

JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT
TEST -2 EXAMINATION- 2019
BTDD/ M.Tech IV Semester

COURSE CODE: 14M1WBT334

MAX. MARKS: 25

COURSE NAME: QC Analysis and Management

COURSE CREDITS: 03

MAX. TIME: 1.5 HR

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

- Q1. Explain why critical quality attributes is of utmost importance for biosimilars? How biosimilars are different from generic drugs? [COIII][4]
- Q2. How process validation and quality control for stability studies of pharmaceutical products are carried out? [COIII][4]
- Q3. Summarize the methods for routine control of biotechnological-derived products. How good manufacturing practice assure quality of products in biotech industry? [COIII][4]
- Q4. Provide all the factors which affect the quality of essential oil. Briefly explain the importance of hyphenated techniques used in QC of essential Oil. [COIV][4]
- Q5. Explain/answer followings. [COIV][1.5 x 6 =9]
- Conjugated product and degradation product
 - Sensory evaluation method for quality control
 - SOP and documentation for process QC
 - QC for Raw material
 - Qualification of equipment
 - QC for reference standard/ reagents