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**UNIVERSITI TUN HUSSEIN ONN MALAYSIA**

**FINAL EXAMINATION  
SEMESTER I  
SESSION 2016/2017**

COURSE NAME : BIOPHARMACEUTICAL  
TECHNOLOGY

COURSE CODE : BNN 40203

PROGRAMME : 4 BNN

DATE : DECEMBER 2016 / JANUARY 2017

DURATION : 3 HOURS

INSTRUCTION : ANSWER ALL QUESTIONS

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THIS QUESTION PAPER CONSISTS OF **THREE (3)** PAGES

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- Q1** (a) Differentiate the terms ‘pharmaceuticals’ and ‘biopharmaceuticals’. Give **ONE (1)** example for each term. (4 marks)
- (b) Name **ONE (1)** technology that can be employed in the synthesis of pharmaceuticals and biopharmaceuticals, respectively. (2 marks)
- (c) Discovery and development of a medicine is a long and complex process. As a general manager of a newly developed pharmaceutical company, a strategic planning is needed mainly to reduce time and cost of the production. Organise a plan for discovering and developing a drug. Include the strategies needed for the company until the full development stage of the product. (15 marks)
- (d) Determine **TWO (2)** possible challenges in the discovery and development of a drug and provide **ONE (1)** solution for each of the challenge. (4 marks)

- Q2** (a) Protein purification involves the isolation of one or a few proteins from a complex mixture and it is a vital process for the characterization of the function, structure and interactions of the protein of interest.
- (i) Identify **THREE (3)** chromatographic methods that can be used to separate the proteins. (3 marks)
- (ii) A mixture of three proteins, namely catalase, haemoglobin and cytochrome c has been retained after cells were broken down. Employing **ONE (1)** of the aforementioned methods in **Q2(a)(i)**, demonstrate the sequence of protein that will be eluted off the column and justify your findings. The characteristics of these proteins are listed in Table 1.

Table 1: Proteins and its characteristics

Protein	Molecular weight (kDA)	Net charge on protein
Catalase	232	-ve
Haemoglobin	64	-ve
Cytochrome c	12	+ve

(7 marks)

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- (b) Effective drug delivery system is an important aspect to ensure higher chances of drug reaching its target and the most convenient and cheapest way is by oral delivery. In addition to oral, few other routes are also available.
- (i) High blood glucose level in diabetic individual can be controlled by taking oral or subcutaneous medication. Discuss **TWO (2)** advantages and disadvantages of these routes and name **ONE (1)** diabetes drug for each route. (6 marks)
- (ii) Peptide X has the potential to be commercialized as *in vitro* studies showed positive results. However, the peptide has a short half-life due to enzymatic degradation and it is also easily removed by the kidney. Studies on its capacity to cross blood-brain barrier resulted in no trace of peptide X in isolated brain cells, indicating no blood-brain transfer of the potential drug. Propose **THREE (3)** ways or technologies that can be adopted to enhance the actions of peptide X. (9 marks)
- Q3** (a) Define the term 'granulation'. (4 marks)
- (b) Compare and discuss the differences between 'wet granulation' and 'dry granulation' techniques. (6 marks)
- (c) The biopharmaceutical company that you are currently working with opts for dry granulation. Propose **ONE (1)** type of dry granulation technology and design the process for your plant. Clearly discuss each step, advantages and disadvantages of the chosen process. Provide a schematic diagram of the process. (15 marks)
- Q5** (a) Define the term 'quality assurance' in pharmaceutical aspect and explain the significance of having quality assurance system in the industry. (5 marks)
- (b) The biopharmaceutical company that you are working with produces several types of vaccines. Propose and elaborate **FIVE (5)** good manufacturing practices (GMP) to be implemented in the company. (10 marks)
- (c) In 2012, it was reported that Cispharma plant in New Jersey had an employee's hand badly injured during compression of acetaminophen tablets. As safety personnel in the company, outline and propose the measures that the company would take to prevent the reoccurrence of this unfortunate event. (10 marks)

- END OF QUESTION -

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