

Dr. Nopal Singh Bhoat

JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT  
TEST -1 EXAMINATION- 2020  
PhD II Semester

COURSE CODE: 14MIWBT334

MAX. MARKS: 15

COURSE NAME: Quality Analysis and Management

COURSE CREDITS: 03

MAX. TIME: 1 HR

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*Note: All questions are compulsory. Carrying of mobile phone during examinations will be treated as case of unfair means.*

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- Q1. Explain robustness and ruggedness of process. [COI][1]
- Q2. Explain how GMP ensures quality control in production of biopharmaceutical? [COI][3]
- Q3. Are stringent regulations legitimate or do they just hampers business? [COI] [3]
- Q4. What are design qualification (DQ), installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) in biopharmaceutical production? [COI][3]
- Q5. Discuss importance of biosimilars development. Compare reference medicine and biosimilars medicine development. [COII][5]