Universiti Tun Hussein Onn Malaysia

UNIVERSITI TUN HUSSEIN ONN MALAYSIA

FINAL EXAMINATION
SEMESTER I
SESSION 2022/2023

COURSE NAME	:	QUALITY ASSURANCE AND QUALITY CONTROL IN BIOTECHNOLOGY
COURSE CODE	:	BNN 20303
PROGRAMME CODE	:	BNN
EXAMINATION DATE	:	FEBRUARY 2023
DURATION	:	3 HOURS
INSTRUCTION	:	1. ANSWERS **ALL** QUESTIONS 2. THIS FINAL EXAMINATION IS CONDUCTED VIA **CLOSED BOOK**. 3.STUDENTS ARE **PROHIBITED** TO CONSULT THEIR OWN MATERIAL OR ANY EXTERNAL RESOURCES DURING THE EXAMINATION CONDUCTED VIA CLOSED BOOK

THIS QUESTION PAPER CONSISTS OF **SEVEN (7)** PAGES

Q1 (a) A good quality assurance and quality control developed by engineers, quality experts, and inspectors can mitigate risk, saving time and cost to industries. State **TWO (2)** differences between *quality assurance* and *quality control.*

(4 marks)

(b) The Food and Drug Administration (FDA) defines current Good Manufacturing Practices (cGMP) as the "minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product". Describe and discuss **FIVE (5)** important principles of cGMP.

(5 marks)

(c) During manufacturing of Vitamin C tablet, pre-compression had to be performed to determine the operating parameters for tablet compression, leading to different settings for every batch. Complaints had also been received on the inconsistencies in the size of tablets formed. Position yourself as a quality officer and based on the abovementioned issues, apply **TWO (2)** immediate interventions in preserving product's quality and justify your actions.

(4 marks)

(d) One of the crucial steps to ensure safety and legality in food production is by conducting hazard analysis critical control point (HACCP). Based on **Figure Q1(d);**

(i) Identify **FOUR (4)** critical points and the potential hazards that may be present at those points.

(8 marks)

(ii) Evaluate the corrective measures that can be developed to control each point for preservation of quality.

(4 marks)

Q2 (a) The implementation of quality by design (QbD) may lead to a successful product development. Debate on the advantages and disadvantages and justify your stand.

(6 marks)

(b) A new recombinant drug which generated by *S. aureus* will be introduced by Novartis and the top management has decided that prior to full scale development, its production must undergo QbD approach.

(i) As the quality assurance officer, you together with your team are responsible for the activities. Evaluate and examine the QbD processes/details that must be taken into considerations during production of high-quality drug. Extensively explain.

(7 marks)

(ii) Identify **TWO (2)** widely use tools to minimize risk and relate their application in QbD activities in **Q2(b)(i).**

(4 marks)

(c) PharmaNoir Sdn. Bhd. processes Gabapentin from powder form to granulates before the granules being compressed into tablet form. However, while in the warehouse, it was found that most of the tablets are loosened and change in size. By using a Fishbone diagram, deduce potential problem sources related to product defects.

(8 marks)

Q3 (a) ProNature Living Solutions Sdn. Bhd. is a medium company with 20 million revenues; hence, it requires Halal Assurance System (HAS). Appointed as the Halal Executive, you are responsible to lead the establishment of HAS for its food supplements. Illustrate the process flow of HAS development and relate **TWO (2)** activities that must be conducted in each stage.

(12 marks)

(b) Prior to its processing to tablet form as food supplement, the plant extracts will undergo freeze drying process. **Table Q3(b)** shows the sizes of samples taken every hour for 8 hours.

(i) Based on **Table Q3(b),** calculate the mean of particle size and sketch the X-bar chart. (Given UCL = 102, CL = 100, LCL = 98)

(10 marks)

(ii) From the sketched Figure in **Q3(b)(i),** predict **ONE (1)** condition of the process. Determine **TWO (2)** further actions to be taken to control the process.

(3 marks)

Q4 (a) The production manager at manufacturing facilities of Cadbury Malaysia is required to improve a delay in production time which has been reported lately. He decided to investigate this issue by screening through recorded data in the facility for three months. **Table Q4(a)** shows the type and frequency of problems that may lead to this delay.

(i) Evaluate the data in **Table Q4(a)** and draw a *Pareto Chart.*

(12 marks)

(ii) Based on the *Pareto Chart* in **Q4(a)(i),** identify **TWO (2)** areas to focus on and provide **TWO (2)** recommendations for improvement.

(3 marks)

(b) A Gantt chart provides a graphical illustration of a schedule that helps to plan, coordinate, and track specific tasks in a project.

(i) Given the information provided in **Table Q4(b)(i),** draw a chart with overlaps as specified.

