JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT
TEST-3 EXAMINATION- JUNE -2016
B.Tech/ M.Tech Xth/IVth Semester

COURSE CODE: 14M1WBT334   MAX. MARKS: 35
COURSE NAME: QC Analysis and Management
COURSE CREDITS: 03   MAX. TIME: 2 HRS

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

Q1. Answer the following questions.   [2 x 5=10]

 a) Why do we need quality assurance in environmental monitoring?

 b) List the steps followed in product annual review.

 c) Why good documentation practices are necessary?

 d) How the concept of quality management evolved over time?

 e) What is stability validation method programme?

Q2. Explain/ answer the following questions   [3 x 5=15]

 a) Audit is necessary in quality management system in any Biotech/Pharma industry. How auditor ensures that GLP is followed in lab or not?

 b) What is validation? Why should process be validated? How it is done?

 c) The role of sensory evaluation in food quality control.

 d) Define each of the following terms as they relate to Kano's model: dissatisfier, satisfier, and exciters/delighters. Explain how an exciter/delighter can become a satisfier in general and then provide a specific product example.

 e) What is meant by "six sigma quality" with respect to defect expectations?

Q3. What are fundamentals of the theory of constraints? How you can identify and tackle a process constraint?   [5]

Q4. Write in detail about the quality control aspects in production of Bio-pharmaceuticals by giving more emphasis on "Validation" strategies?   [5]