

JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT

TEST -1 EXAMINATION- MARCH-2023

COURSE CODE (CREDITS): 20M1WBT231 (3)

MAX. MARKS: 15

COURSE NAME: Quality Control Analysis and Management

COURSE INSTRUCTORS: Dr. Gopal Singh Bisht

MAX. TIME: 1 Hour

Note: All questions are compulsory. Marks are indicated against each question in square brackets.

- Q1. Design an experiment for stability studies for a new active pharmaceutical ingredient for quality control and assurance. [3]
- Q2. Discuss various parameters of HPLC systems which can affect the analytical quality of measurements? How system suitability tests are used to ensure the quality of the data and of the analysis? [4]
- Q3. It is essential to follow cGMP and Good Documentation guidelines to ensure quality of finished product/API. Justify the statement. [3]
- Q4. Answer/explain the following questions.
- Compare Quality control vs. quality assurance [1]
 - How to ensure quality of raw material received in manufacturing unit. [1]
 - How infra red spectra can be used for quality testing of API. Explain [1.5]
 - Explain basic aim and benefits of ISO certification system. [1.5]