UNIVERSITI KUALA LUMPUR
ROYAL COLLEGE OF MEDICINE PERAK

FINAL EXAMINATION
MARCH 2026 SEMESTER

COURSE CODE	:	**RPD22403**
COURSE NAME	:	**ASEPTIC DISPENSING AND CLINICAL PHARMACOKINETIC SERVICES**
PROGRAMME NAME	:	**DIPLOMA IN PHARMACY**
DATE	:	**25 JUNE 2026**
TIME	:	**9.00 AM – 11.00 AM**
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 and THREE (3) questions in section B.**
5. **Please mark/write your answers on the OMR answer script and answer booklet provided.**
6. **Answer all questions in English language ONLY.**

THERE ARE 16 PAGES OF QUESTIONS, EXCLUDING THIS PAGE.

SECTION A (Total: 25 marks)

INSTRUCTION: Answer ALL questions.
Please use the objective answer sheet provided.

1. What is the correct pressure differential requirement for a cleanroom used to prepare standard, non-hazardous sterile products?
   A. Negative pressure in both the buffer room and ante-rooms.
   B. Equal pressure between the buffer room and the general pharmacy area.
   C. Negative pressure in the buffer room relative to the ante-room.
   D. Positive pressure in the buffer room relative to the ante-room.

2. Which ISO classification is strictly required for the air quality inside a Primary Engineering Control (PEC)?
   A. ISO Class 5
   B. ISO Class 6
   C. ISO Class 7
   D. ISO Class 8

3. High-Efficiency Particulate Air (HEPA) filters used in sterile compounding facilities are designed to remove what percentage of airborne particles that are 0.3 microns or larger?
   A. 95.00%
   B. 99.00%
   C. 99.97%
   D. 99.99%

4. When working inside a Horizontal Laminar Airflow Cabinet (LAFC), where should all aseptic manipulations be performed to ensure proper protection by the HEPA filter and avoid air turbulence?
   A. Exactly at the front edge of the stainless-steel workbench.
   B. At least 6 inches inside the outer edge of the workbench.
   C. As close to the HEPA filter grill as physically possible.
   D. Outside the workbench before transferring items inside.

5. In aseptic technique, what does the term "first air" refer to?

A. The initial burst of air when the LAFC is turned on in the morning.

B. The clean, unobstructed air exiting the HEPA filter before it hits any object.

C. The air that circulates in the ante-room before entering the buffer area.

D. The air inside the syringe barrel used to equalize vial pressure.

6. A pharmacist assistant is preparing to open a glass ampoule.
Which of the following describes the correct aseptic technique?

A. Break the ampoule neck directly towards the HEPA filter to push away glass shards.

B. Swab the neck with 70% IPA, allow to dry, and snap the neck away from the HEPA filter.

C. Use a standard 23G needle to aspirate the fluid directly after breaking.

D. Leave the ampoule open in the cabinet for 5 minutes to allow internal pressure to escape.

7. When withdrawing medication from a vial, what action is necessary to prevent a vacuum from forming inside the vial?

A. Removing the air bubbles entirely before withdrawing the liquid.

B. Puncturing the rubber stopper multiple times to allow room air to enter.

C. Withdrawing the fluid extremely slowly without adding any air.

D. Injecting an amount of air into the vial equal to the volume of fluid to be withdrawn.

8. Which of the following is a fundamental characteristic of an ideal container for intravenous admixtures?

A. It must be highly reactive to the medications to enhance absorption.

B. It must yield microscopic solid particles to act as a physical buffer.

C. It must not have any physical or chemical effect on the therapeutic properties of the drug.

D. It must be completely opaque to prevent the pharmacist from checking for precipitates.

9. While compounding an IV admixture, a pharmacist assistant notices a hazy, white precipitate forming in the IV bottle immediately after adding a second medication. What type of incompatibility has occurred?

A. Therapeutic incompatibility
B. Chemical incompatibility
C. Synergistic incompatibility
D. Physical incompatibility

10. To prevent "coring" when introducing a diluent into a sterile powder vial, how should the needle be correctly inserted through the rubber stopper?

A. Inserted at a 90-degree angle with maximum downward force.
B. Inserted at a 45 to 90-degree angle with the bevel facing up.
C. Inserted at a 45-degree angle with the bevel facing down.
D. Inserted horizontally directly under the aluminum cap.

