



**UTHM**

Universiti Tun Hussein Onn Malaysia

**UNIVERSITI TUN HUSSEIN ONN MALAYSIA**

**FINAL EXAMINATION  
SEMESTER I  
SESSION 2017/2018**

**COURSE NAME** : BIOPHARMACEUTICAL  
TECHNOLOGY

**COURSE CODE** : BNN 40203

**PROGRAMME** : BNN

**DATE** : DECEMBER 2017 / JANUARY 2018

**DURATION** : 3 HOURS

**INSTRUCTION** : ANSWER ALL QUESTIONS

**THIS PAPER CONSISTS OF FIVE (5) PAGES**

**Q1 (a)** As the head of project team in a newly developed pharmaceutical company, prepare a sensible 15-year plan of the company. The plan should include strategies of the company from pharmaceutical research and development (R&D) to marketing of a product.

(10 marks)

**(b)** Pharmaceutical industry is a highly innovation driven industry which currently worth USD 300 billion. However, in the past decade the industry has faced and continuing to face several challenges in terms of patent expiration and growing competition from generic drug competition. Analyse these situations and relate with the future prospects of biopharmaceuticals and associated companies.

(10 marks)

**Q2 (a)** Identify **THREE (3)** possible pharmacokinetics on the drug administered into a human body.

(3 marks)

**(b)** Preclinical studies were conducted prior to clinical trials. Briefly discuss **TWO (2)** reasons why preclinical studies are important.

(4 marks)

**(c)** Recombinant DNA technology is a method of joining together DNA molecules from two different species. The desired genes are inserted into a host organism and as a result, new genetic combinations that are valuable to science, medicine, agriculture and industry are produced.

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**(i)** Illustrate and thoroughly explain **ONE (1)** ~~method of copying the gene of~~ interest.

(6 marks)

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- (i) Determine how to choose and isolate the transformed microorganisms (microbes that carry the desired gene) for cloning.

(7 marks)

**Q3 (a)** During pharmaceutical development, the choice of manufacturing process is a vital aspect to prevent any chemical changes of the drug and most importantly, its efficacy and effectiveness.

- (i) List **TWO (2)** important physicochemical characteristics of the finished product that must be maintained throughout its developing process.

(2 marks)

- (ii) Explain and relate with example why the characteristics mentioned in **Q3(a)(i)** are vital.

(3 marks)

(b) Scrutinize **FIVE (5)** advantages and limitations of a drug administered orally and intravenously.

(5 marks)

(c) Drug delivery systems are continuously improved with the purpose to maximize therapeutic activity and to minimize undesirable side effects. Evaluate and validate the use of nanotechnology in developing advanced therapeutic delivery systems. Provide **ONE (1)** example.

(10 marks)

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**Q4** (a) Granulation is the process of collecting particles together by creating bonds between them. Bonds are formed by compression or by using a binding agent.

(i) Discuss **THREE (3)** significant reasons of carrying out granulation process in pharmaceutical industry.

(3 marks)

(ii) Apply and thoroughly discuss **ONE (1)** advanced granulation technology to prepare solid dose tablet drugs.

(7 marks)

(b) Construct a process validation scheme to maintain the quality of biopharmaceutics production. Extensively explain.

(10 marks)

**Q5** (a) Employ **TWO (2)** fundamental safety, health and environment (SHE) principles during formulation and packaging processes of living microorganism in a vaccine.

(2 marks)

(b) Determine and explain in detail **THREE (3)** potential hazards during production of recombinant human insulin in *E.coli*.

(3 marks)

(c) The Occupational Health and Safety Act of 1993 places responsibility for the implementation and management of safety on a number of people in every company. As one of SHE personnel in CCM Pharmaceutical, propose and design a system in implementing and maintaining a robust safety and health management system.

(10 marks)

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- (d) One of the responsibilities of a pharmaceutical company is to protect the environment. Being a technologist in company X, recommend and discuss **FIVE (5)** measures that could be taken by your company to protect the environment.

(5 marks)

- **END OF QUESTIONS** -

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