(7 marks)

(ii) By referring to your Gantt Chart in **Q4(b)(i)**, estimate how long the project should last?

(1 mark)

(iii) Identify **ONE (1)** critical activity in the project planning and explain the controls that may be taken to make sure that the plan is delivered on time.

(2 marks)

-END OF QUESTIONS –

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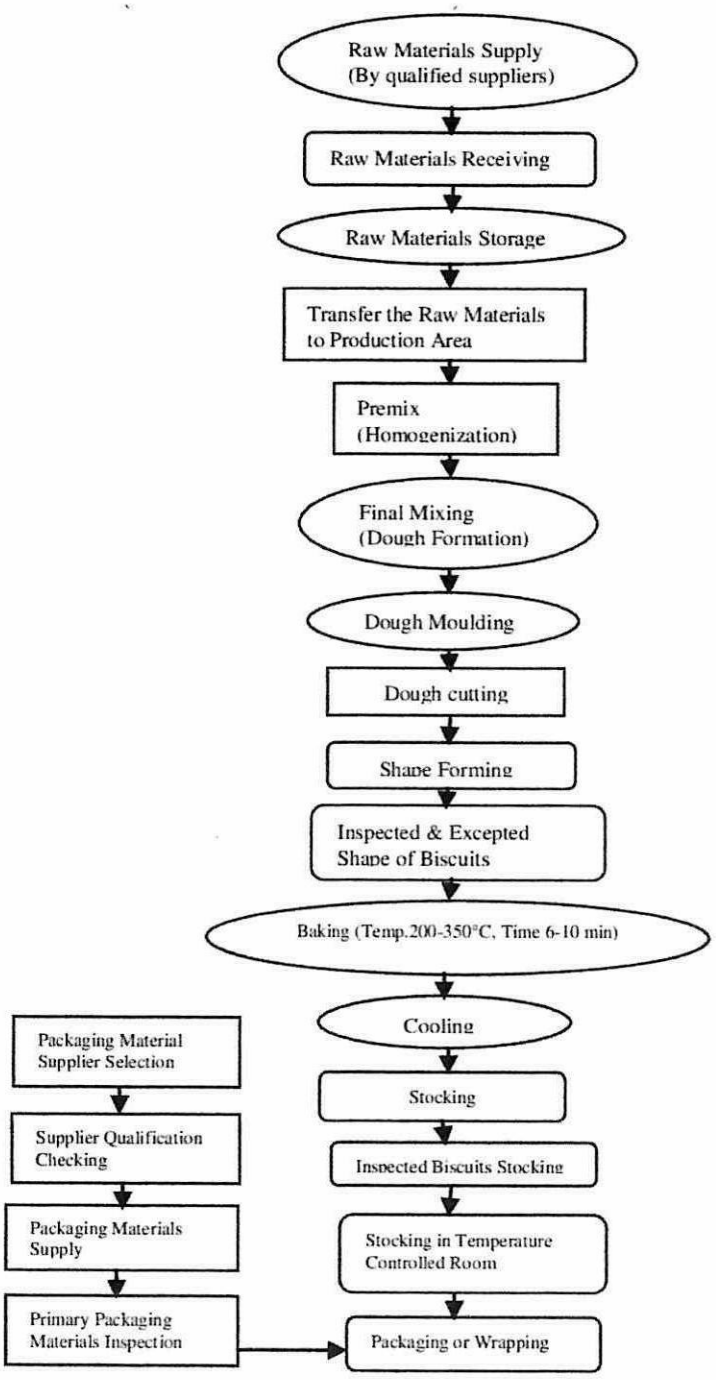

Figure Q1 (d)

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Table Q3(b): The size of particles

Sample (hour taken)	Item No.		
	1	2	3
1	99.8	99.6	99.5
2	98 .5	98 .2	98 .6
3	101.1	100.8	100 7
4	100.3	100.2	100.4
5	101.3	101.4	101.6
6	101.6	101.5	101. 7
7	101.8	101.6	101. 7
8	102 7	102.6	102.9

Table Q4(a): Frequency of problems in Cadbury Malaysia facility.

Problems	**March**	**April**	**May**
Calibration of equipment	25	27	30
Personnel	18	17	15
Environment	5	4	7
Reagent used	4	6	3
Calibration method	2	4	3

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Table Q4(b)(i): List of activities description and duration.

Activity Letter	Activity Description	Predecessor	Duration (months)	Overlap (months)
A	Train project team	None	1	None
B	Project paperwork and process design	A	2 ½	¼
C	Modify purchased package	B	2	1
D	Manual systems flow	B	1 ½	1
E	Modify in-house procedures	B	4	1
F	Test and implement modifications to purchased package	C	1 ½	1/8
G	Test and implement manual	D	¾	1/ 8
H	Test and implement modifications to in-house procedures	E	1	1/ 8