11. In a Total Parenteral Nutrition (TPN) solution, which macronutrient serves as the primary source of non-protein calories for the patient?

A. Dextrose
B. Trace elements
C. Essential amino acids
D. Electrolytes

12. To prevent the potentially fatal precipitation of calcium phosphate in a TPN compounding bag, what is the mandatory sequence of mixing?

A. Add phosphate and calcium simultaneously into the bag.
B. Add phosphate first, mix thoroughly with other components, and add calcium last.
C. Add calcium first, mix thoroughly with other components, and add phosphate last.
D. Mix calcium and phosphate in a separate syringe before injecting into the bag.

13. What type of PEC must be utilized to safely prepare hazardous, cytotoxic oncology drugs?

A. Horizontal Laminar Airflow Workbench
B. Class I Biological Safety Cabinet
C. Class II Biological Safety Cabinet
D. Compounding Aseptic Isolator

14. During the preparation of a cytotoxic drug vial, why is it critical to maintain slight negative pressure within the vial?

A. To prevent the hazardous drug solution from spraying out when the needle is withdrawn.
B. To rapidly speed up the dissolution of the lyophilized powder.
C. To prevent room air from oxidizing the sensitive antineoplastic agent.
D. To ensure the rubber stopper does not core during needle insertion.

15. What is the typical tonicity of human tears, which ophthalmic preparations should ideally match to prevent severe eye pain?

A. Equivalent to 0.45% Sodium Chloride
B. Equivalent to 0.9% Sodium Chloride
C. Equivalent to 3.0% Sodium Chloride
D. Equivalent to 5.0% Sodium Chloride

16. A patient complains of a severe stinging and burning sensation immediately after instilling a prescribed eye drop.
Which physicochemical property of the formulation is most likely out of the physiological range?

A. pH
B. Clarity
C. Sterility
D. Viscosity

17. Which of the following healthcare professionals is a key member of the Clinical Pharmacy Services (CPS) or Therapeutic Drug Monitoring (TDM) team?

A. Radiographer
B. Clinical pharmacist
C. Pharmacist assistant
D. Medical assistant

18. What is the main purpose of CPS or TDM?

A. To measure drug concentration in blood samples
B. To increase drug absorption in the gastrointestinal tract
C. To determine the chemical structure of drugs in plasma
D. To optimize drug therapy by maintaining drug levels within the therapeutic range

19. Which of the following best explains why trough levels are preferred for drugs like Vancomycin and Aminoglycosides?

A. They increase therapeutic drug effects
B. They reflect drug absorption in the gastrointestinal tract
C. They are convenient and reduce sampling errors
D. They help monitor toxicity related to drug accumulation

20. Which statement best describes Quality Assurance (QA)?

A. Focuses on detecting defects after production
B. Ensures processes are followed to prevent defects
C. Inspects finished products only
D. Performed only by testing team

Question 21 to 25 requires the following answer.

A	B	C	D
I and III	II and IV	I, II and III	II, III and IV

21. Which of the following statements regarding the proper use and maintenance of a BSC are correct?
    I. The stainless-steel work surface should be disinfected with 70% Isopropyl Alcohol.
    II. The cabinet blower should be turned off immediately after every compounding batch.
    III. The cleaning motion must proceed smoothly from the back to the front area.
    IV. The HEPA filter grill should be clean with sterile water daily.

22. Which of the following patient conditions are considered primary clinical indications for initiating TPN?
    I. A fully functioning gastrointestinal tract requiring overnight hydration.
    II. Post-traumatic patient with increased metabolic demands.
    III. A mild, isolated vitamin deficiency requiring oral supplementation.
    IV. Premature infant unable to tolerate enteral feeding.

23. What are the essential, strictly controlled physicochemical characteristics of an ideal ophthalmic preparation?
    I. Absolute sterility to prevent ocular infections.
    II. Isotonicity to match the osmotic pressure of human tears.
    III. Physiological pH to minimize stinging upon instillation.
    IV. High acidity to increase the chemical stability of the drug.

24. Which of the following are common problems encountered in CPS or TDM?
    I. Inappropriate sampling time
    II. Lack of consultation when problems arise
    III. Insufficient patient history and clinical data
    IV. Increased drug bioavailability

25. Which of the following practices are essential for preventing contamination in Good Manufacturing Practices (GMP) controlled environments?

