JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT

TEST -2 EXAMINATIONS-2022

M.Tech-II Semester (BT)

COURSE CODE (CREDITS): 14M1WBT334 (3) MAX. MARKS: 25

COURSE NAME: QC ANALYSIS AND MANAGEMENT

COURSE INSTRUCTORS: Dr. GOPAL SINGH BISHT MAX. TIME: 1 Hour 30 Min

Note: All questions are compulsory. Marks are indicated against each question in square brackets.

Q1. Find below a optimized process for disulphide bond formation of a therapeutic peptide. Design a quality assurance sheet for the process. [4]
Dissolve the lyophilized peptide at 0.5 mM concentration in a 5% acetic acid (10ml) solution. Add 10% volume of DMSO in a large beaker. Adjust the pH to 6.0 to 7.0 with a 0.5 M ammonium acetate solution. Stir the solution vigorously at room temperature for 12 h to incorporate atmospheric oxygen into the solution. Monitor disulphide bond formation by reverse phase HPLC. Purify the peptide reverse phase HPLC after acidification with a TFA solution (pH 2.0). Lyophilize the solution containing the collected fractions. Report yield of product obtained.

Q2. Design stability studies for a new active pharmaceutical ingredient for quality control and assurance [3]

Q3. By taking suitable example explain the utility of PDCA method in quality control of biopharmaceuticals. [3]

Q4. Make a relationship and differentiate among QA, QC AND GMP and substantiate that quality control is a part of good manufacturing Practice and good manufacturing practices is a part of quality assurance activities. [5]

Q5. Answer the following questions in context of quality control and assurance.

a) How system suitability test for HPLC is designed and highlights its importance. [2]

b) Provide all the factors which affect the quality of essential oils. Which important aspect is often overlooked when considering quality issues of essential oils? [3]

c) Give account of main tests that need to be carried out to establish identity, content and purity of chemically synthesized or biotechnologically produced peptides of proteins. [3]

d) It is important to utilize a validated liquid chromatography (LC) method when performing analysis. Enumerate analytical LC validation characteristics according to US Food Drug Administration (FDA). [2]