UNIVERSITI KUALA LUMPUR
MALAYSIAN INSTITUTE OF CHEMICAL AND BIO-ENGINEERING TECHNOLOGY

FINAL EXAMINATION

OCTOBER 2025 SEMESTER

COURSE CODE	:	CSB30603
COURSE TITLE	:	QA & QC IN BIOPRODUCTS
PROGRAMME NAME	:	BACHELOR OF CHEMICAL ENGINEERING TECHNOLOGY (BIOPROCESS) WITH HONOURS
DATE	:	03 FEBRUARY 2026
TIME	:	2:00PM - 5:00PM
DURATION	:	3 HOURS

INSTRUCTIONS TO CANDIDATES

1. Please read the instructions given in the question paper CAREFULLY.
2. This question paper is printed on both sides of the paper.
3. This question paper consist of TWO sections.
4. Answer ALL questions for Section A.
5. Section B consist of four questions. Answer THREE (3) questions only.
6. Please write your answer on the answer booklet provided.
7. Please answer all questions in English only.
8. Please answer MCQ/EMQ questions using OMR sheet. ☐ *Tick if applicable*
9. Refer to the attached Formula/ Appendies. ☐ *Tick if applicable*

THERE ARE 8 PAGES OF QUESTIONS INCLUDING THIS PAGE

SECTION A (Total: 40 marks)

Answer ALL questions.

Please use the answer booklet provided.

Question 1

Quality is a critical requirement in bioproduct manufacturing to ensure products consistently meet specified standards for safety, efficacy, and regulatory compliance.

(a) Explain the difference between Quality Assurance (QA) and Quality Control (QC) in the context of bioproduct manufacturing.

(5 marks)

(b) A company produces a probiotic drink as a bioproduct. Describe FIVE (5) key quality characteristics that should be checked before product release.

(5 marks)

Question 2

Total Quality Management (TQM) and ISO 9001:2015 provide structured approaches to build quality into bioprocess operations.

(a) Explain FIVE (5) core principles of Total Quality Management (TQM).

(5 marks)

(b) Describe how the Plan-Do-Check-Act (PDCA) cycle supports the structure of ISO 9001:2015 by linking PDCA to the major ISO 9001 clause groups (Clauses 4–10).

(5 marks)

Question 3

Please answer these questions.

(a) Differentiate between chance-cause variation and assignable-cause variation in a process with ONE (1) example of each in a bioprocess operation.

(5 marks)

(b) Describe FIVE (5) GMP practices used to prevent contamination and mix-up in a bioproduct manufacturing area.

(5 marks)

Question 4

These questions are related to Hazard analysis critical control point (HACCP) and Halal in bioprocess industry.

(a) Define hazard and give examples for each type of hazards.

(5 marks)

(b) Describe halal pharmaceuticals according to MS 2424:2019.

(5 marks)

SECTION B (Total: 60 marks)

Answer THREE (3) questions only.

Please use the answer booklet provided.

Question 1

A packaging line fills enzyme powder sachets with a target net weight of 50.0 g. Every 30 minutes, 5 sachets are sampled (subgroup size n = 5) and recorded for 10 subgroups. The data is tabulated in the following table.

Refer Below - Table1 : Weight of sachets .

Table 1: Weight of sachets

	Weight of sachets (g)				
Subgroup	**X1**	**X2**	**X3**	**X4**	**X5**
1	49.98	50.04	49.98	49.98	49.93
2	49.99	50.08	50.03	50.07	50.02
3	50.03	50.01	49.88	50.06	50.04
4	50.03	49.88	49.88	49.94	49.97
5	50.02	50.00	50.04	49.96	50.02
6	50.03	49.95	50.12	50.04	50.08
7	49.62	49.88	50.01	50.11	50.42
8	50.31	50.30	50.33	50.34	50.39
9	50.37	50.32	50.28	50.31	50.44
10	50.29	50.37	50.38	50.25	50.35

(a) Analyse the data to calculate the overall average ($\bar{\bar{x}}$) and determine the $\bar{x}$-chart parameters (center line, UCL, and LCL). Given $A_2 = 0.577$ for n = 5.

(10 marks)

(b) Decide whether the process is in control or out of control based on $\bar{x}$ chart plot with justification.

(10 marks)

Question 2

During a GMP internal audit of a non-sterile bioproduct manufacturing area, the following observations were recorded:

i. Handwritten corrections in batch records were made using correction fluid (no signature/date).

ii. A bulk intermediate container was found **without label status** (no batch number, no "Quarantine/Released" status).

iii. Incoming raw materials were stored directly in the production area before QC release.

iv. Two different products were processed consecutively in the same room with no documented line clearance.

v. No record on weighing balance calibration.

(a) Analyse FIVE (5) GMP non-compliances based on the internal audit observations.

(10 marks)

(b) Assess the potential impact of non-compliances on product quality and safety.

(10 marks)

Question 3

The following processes are part of ice cream manufacturing steps. Hazard analysis and identification has been conducted and the results are presented in the table below:
Refer Below - Table2 : Ice cream manufacturing steps .

Table 2: Ice cream manufacturing steps

Process step	Identified hazard	Control measures
Mixing the ingredients	Residual chemicals from cleaning agents used on mixing equipment	Implement good manufacturing practices (GMP), including cleaning and sanitization protocols
Pasteurisation	Living pathogens after pasteurisation	Maintain pasteurisation at the correct temperature and time
Homogenisation	Physical contamination (e.g., metal fragments) from homogeniser wear/seal failure	Preventive maintenance and inspection of homogeniser parts (seals, valves)

(a) Analyse the process to determine ONE (1) critical control point using decision tree.
Refer Appendix Attachment - Decision tree .

(10 marks)

(b) Develop the monitoring element by specifying the critical limit, monitoring method and frequency, corrective action, verification, and records for the identified CCP.

(10 marks)

Question 4

A bioprocess facility intends to certify a Halal probiotic capsule product. The formulation and process include:
Capsule shell: gelatin (supplier did not state animal source and slaughtering status)
Lubricant: magnesium stearate (source not declared)
Process aid: enzyme (trypsin) used in processing
Shared equipment previously used for a non-halal product line, with cleaning records available but no halal-specific segregation records
Solvent: Ethanol (alcohol) used during preparation and extraction (source and residual level not declared, no halal-compliance documentation).

(a) Discuss halal concern related to the formulation and processing of probiotic capsule.

(10 marks)

(b) Identify the control methods for each concerns to ensure halal status of the product (include controls related to materials documentation, equipment/segregation, personnel/training, and records/auditing).

(10 marks)

END OF EXAMINATION PAPER

APPENDIX

Appendix for Section B Question 3 (a) : Decision tree