I. Use of appropriate personal protective equipment (PPE)

II. Proper handling and disposal of waste

III. Routine cleaning and sanitization of facilities

IV. Storage of food and beverages in designated areas within the production facility

SECTION B (Total: 75 marks)

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

Question 1

(a) State **ONE (1)** primary purpose of proper garbing before entering a sterile cleanroom environment.

(1 mark)

(b) Describe **TWO (2)** correct practices when handling syringes during aseptic preparation to strictly avoid touch contamination.

(4 marks)

(c) Explain **TWO (2)** specific factors that can contribute to physical incompatibilities (such as precipitation) in intravenous admixtures.

(4 marks)

(d) TPN requires careful clinical management and specialized personnel.

i. Explain **THREE (3)** clinical indications for TPN related specifically to a nonfunctional gastrointestinal (GI) tract or GI disease.

(3 marks)

ii. List **THREE (3)** specific duties of a TPN Pharmacist.

(3 marks)

(e) Explain **TWO (2)** specific PPE requirements when handling cytotoxic drugs.

(4 marks)

(f) Explain **TWO (2)** reasons why a standard surgical mask is insufficient for oncology compounding.

(2 marks)

(g) Explain the clinical applications of **TWO (2)** sterile irrigating solutions used for Bladder Irrigation.

(2 marks)

(h) Explain **ONE (1)** reason why isotonicity must be strictly controlled in eye drops.

(2 marks)

Question 2

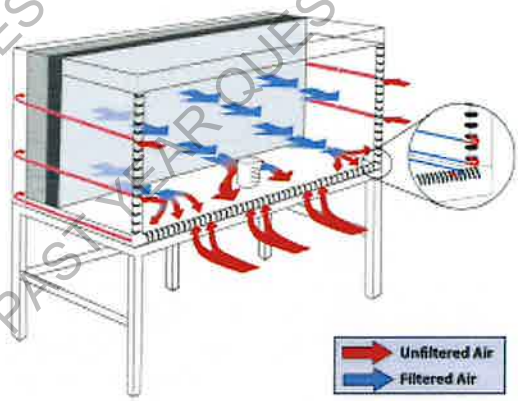
(a) Explain the differences between a positive air pressure clean room and a negative air pressure clean room.

(4 marks)

(b) A new pharmacist assistant is assigned to clean the clean room. Describe a correct cleaning method for the ceilings, walls, and surfaces based on the facilities maintenance guidelines.

(3 marks)

(c)



Explain the working principle of this equipment regarding how the air flows.

(3 marks)

(d) Identify the correct procedure for preparing the LAFC before compounding.

(3 marks)

(e) An IV admixture shows signs of gas formation and precipitation.
Classify this type of incompatibility and explain what happens to the drug.

(3 marks)

(f) An IV drug admixture breaks down due to an acidic pH, losing its effectiveness.
Analyze this situation to identify the type of incompatibility and how it affects the drug.

(3 marks)

A pharmaceutical company initiated a recall after discovering that a pouch labeled as Magnesium Sulfate in Water for Injection (4 g/100 mL) was found to contain an IV bag of Tranexamic Acid (10 mg/mL). Magnesium sulfate is indicated for the prevention and control of seizures in preeclampsia and eclampsia.

The product had been distributed to healthcare facilities before the discrepancy was detected. The incident was identified during internal quality checks, and a recall was subsequently initiated to prevent patient harm.

(g) i. Based on the above incident, identify **TWO (2)** key aspects of Good Manufacturing Practices (GMP) that should be reinforced to prevent such errors in the future.

(2 marks)

ii. Explain your answer in (g) i.

(4 marks)

Answer either Question 3 OR Question 4

Question 3

(a) Define "coring" in the context of aseptic preparation.

(1 mark)

(b) A pharmacist assistant withdrawing a drug from a vial notices a piece of the rubber stopper inside the solution.
Identify this phenomenon and formulate the correct needle insertion technique to prevent it.

(4 marks)

(c) A patient requires a TPN solution. You must calculate the daily requirements based on the patient's body weight of 50 kg.

i. Calculate the daily amount of protein required if the standard dose is 1.5 g/kg/day.

