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JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT  
TEST -2 EXAMINATION- MARCH 2018  
M.Tech (IV<sup>th</sup>)/BTDD VIII<sup>th</sup> Semester

COURSE CODE: 14M1WBT334

MAX. MARKS: 25

COURSE NAME: Quality Control Analysis and Management

COURSE CREDITS: 3

MAX. TIME: 1.5Hr

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

Q1. Answer following questions.

- a) In the quality management, explain with example how cost of a product is linked with the quality? [2]
- b) Any systematic study on pharmaceutical products in human subject, whether in patients or other volunteers, in order to discover or verify the effects of, and/or identify any adverse reaction clinical trials are carried; how many phases clinical trials are divided? Each phase has characteristics, explain the each phase and distinguish each from other phases so as to ascertain the quality of the pharmaceuticals products? [3]
- c) Quality of food product is essentials; give accounts of why foods are processed? What quality parameters are required to pass through for processed food before its utilization? [3]

Q2. a) Describe important quality control guidelines related to Animal Facility and usage of animals in an University/ Research institute. What is the role of CPCSEA in implementation of such guidelines? [5]

Q3. Discuss 5Rs of ethics related to experimentation on animals. [3]

Q4. Answer the following questions.

- a) What parameters of HPLC systems 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]
- b) What are the main tests that need to be carried out to established identity, content and purity of chemically synthesized/or biotechnologically produced peptides/ proteins? Explain how stability studies of active pharmaceutical ingredients are carried out. [3]
- c) How GMP assure the quality of products in biotech industry? [2]