UNIVERSITI KUALA LUMPUR
ROYAL COLLEGE OF MEDICINE PERAK

FINAL EXAMINATION
MARCH 2026 SEMESTER

COURSE CODE	:	RCB31203
COURSE NAME	:	HALAL MANUFACTURING PRACTICE
PROGRAMME NAME	:	BACHELOR IN PHARMACEUTICAL TECHNOLOGY (HONOURS)
DATE	:	1 JULY 2026
TIME	:	2.30 PM – 4.30 PM
DURATION	:	2 HOURS

INSTRUCTIONS TO CANDIDATES

1. Please read CAREFULLY the instructions given in the question paper.
2. This question paper has information printed on both sides of the paper.
3. This question paper consists of TWO (2) sections; Section A and Section B.
4. Answer ALL questions in Section A. For Section B, answer THREE (3) questions WITH AT LEAST ONE (1) question from question 3 or question 4.
5. Please write your answers on the OMR answer script and answer booklet provided.
6. Answer all questions in English language ONLY.

THERE ARE 8 PAGES OF QUESTIONS, EXCLUDING THIS PAGE.

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SECTION A (Total: 40 marks)

I) MULTIPLE CHOICE QUESTIONS (20 marks)

INSTRUCTION: Answer ALL questions.

Use the OMR sheet provided.

1. Which statement best explains the meaning of *Syariah-compliant* in pharmaceutical practices?
   A. Products approved by international regulatory agencies.
   B. Activities that follow Islamic law derived from *Quran* and *Hadith.*
   C. Medicines produced only in Muslim countries.
   D. Products are free from synthetic chemicals.
   E. Products with the highest market demand.

2. Which of the following best describes the concept of *halal*?
   A. Products that are safe but not necessarily permitted.
   B. Items allowed and permissible under Islamic law.
   C. Only food products approved by health authorities.
   D. Products manufactured in hygienic conditions.
   E. Products that are low in cost.

3. How does *haram* differ from *halal*?
   A. *Haram* refers to doubtful products, while *halal* refers to clean products.
   B. *Haram* refers to prohibited items, while *halal* refers to permitted items.
   C. *Haram* applies only to food, while *halal* applies to medicine.
   D. *Haram* refers to natural products, while *halal* refers to synthetic products.
   E. *Haram* refers to imported products, while *halal* refers to local products.

4. Which situation best illustrates *najs* contamination?
   A. A product stored at high temperature.
   B. A *halal* product exposed to pig-derived substances.
   C. A medicine with reduced efficacy.
   D. A product without proper labeling.
   E. A product with expired shelf life.

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5. Which statement best interprets the concept of *halallan-toyyiban*?
   A. Products must only be *halal* certified.
   B. Products must be cheap and widely available.
   C. Products must be both permissible and beneficial.
   D. Products must be imported from Islamic countries.
   E. Products must be produced in large quantities.

6. Why is junk food considered *halal* but not *thoyyib*?
   A. It is prohibited in Islam.
   B. It is not certified *halal*.
   C. It is permissible but not beneficial to health.
   D. It contains non-*halal* ingredients.
   E. It is produced using outdated technology.

7. In Malaysia, which body is primarily responsible for issuing *fatwa* at the national level?
   A. *Majlis Raja-Raja*
   B. Prime Minister's Department
   C. *Jawatankuasa Majlis Fatwa Kebangsaan*
   D. Ministry of Health Malaysia
   E. Companies Commission of Malaysia

8. According to the 7th *Muzakarah* of the National *Fatwa* Committee (1984), which statement about alcohol is **CORRECT**?
   A. All alcohol is considered liquor and is *najs*.
   B. Alcohol produced from liquor process is *najs*, but not all alcohol is liquor.
   C. Soft drinks produced like liquor are lawful if they contain trace alcohol.
   D. Fermented rice is *haram* to consume.
   E. Medicines containing alcohol are always prohibited.

9. What is the main reason methanol is considered *haram* in pharmaceutical products?
   A. It is naturally occurring and therefore impure.
   B. Its chemical properties are different from natural alcohol.
   C. It is used only in food products.
   D. It exerts high toxicity and is considered *najs*.
   E. It is only prohibited in beverages.

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10. Which of the following **BEST** describes the difference between alcohol and *khmar*.

A. Alcohol and *khmar* refer to the same substance with no distinction.

B. *Khmar* is a class of chemicals while alcohol refers only to fermented beverages.

C. Alcohol is a class of chemicals while *khmar* specifically refers to alcoholic beverages.

D. Alcohol is *haram* while *khmar* is *halal* in all forms.

E. *Khmar* includes all types of solvent used in pharmaceutical products.

11. Which of the following is the **CORRECT** alternative used in modern pharmaceutical technology to replace animal-derived ingredients?

