JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT
TEST -3 EXAMINATIONS- 2024
Ph.D./M.Tech.- I/M.Sc.III- Semester (BT)

COURSE CODE (CREDITS):20M1WBT231/21MS2MB414 (3)

COURSE NAME: QC ANALYSIS AND MANAGEMENT

COURSE INSTRUCTORS: Dr. Gopal Singh Bisht/Dr. Poonam Sharma

MAX. MARKS: 35

MAX. TIME: 2 Hour

Note: (a) All questions are compulsory.
(b) Marks are indicated against each question in square brackets.
(c) The candidate is allowed to make Suitable numeric assumptions wherever required for solving problems

Q1. Answer the followings questions. [10]
   a) Elaborate the Factors Affecting Microbiological Strain Quality. [2]
   b) Explain the relationship between GLP and GMP in QC.[3]
   c) Elaborate the different types of Quality Audit. [3]
   d) Describe the qualitative and quantitative analysis for pharmaceutical products. [2]

Q2.a) A production manager at a tire manufacturing plant has inspected the number of defective tires in twenty random samples with twenty observations each. Following are the number of defective tires found in each sample:

Sample no	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
No. of defective Tires	3	2	1	2	1	3	3	2	2	2	3	2	2	1	1	2	4	3	1	1
No. of observation sampled	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20

Construct a three-sigma control chart ($z= 3$) with this information. [5]

B)

Given below are the values of sample mean and range for 10 samples each of size 5. Draw the appropriate mean and range charts and comment on the state of control of the process. [5]

Sample no	1	2	3	4	5	6	7	8	9	10
Mean	43	49	38	43	45	36	51	46	42	46
Range	4	6	5	7	7	8	8	6	4	6

From the table of control chart constant for sample size n=5 we have $A_2=0.577$, $D_3=0$ and $D_4=2.115$

Q3. Discuss importance of sensory evaluation in Quality Control. Explain Triangle test and Duo-trio test used in sensory evaluation. Enumerate factors influencing sensory perception. [4]

Q4. Study the following case and suggest a solution. [6]

CASE STUDY
ABC Biotech is a leading biotechnology firm that specializes in the development and production of biopharmaceuticals, including vaccines, monoclonal antibodies, and recombinant proteins. With a strong focus on innovation and quality, ABC Biotech is committed to delivering safe and effective products to patients worldwide.

Problem Statement
ABC Biotech experienced an increase in the number of deviations and non-conformances reported during the production of a critical monoclonal antibody product. These quality issues led to delays in product release, increased production costs, and concerns from regulatory bodies. YOU HAVE BEEN ASIGNED A TASK to revamp their quality control (QC) processes to address these challenges and ensure compliance with stringent regulatory requirements.

Quality Control Objectives
1. Reduce the number of deviations and non-conformances by 40% within one year.
2. Implement a robust QC system to ensure product safety and efficacy.
3. Achieve compliance with international regulatory standards (e.g., FDA, EMA).

Q5. Enumerate the responsibilities of the Food Safety and Standards Authority of India (FSSAI). Explain the essential components that make up QC for a Food Manufacturer. [5]