 |
| Q12. | | Explain the reason for GLP creation. Identify the objectives of GLP. What are the basic elements in GLP? Identify the possible violations in GLP and also the consequences of noncompliance. | CO2 |
| Q13. | A. | Describe the requirements of a good pharmaceutical warehouses. | CO2 |
| | B. | Outline different types of product recall. Discuss the process of pharmaceutical product recall. | CO2 |

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