JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT

TEST -1 EXAMINATION- 2026

M.Tech-I/M.Sc.Semester 2th/4TH (BT)

COURSE CODE (CREDITS): 20M1WBT231/21MS2MB414 (3) MAX. MARKS: 15

COURSE NAME: QUALITY CONTROL ANALYSIS AND MANAGEMENT

COURSE INSTRUCTOR: Dr. Gopal S Bisht MAX. TIME: 1 Hour

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

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

(c) Use of calculators is not allowed

Q.No	Question	Marks
Q1	A biotechnology company involved in the production of recombinant insulin using *E. coli* reported low batch yield and frequent batch rejection during downstream quality testing. The average yield was 65%, whereas the acceptable standard was ≥85%. PDCA (Plan–Do–Check–Act) cycle along with the Seven Quality Control (QC) tools to identify root causes, implement corrective actions	6
Q2	Design stability studies of a pharmaceutical active ingredient, keeping all quality control parameters under consideration.	3
Q3	Answer the following question a) Explain how quality of conformance, quality of design and quality of performance are related. b) Comment on cost of poor quality c) Analyze the importance of ISO certification in managing quality of biotech product	2x3=6

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