Universiti Tun Hussein Onn Malaysia

UNIVERSITI TUN HUSSEIN ONN MALAYSIA

FINAL EXAMINATION
SEMESTER I
SESSION 2021/2022

COURSE NAME	:	QUALITY ASSURANCE & QUALITY CONTROL IN BIOTECHNOLOGY
COURSE CODE	:	BNN 20303
PROGRAMME CODE	:	BNN
EXAMINATION DATE	:	JANUARY / FEBRUARY 2022
DURATION	:	3 HOURS
INSTRUCTION	:	1. ANSWERS **ALL** QUESTIONS. 2. THIS FINAL EXAMINATION IS AN **ONLINE** ASSESSMENT AND CONDUCTED VIA **OPEN BOOK.**

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

Q1 Current Good Manufacturing Practice (cGMP) is a very delicate issue. It looks simple but it is very difficult to practice successfully. Everybody knows rules of cGMP but very few are successful in interpreting the same precisely. Following is a case regarding the cGMP:

Company:
Bulk Drug unit at Nashik
Candidate:
Doctorate in Biochemistry. No apparent experience and knowledge of Pharmaceuticals. No much awareness on method validation, impurity profiling and High Performance Liquid Chromatography (HPLC) operations.
Appointed as:
Quality Control (QC) In charge
Problem encountered:
The person was effective in conducting day today analysis. However, he miserably failed in resolving complaints regarding stability, forced degradation and bioburden. He could not achieve standardization of the products with alternative methods. He failed in organizing drug master files.

(a) From the above case, predict **ONE (1)** mistake resulting in failures in cGMP compliance.

(1 mark)

(b) Based on answer in **Q1 (a),** outline **FOUR (4)** characteristics that the QC In Charge shall have to ensure cGMP is complied.

(4 marks)

(c) As a general manager of the company, extensively analyze the elements of your company must adhere in order to provide a high level assurance that medicines are manufactured in a way that ensures their safety, efficacy and quality.

(15 marks)

Q2 *Process design* means the complete delineation and description of specific steps in the production process and linkage among the steps that will enable the production system to produce products of the desired quality, in the required quantity.

(a) As a project manager of B-SMAT Resources Sdn Bhd, prepare the design process approach for a new biopharmaceutical product (*Babylaena Wound Healing Cream*), in order to ensure that it can be feasibly developed with adherence to schedules and cost.

(15 marks)

(b) During production of *Babylaena Wound Healing Cream*, it is considerably more challenging due to incomplete understanding of their mechanisms of action, as well as the variability of starting materials.

(i) Identify **ONE (1)** technique that can be implemented to overcome these challenges (for upstream manufacturing processes).

(1 mark)

(ii) Conclusively summarize the technique mentioned in **Q2 (b) (i).**

(4 marks)

Q3 Halal Assurance System (HAS) provides a systematic approach to ensure and preserve halal integrity of products. To date, halal awareness and detailed on halal implementation in food and beverages industry have been established. However, there is lacking in halal implementation for pharmaceutical industry.

(a) Discuss **FOUR (4)** responsibilities of Halal Executive (HE) in a pharmaceutical company.

(4 marks)

(b) Being an Internal Halal Committee (IHC) member at processing area of RNA production, determine **THREE (3)** halal control points (HCP) in **Figure Q3 (b).** Justify your selections.

(6 marks)

(c) BioAmore is a pharmaceutical company which plans to set up HAS in the company. Position yourself as one of the appointed IHC members, analyze the components of HAS that may be related to your company and the activities that must be performed in order to establish HAS in the company.

(10 marks)

Q4 (a) During granulation process, active pharmaceutical ingredient was mixed together with its excipients to aid for a better flow in compacting process. However, upon granulation process it was found that the ingredients were not binding together and produced uneven sizes of materials. The QC team needs to find the root cause of this problem before starting granulation process of next batch of medicine. By employing **ONE (1)** appropriate QC technique, draw and evaluate the possible causes that could lead to the abovementioned problems.

(10 marks)

(b) Data in **Table Q4 (b)** were collected after the dispense of granulated medicine into its capsule. The specification of weight for the intended medicine is in the range of 1.5 – 1.7g.

(i) Utilise **ONE (1)** suitable tool to process and examine the data.

(8 marks)

(ii) From the pattern seen in the graph produced in **Q4 (b) (i),** deduce whether the production process is successful or not and why do you think so.