A. Mineral-based compounds and heavy metal salts

B. Fermented plant extracts and essential oils

C. Chemically synthesized and DNA recombinant technology-derived ingredients

D. Radioactive isotopes and gamma-irradiated materials

E. Seawater extract and marine algae derivatives

12. Which of the following is a *halal*-compliant source of gelatine used in pharmaceutical products such as a capsule shell, emulsifier, and filler?

A. Porcine skin and bone

B. Canine joints

C. Vegetable (soy)

D. Porcine intestine lining

E. Fatty acids from porcine stomach

13. What does the Islamic concept of *rukhsah* refer to in the context of pharmaceutical use?

A. A permanent religious exemption allowing all *haram* medicines to be consumed freely.

B. A *fatwa* that prohibits the use of any animal-derived ingredient in medicine.

C. A committee review process before a new pharmaceutical ingredient is approved.

D. The permissible ease granted to reduce difficulty during medical treatment or in emergency cases.

E. A label required on all *halal*-certified pharmaceutical packaging.

14. According to the *fatwa*, what is the Islamic ruling on animal-derived pharmaceutical ingredients that are classified as *najs*?

A. They are permissible if prescribed by a licensed doctor.
B. They are permissible for external use only, regardless of source.
C. They are *haram* to be consumed, *halal* alternatives must be actively required.
D. They are *halal* if processed through high-temperature sterilization.
E. They are always permissible if they serve a medicinal purpose.

15. Why are serious offences presented to the *Halal* Certification Panel?

A. To reduce penalties
B. To finalize administrative records
C. To obtain a final decision after inspection findings
D. To delay revocation
E. To avoid prosecution

16. What distinguishes enforcement inspection from scheduled inspection?

A. It is planned regularly.
B. It is conducted only annually.
C. It is triggered by complaints or findings.
D. It is limited to documentation review.
E. It excludes external agencies.

17. Why are auditors allowed to access the entire premises?

A. To monitor employee attendance
B. To ensure full verification of compliance
C. To evaluate company profile
D. To inspect customer satisfaction
E. To manage operations

18. What is the validity period of the *Halal* certification fee for most categories?

A. Six months
B. 1 year
C. 2 years
D. 3 years
E. 5 years

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19. Why is the fee for slaughterhouses different from other categories?

A. It is higher than others.
B. It is based on production volume.
C. It is valid for a shorter duration.
D. It includes auditing costs.
E. It is refundable.

20. Which of the following best explains the payment method for *halal* certification fees?

A. Only cash payments are accepted.
B. Payments must be made to private auditors.
C. Payments can be made through multiple official financial instruments.
D. Payments are made after certification approval.
E. Payments can be made in installments.

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II) SHORT ANSWER QUESTIONS (20 marks)

INSTRUCTION: Answer ALL questions in the answer booklet provided.

Each question carries TWO (2) marks.

1. Describe the legal jurisdiction structure of *syariah* law in Malaysia.

2. State **TWO (2)** types of alcohol used in pharmaceuticals.

3. List **TWO (2)** functions of animal-derived substances in pharmaceutical products.

4. List **TWO (2)** conditions under which using a *haram* pharmaceutical product is forgiven according to the concept of *rukhsah*.

5. Describe the actions taken regarding the decision on the complaint made to JAKIM.

6. State the appointment period and reappointment date of JAIN *Halal* Certification Panel members.

7. State **TWO (2)** internal benefits of obtaining *halal* certification.

8. Define carrier protein.

9. Outline the document hierarchy that must be established in Good Islamic Manufacturing Practice (GIMP).

10. Describe the concept of a "Transition Zone" in a conceptual layout.

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SECTION B: MODIFIED ESSAY QUESTIONS (Total: 60 marks)

INSTRUCTION: This section consists of FOUR (4) questions.
You are required to answer THREE (3) questions in the answer booklet provided.
Question 1 and 2 are COMPULSORY.
Answer EITHER Question 3 OR 4.

Question 1

(a) Explain the guidelines in packaging and labelling of *halal* cosmetics according to MS 2634:2019.

(10 marks)

(b) Explain the *halal* capital system in GIMP.

(10 marks)

Question 2

(a) Explain the requirements for good facility layout in *Halal* Pharmaceuticals manufacturing.

(10 marks)

(b) Suggest **TEN (10)** audit criteria to verify the authenticity and accuracy of *halal* documentation and practices.

(10 marks)

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Question 3

(a) Outline the basic unit operations involved in the manufacturing process of a sterile drug product filled into a vial.

(10 marks)

(b) Explain principles 1 and 2 of Islamic Manufacturing Practice.

(10 marks)

Question 4

(a) Explain **FIVE (5)** different types of containers used for sterile drug products.

(10 marks)

(b) Explain principle 8 of Islamic Manufacturing Practice.

(10 marks)

END OF EXAMINATION PAPER

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