JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT

TEST -3 EXAMINATION- 2025

M.Tech-II/M.Sc MB (IV) Semester (BT&BI)

COURSE CODE (CREDITS):20M1WBT231/20MS2MB414 (3) MAX. MARKS: 35

COURSE NAME: Quality Control Analysis and Management

COURSE INSTRUCTORS: Dr. Gopal Singh Bisht MAX. TIME: 2 Hours

Note: *(a) All questions are compulsory.*

(b) The candidate is allowed to make Suitable numeric assumptions wherever required for solving problems

Q.No	Question	Marks
Q1a	In a biotech company, the fermentation process for producing a therapeutic protein has a mean yield (μ) of 120 grams per batch with a standard deviation (σ) of 8 grams. Customer specification limits (LSL and USL) are: Lower Specification Limit (LSL): 100 grams Upper Specification Limit (USL): 140 grams [5] a) Calculate Process Capability Index (Cp)? b) Calculate Process Capability Performance (Cpk)? c) Is the process capable? d) Discuss Six Sigma-based improvements can be made to increase capability?	[5]
1b)	A company manufactures 3,00,000 smartphone screens per month. During quality inspection, 190 defective screens are found. Calculate the Defects Per Million Opportunities (DPMO) if each screen has 3 opportunities for defects (e.g., scratches, dead pixels, touch sensitivity issues). Find the Sigma Level.	[2]
Q2	A biotechnology company is setting up a new facility for the production of monoclonal antibodies. Develop a Validation Master Plan (VMP) for company that outlines the strategy for validating equipment, utilities, processes, cleaning, and computer systems	[5]
Q3	Analyze the effectiveness all the elements in 5'S principle and also the implementation procedure of 5'S in a manufacturing company.	[5]

Q4	Explain the role of sensory evaluation in food/pharma/biotech quality control and analyze how the triangle test and duo-trio test are applied by taking suitable examples. Evaluate the effectiveness of these tests in detecting product differences. Discuss the factors that influence sensory perception.	[6]
Q5	Answer the following questions a) How the concept of quality Management evolved over time? b) Discuss risk identification process and tools/techniques used for risk identification by taking example of HAZOP and HACCP. c) In pharmaceutical industry every process is validated, then why do we have failure. Writing investigation report of quality failure is mandatory, discuss briefly. d) Explain advance QC approaches such as Quality by design. Why it is important to indentify critical quality attributes (CQA), critical process parameters (CPP) and Critical Process control (CPC) for a process.	[2] [3] [3] [4]