(2 marks)

Q5 (a) In 2020, production of Vaccine X reached 95% of its target for the first quarter. However, in the same period of time in 2021, the production showed significant reduction. As the production manager, you are responsible to track the incidences of lost time on the production floor and they are all as recorded in **Table Q5 (a).**

(i) Based on the data given in **Table Q5 (a)**, generate a meaningful chart and conclude on the best action that needs to be taken.

(8 marks)

(ii) Propose **TWO (2)** solutions to rectify the problem(s) identified in **Q5 (a) (i)**.

(2 marks)

(b) Process validation and verification plays an important part in quality control. As quality control officer in a company producing monoclonal antibodies, internal audit is conducted frequently on the production line to ensure high quality products are being developed. Based on **Figure Q5 (b)**, determine **FIVE (5)** critical points in the bio-manufacturing of the biopharmaceutic and relate any changes in the factors/parameters on each point to the quality of product.

(10 marks)

-END OF QUESTIONS –

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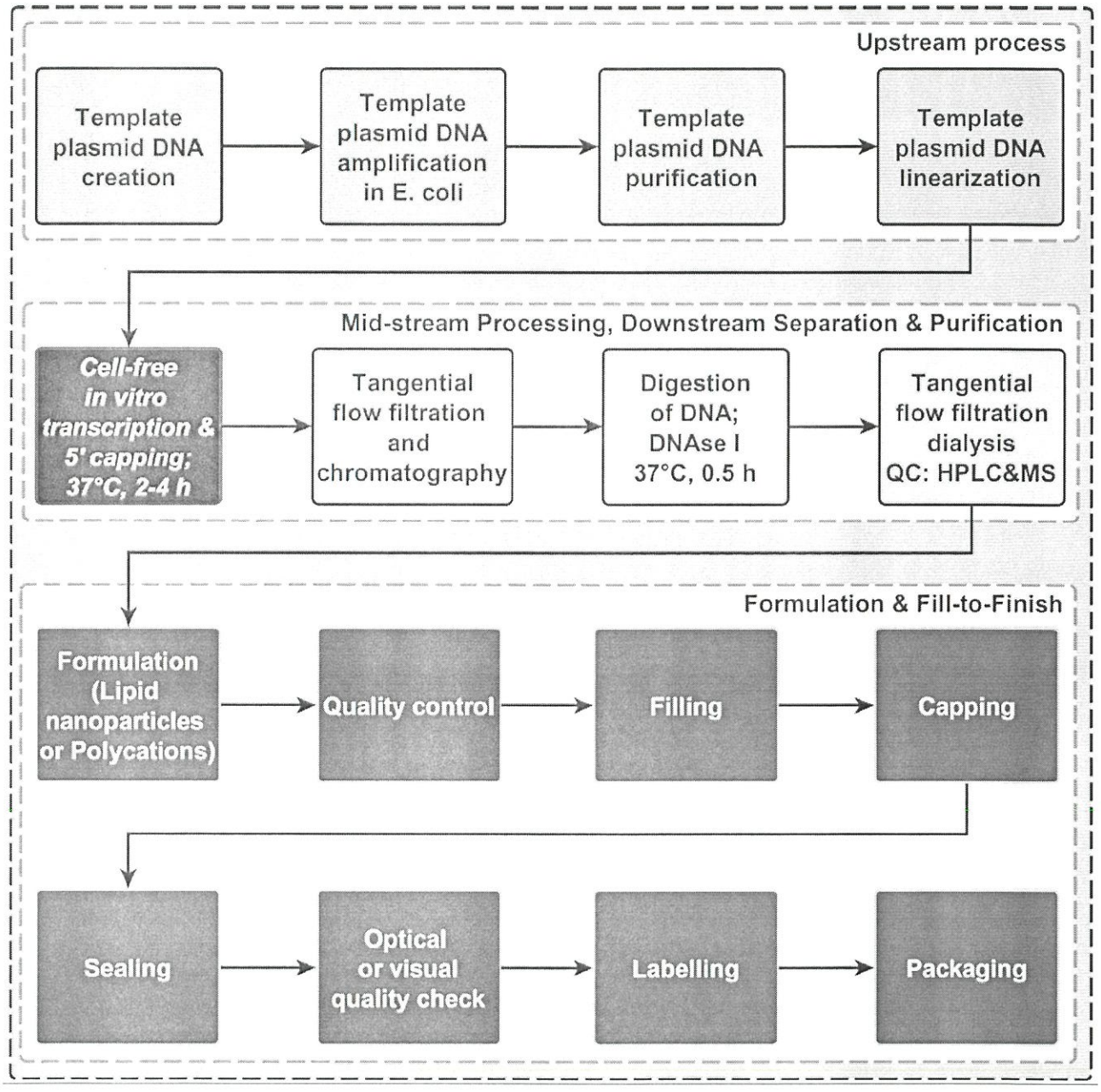

