JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT

TEST -2 EXAMINATION- 2025

M.TECH.-II/M.Sc.-IV Semester (BT/BI)

COURSE CODE (CREDITS):20MIWBT231/21MS2B414 (2) MAX. MARKS: 25 Min

COURSE NAME: QC Analysis and Management

COURSE INSTRUCTORS: Dr. Gopal Singh Bisht MAX. TIME: 1 Hour & 30 Minutes

Note: *(a) All questions are compulsory.*
(b) The candidate is allowed to make Suitable numeric assumptions wherever required for solving problems

<table>
<tr><th>Q.No</th><th>Questions</th><th>Marks</th></tr>
<tr><td>Q1</td><td>15 samples of 200 items each were drawn from the output of a process. The Number of defective items in the samples is given below. Prepare a control chart for the fraction defective and comment on the state of control.
<table>
<tr><td>Sample no (i)</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td><td>11</td><td>12</td><td>13</td><td>14</td><td>15</td></tr>
<tr><td>No of defectives (np)</td><td>12</td><td>15</td><td>10</td><td>8</td><td>19</td><td>15</td><td>17</td><td>11</td><td>13</td><td>20</td><td>10</td><td>8</td><td>9</td><td>5</td><td>8</td></tr>
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</td><td>6</td></tr>
<tr><td>Q2</td><td>Develop a detailed plan for conducting a Hazard and Operability (HAZOP) Study in the Biotech/Pharma industry. Outline the key steps involved in the analysis, using suitable examples from biopharmaceutical manufacturing or related processes. Additionally, explain the benefits and limitations of the HAZOP methodology in this industry</td><td>5</td></tr>
<tr><td>Q3</td><td>Design a validation Master Plan (VMP) for development of API in XYZ Biotechnology Company.</td><td>4</td></tr>
<tr><td>Q4.</td><td>Explain the role of Gas Chromatography-Mass Spectrometry (GC-MS) in the quality control of essential oils. Examine the various factors influencing the chemical composition of essential oils.</td><td>4</td></tr>
<tr><td>Q5.</td><td>a) What factors can cause variations in HPLC results, and how can they be minimized? Critically evaluate the advantages and limitations of HPLC compared to Gas Chromatography (GC) in quality control.
b) If a Pareto chart for an HPLC laboratory shows that calibration errors account for 45% of failures, but addressing calibration alone does not improve results significantly, what should be the next step?</td><td>4

2</td></tr>
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