

Top of the list

JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT

TEST -3 EXAMINATION May-2018

BTDD/M.Tech Semester

COURSE CODE: 14M1WBT334

MAX. MARKS: 35

COURSE NAME: QC Analysis and Management

COURSE CREDITS: 3

MAX. TIME: 2 Hrs

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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. Answer the following questions.

- a) What is six sigma concepts? How it helps to improve the quality of the product?(2) [CO I]
- b) Good Manufactures Practices are specific to the biological products, what are they?(2) [CO II]
- c) There are certain quality characteristics for the food product before the human consumption, what quality parameters you assess to pass food products before its utilization? (3)[CO III]
- d) Food X-ray Inspection Equipment Provides Quality Assurance and Quality Control in the Food Industry, explain how? (3) [CO III]
- e) In case of spill or splash of biological products in the working area, what steps you will follow to avoid any potential injury? (3) [CO I]

Q2. Discuss quality control tests recommended by WHO during the final production of BCG vaccine. (3)[CO V]

Q3. Write Short Notes on the following: (6 X 2 = 12) [CO IV]

- A. Good Cell culture Practices (GCCP) followed in the quality control of Animal Cell Lines.
- B. Determination of ash content in Quality Control of Herbal Raw Materials.
- C. Quality control parameters for Probiotics and Role of Organisation for Economic Co-operation and Development (OECD).
- D. Quality control tests before release of Monoclonal Antibody Trastuzumab.
- E. Quality Control of Sterilization Processes for Pharmaceutical Products.
- F. Quality Control Tests for Radiopharmaceuticals.

Q4. Answer the following questions. [CO V]

- a) What are the components of process control chart? How they are determined? (2)
- b) What affects the quality of essential oil? Give any two examples for hyphenated techniques used in essential oil QC? (2)
- c) Write short notes on Validation" strategies for quality control? (2)
- d) Why is ISO important? (1)