Figure Q3 (b)

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Table Q4 (b)

1.43	1.66	1.2	1.34	1.8
1.52	1.69	1.94	1.85	1.97
1.47	2.19	1.12	1.93	1.55
1.81	1.73	1.71	1.64	1.59
1.4	1.99	1.83	1.19	1.95
1.62	1.92	1.74	1.96	1.24
1.76	1.45	2.01	1.7	1.68
1.72	1.43	1.03	1.45	1.82
1.56	1.47	1.87	1.38	1.79
1.68	1.15	1.8	1.16	1.58

Table Q5 (a)

Causes of lost time	Incidences
Work instructions	87
Bill of materials	26
Out of stock	15
Packaging	12
Wrong parts	8
Final product defects	2
TOTAL	**150**

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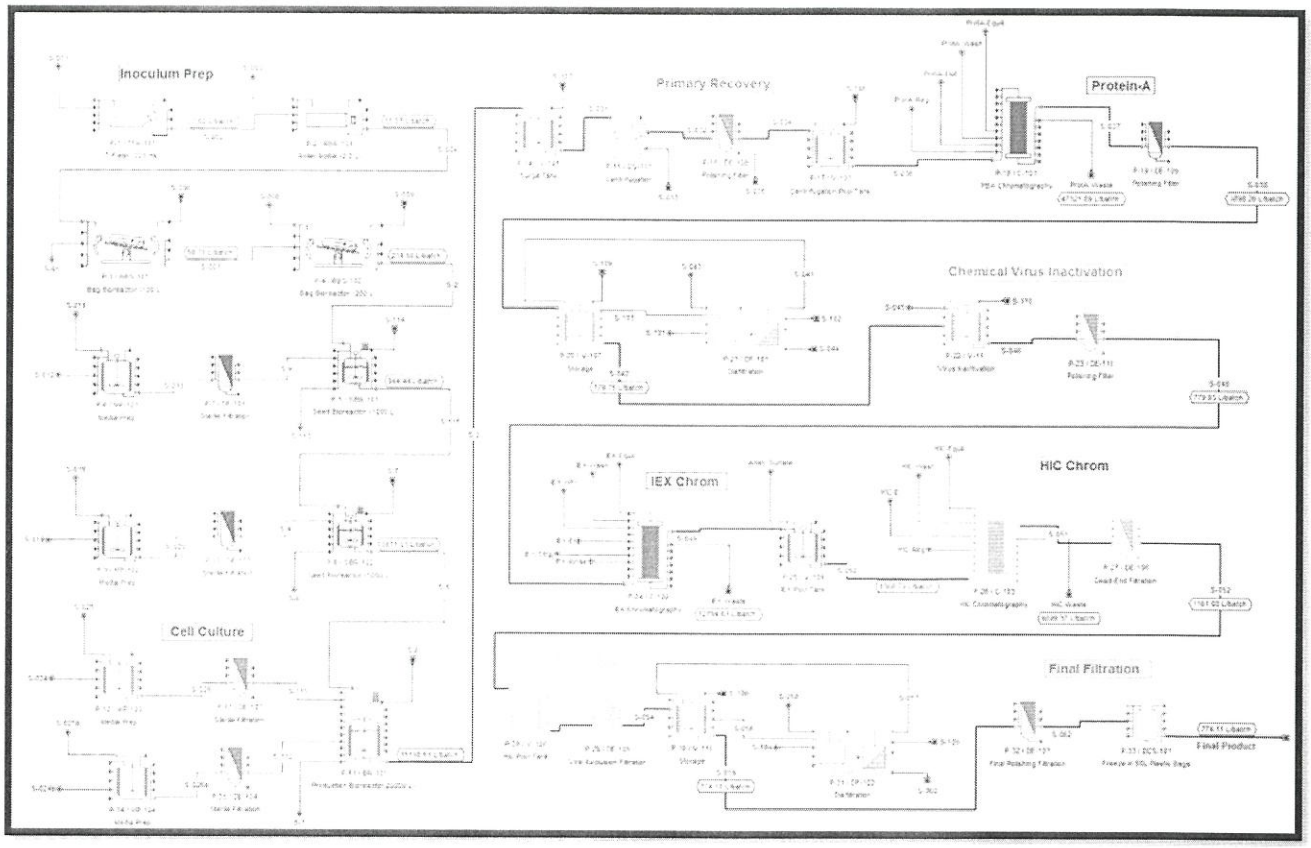

Figure Q5 (b)