



M.TECH. DEGREE EXAMINATIONS: APRIL / MAY 2023

(Regulation 2018)

Second Semester

BIOTECHNOLOGY

P18BTI2201: Quality Control and Quality Assurance in Biomanufacturing

COURSE OUTCOMES

- CO1:** Comprehend concept of quality assurance by design in industrial bio manufacturing practices of different biotechnology products.
- CO2:** Relate quality attributes, process parameters and target quality product profile and critically evaluate the product development process of bio based products.
- CO3:** Select appropriate analytical methods for the quality control of bio-based products.
- CO4:** Develop competency in constructing novel control chart to analyze the variation in data to analyze the probability of non-conforming units.
- CO5:** Understand quality assurance responsibilities.
- CO6:** Describe validation principles as applied to Bio manufacturing.

Time: Three Hours

Maximum Marks: 100

Answer all the Questions:-

PART A (10 x 1 = 10 Marks)

1. A typical large-scale cell culture process consists of a number of unit operations, including, _____ CO1 [K₃]
- (i) Production run
(ii) Seed train
(iii) Inoculum train
(iv) Evidence based decision making
- a) (ii) & (iii) only b) (ii), (iii) & (i)
c) (ii), (iii) & (iv) d) (iv) & (i)
2. _____ is NOT an element of ICHQ10 quality system. CO1 [K₂]
- a) Corrective action and Preventive action b) Pharmaceutical Quality system
c) Process Performance Product QMS d) Change Management system

Answer any FOUR Questions

PART D (4 x 10 = 40 Marks)

27. Demonstrate the process development involved with the production of monoclonal antibody with industrial examples. 10 CO1 [K₂]
28. Appraise the significance of the biological assays with industrial case studies in the development of recombinant/ herbal medicinal products. 10 CO2 [K₂]
29. Assess the industrial case studies associated with the evaluation of protein degraded products through cutting edge analytical methods. 10 CO3 [K₂]
30. Discuss the solution pertaining to the quality assurance during equipment breakdowns and maintenance. Add short notes on the following, (i) Out of Specifications (OOS) and (ii) Out of trend (OOT) 10 CO4 [K₃]
31. Develop a validation process for a new antibiotic which involves microbial inoculum development, product and downstream process validation. 10 CO5 [K₄]