(2 marks)

ii. Calculate the total volume of 50% Dextrose solution needed if the patient requires 350 g of dextrose daily.

(3 marks)

(d) IV Vincristine spilled inside the safety cabinet.
Suggest the correct sequences of the step to manage this spill according to the spill management procedure.

(6 marks)

(e) Describe **TWO (2)** general requirements for a facility to safely prepare ophthalmic eye drops.

(2 marks)

A patient receiving Dilantin® for seizure control presents with slurred speech, dizziness, and confusion despite regular dosing. On further review, the patient recently started on cimetidine for peptic ulcers. Therapeutic Drug Monitoring (TDM) shows a serum concentration of 26mg/L. (Use the TDM reference table provided in ***Appendix 1*** to interpret the results.)

(f) Based on the above scenario, answer the following questions:

i. Interpret the TDM result. Explain your answer.

(2 marks)

ii. Explain the pharmacokinetic reason for the patient's serum drug concentration in (f) i.

(3 marks)

iii. Suggest **ONE (1)** appropriate management strategy for this patient and justify your answer.

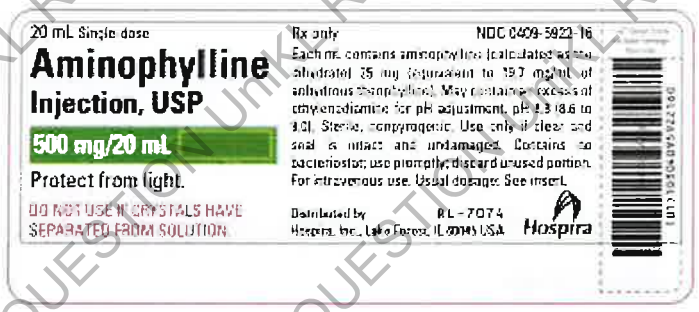
(2 marks)

Question 4

(a) State **ONE (1)** commonly overlooked area on the hands during the handwashing process.

(1 mark)

(b)



You received a medication order for IV Aminophylline in Dextrose 5% as follows:

Rx
IV Aminophyline 90mg/30ml in D5W tds

Calculate the volume of Aminophylline (in mL) and quantity of D5W (500ml per bottle) required.

(4 marks)

(c) A patient requires a TPN solution. You must calculate the daily requirements based on the patient's body weight of 60 kg.

i. Calculate the daily amount of lipid required if the standard dose is 1.0 g/kg/day.

(2 marks)

ii. Based on your answer in (c) i, calculate the total volume (mL) of 20% lipid emulsion needed daily.

(3 marks)

(d) 3 vials containing Mitomycin powder broke during the arrangement in store. As a pharmacist assistant, suggest the correct sequences of the step to manage this spill according to the spill management procedure.

(6 marks)

(e) Explain the specific clinical purposes of **TWO (2)** types of ophthalmic preparations and their functions commonly dispensed in a hospital setting.

(2 marks)

A 45-year-old patient has been on Epilim® for the past 2 years for seizure control. He was admitted to the emergency department yesterday following a breakthrough seizure. TDM was performed, and the serum concentration was 40mg/L.
(Use the TDM reference table provided in ***Appendix 1*** to interpret the results.)

(f) Based on the above scenario, answer the following questions:

i. Interpret the TDM result. Explain your answer.

(2 marks)

ii. Explain **TWO (2)** possible causes for the patient's serum drug concentration in (f) i.

(4 marks)

iii. Suggest **ONE (1)** appropriate management strategy for this patient and justify your answer.

(1 marks)

END OF EXAMINATION PAPER

APPENDIX 1

DRUG	THERAPEUTIC RANGE IN PLASMA	
	LEVEL	UNITS
Amiodarone	1.0 - 2.5	mg/L
Aminoglycoside	5 - 10 (Peak)	mg/L
	<2 (Trough)	mg/L
Carbamazepine	5 - 12	mg/L
Digoxin	0.8 - 2.0	ng/mL
Lignocaine	2.0 - 5.0	mg/L
Lithium	416 - 694	mg/100ml
Phenobarbitone	15 - 40	mg/L
Phenytoin	10 - 20	mg/L
Quinidine	2.0 - 5.0	mg/L
Sodium valproate	50 - 100	mg/L
Theophylline	10 - 20	mg/L