Universiti Tun Hussein Onn Malaysia

UNIVERSITI TUN HUSSEIN ONN MALAYSIA

FINAL EXAMINATION
SEMESTER II
SESSION 2023/2024

COURSE NAME	:	BIOPHARMACEUTICAL TECHNOLOGY
COURSE CODE	:	BNN 40203
PROGRAMME CODE	:	BNN
EXAMINATION DATE	:	JULY 2024
DURATION	:	3 HOURS
INSTRUCTION	:	1. ANSWER ALL QUESTIONS 2. THIS FINAL EXAMINATION IS CONDUCTED VIA ☐ Open book ☒ 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 **FOUR (4)** PAGES

Q1 (a) Vaccination is one of the most successful public health interventions in reducing disease spread, preventing complications and even deaths from vaccine preventable diseases. Even so, all medications and vaccines have potential risks that must be carefully weighed against the benefits that medications and vaccines offer to prevent illness. As such, continues studies as well as monitoring of the use of medications and vaccines are conducted.

(i) Name **ONE (1)** global regulatory agency and describe its specific function in controlling pharmaceutical industry.

(2 marks)

(ii) Explain the activities that are conducted in **FOUR (4)** phases of a clinical trial for a new vaccine.

(4 marks)

(iii) Discuss **TWO (2)** challenges in ensuring continuous development of safe and effective vaccines.

(4 marks)

(b) The projected growth of the global pharmaceutical market in the next few years is expected to be significant. According to the market survey, the pharmaceutical market worldwide is projected to grow by 6.19% from 2024 to 2028, resulting in a market volume of US$1470.00 billion in 20281. Additionally, the global pharmaceutical market size is expected to grow from USD 1482.4 million to USD 2067.36 million by 2028, at a compound annual growth rate (CAGR) of approximately 5.70%. Examine **FIVE (5)** key aspects that are shaping the future landscape of the pharmaceutical sector and evaluate further on these aspects.

(15 marks)

Q2 (a) Pre-formulation step investigates the physical-chemical properties of the drug substance, alone and in combination with excipients to assess possible incompatibilities between the drug and different excipients.

(i) Define the term excipient.

(1 mark)

(ii) Provide your opinions on the effectiveness and toxicity of excipients. Explain and justify your opinions appropriately.

(4 marks)

(b) The route of administration of a drug is vital as it will determine the drug's bioavailability to the targeted cells or organs, hence its efficacy. Differentiate between enteral and parenteral routes of administration and give an example for each route of administration.

(4 marks)

(c) Daily subcutaneous injection of insulin causes discomfort to individuals as well as increased the risk of infection due to the needle used. In order to maintain compliance and reduce infection, better alternative for administration is required. Choose **ONE (1)** advanced insulin delivery technology and thoroughly explain the development of its technology and application to overcome disadvantages in subcutaneous administration.

(6 marks)

(d) During commercial production of biopharmaceutics, the onset of cell death must be slowed down and concurrently high cell viability is maintained in the culture to maximize productivity. Adopt and relate **TWO (2)** strategies and technologies that can be employed to ensure constant high cell viability during upstream bioprocess.

(4 marks)

(e) Routine sampling found that the yield of rDNA insulin did not achieve its targeted productivity at designated period. When the process record was checked, it was eventually identified that the issues originated from scale-up process. As the bioprocess engineering technologist, determine **THREE (3)** critical parameters in the bioreactor that could have affected rDNA insulin production and analyse the possibility of each parameter affecting the production.

(6 marks)

Q3 (a) Bioseparation is to refine molecules, cells and parts of cells into purified fractions based the following characteristics: density, diffusivity, electrostatic charge, polarity, shape, size, solubility and volatility.

(i) Discuss **TWO (2)** challenges in bioseparation of pharmaceutics and what can be done to overcome those challenges.

(4 marks)

(ii) Compare and contrast the principles of affinity chromatography and ion exchange chromatography in the protein purification. Sketch diagrams to assist your answer.

(8 marks)

(b) (i) Discuss **THREE (3)** roles of granulation in pharmaceutical industry.

(3 marks)

(ii) Illustrate and explain wet granulation process of a drug.

(4 marks)

(c) The stability of drug is very important for safety and efficacy. Determine **TWO (2)** analytical methods that can be conducted regularly during drug tablet production and briefly explain on the methods.

(6 marks)

Q4 (a) Good Manufacturing Practices (GMP) is the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use. Identify **THREE (3)** requirements in GMP and provide examples of situations where GMP has played a crucial role.

(9 marks)

(b) Discuss issues such as the globalization of the pharmaceutical supply chain, emerging technologies, and the increasing complexity of biopharmaceutical products. Propose innovative solutions to address these challenges and maintain high-quality standards.

(6 marks)

(c) You are the head of safety officers in Natura Pharmaceutical Sdn. Bhd who is responsible in managing and monitoring safety aspects. Examine **FIVE (5)** important elements of Safety, Health and Environment Protection (SHE) to be applied in the factory and evaluate in detail the reasons why these elements are critical.

(10 marks)

- END OF QUESTIONS -