CSPT Sterile Compound Prep

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Practice Questions

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1. What is the required ISO classification inside a primary engineering control such as a laminar airflow workbench during sterile compounding?

A. ISO Class 7
B. ISO Class 6
C. ISO Class 8
D. ISO Class 5

2. Which type of primary engineering control should be used when compounding hazardous sterile preparations?

A. Standard compounding aseptic isolator
B. Open bench in buffer room
C. Biological safety cabinet
D. Horizontal laminar airflow workbench

3. What is the correct pressure differential relationship between a buffer room and an anteroom when compounding non-hazardous sterile preparations?

A. Buffer room neutral to anteroom
B. Buffer room positive to anteroom
C. Buffer room negative to anteroom
D. Buffer room equal pressure to anteroom

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4. Which component is essential for maintaining ISO Class 5 air quality in a laminar airflow workbench?

A. HEPA filter
B. Carbon filter
C. Electrostatic precipitator
D. UV light

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5. What is the minimum ISO classification required for an anteroom in a facility performing sterile compounding?

A. ISO Class 5
B. ISO Class 7
C. ISO Class 9
D. ISO Class 8

6. Which type of environmental monitoring detects living microorganisms in the compounding area?

A. Pressure differential monitoring
B. Temperature monitoring
C. Viable air sampling
D. Non-viable air sampling

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7. What action should be taken when surface sampling results in a buffer room exceed established action levels?

A. Replace HEPA filters immediately
B. Clean, disinfect, and retest the area
C. Continue compounding and document the result
D. Increase air changes per hour only

8. Which type of biological safety cabinet provides both product and personnel protection while venting HEPA-filtered air back into the room?

A. Class II Type A
B. Class I
C. Class III
D. Horizontal laminar airflow

9. How frequently must non-viable particle sampling be performed in an ISO Class 5 primary engineering control?

A. Daily
B. Weekly
C. Annually
D. At least every six months

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10. What is the primary purpose of a segregated compounding area?

A. To allow limited low-risk compounding when a full cleanroom is not available
B. To compound hazardous preparations exclusively
C. To store finished sterile preparations

11. Which pressure relationship must exist in a containment segregated compounding area used for hazardous drugs?

A. Alternating pressure cycles
B. Negative pressure relative to surrounding areas
C. Positive pressure relative to surrounding areas
D. Equal pressure to surrounding areas

12. What is the minimum number of air changes per hour required in an ISO Class 7 buffer room?

A. 30 air changes per hour
B. 20 air changes per hour
C. 15 air changes per hour
D. 10 air changes per hour

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13. Which environmental monitoring method assesses the effectiveness of aseptic technique by testing the compounding personnel directly?

A. Surface sampling of workbenches
B. Non-viable air sampling
C. Media fill testing
D. Gloved fingertip sampling

14. What type of primary engineering control uses a completely enclosed environment with glove ports for compounding?

A. Biological safety cabinet Class I
B. Vertical flow hood
C. Compounding aseptic isolator
D. Laminar airflow workbench

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15. Which parameter tolerance must be continuously monitored and documented in a buffer room to ensure proper environmental control?

A. Wall color
B. Temperature and pressure differentials
C. Light intensity only
D. Floor texture

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16. Why is food and drink prohibited in the buffer room and anteroom during sterile compounding operations?

A. To prevent introduction of contaminants and microorganisms
B. To comply with OSHA ergonomic standards only
C. To reduce electricity costs
D. To prevent equipment damage only

17. What is the primary difference between a horizontal and vertical laminar airflow workbench?

A. Size of the work surface
B. ISO classification achieved
C. Power consumption requirements
D. Direction of HEPA-filtered airflow

18. How should out-of-specification environmental monitoring results be documented?

A. Report to FDA within 24 hours only
B. Stop all operations permanently
C. Document the result, corrective actions, and retest outcomes
D. Discard the sample and retest only

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19. Which feature distinguishes a compounding aseptic containment isolator from a standard compounding aseptic isolator?

A. Lower ISO classification
B. Negative pressure with externally vented exhaust
C. Larger work area dimensions
D. Positive pressure with room recirculation

20. What is the maximum humidity level recommended for maintaining proper environmental control in a buffer room?

A. 60% relative humidity
B. 80% relative humidity
C. 40% relative humidity
D. 90% relative humidity

21. Which medication is classified as a high-alert drug requiring special handling procedures during compounding?

A. Normal saline
B. Sodium bicarbonate 8.4%
C. Dextrose 5% in water
D. Concentrated potassium chloride

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22. What is the primary reason insulin is considered a narrow therapeutic index medication?

A. It can only be administered intravenously
B. It has a very short shelf life after opening
C. Small dose changes can cause significant blood glucose alterations
D. It requires refrigerated storage at all times

23. Which factor would require a compounded sterile preparation containing amphotericin B to be stored in a light-protected container?

A. The drug has high osmolarity
B. The drug is photosensitive and degrades with light exposure
C. The drug requires refrigerated storage
D. The drug is a narrow therapeutic index agent

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24. What information found in a Safety Data Sheet is most critical for determining personal protective equipment requirements when compounding hazardous drugs?

A. Hazard classification and risk statements
B. Manufacturer contact information
C. Product identification number
D. Storage temperature recommendations

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25. Which base solution is incompatible with phenytoin sodium injection due to precipitation risk?

A. 0.9% sodium chloride
B. Sterile water for injection
C. Bacteriostatic water for injection
D. Dextrose 5% in water

26. According to package insert information, what is the maximum recommended concentration for peripheral administration of potassium chloride to minimize vein irritation?

A. 40 mEq per 100 mL
B. 5 mEq per 100 mL
C. 10 mEq per 100 mL
D. 20 mEq per 100 mL

27. Which therapeutic class includes medications that require special containment procedures due to their antineoplastic properties?

A. Antibiotics
B. Chemotherapy agents
C. Anticoagulants
D. Electrolyte solutions

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28. What type of container closure system should be avoided when compounding paclitaxel due to leaching concerns?

A. Polyvinyl chloride (PVC) bags
B. Glass bottles
C. Polyolefin bags
D. DEHP-free plastic bags

29. Which side effect is most commonly associated with rapid intravenous administration of vancomycin that requires rate control during compounding calculations?

A. Nephrotoxicity and kidney damage
B. Ototoxicity and hearing loss
C. Thrombocytopenia and bleeding
D. Red man syndrome with flushing and hypotension

30. What is the primary contraindication for using lactated Ringer's solution as a diluent for ampicillin sodium?

A. pH incompatibility causing precipitation
B. Lactate metabolism interfering with drug action
C. Chemical incompatibility with calcium ions causing degradation
D. Excessive sodium content causing hypernatremia

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Answer Key & Explanations

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1. D — ISO Class 5
ISO Class 5 is the required air quality classification for the direct compounding environment inside primary engineering controls to minimize particulate contamination during sterile preparation.

2. C — Biological safety cabinet
A biological safety cabinet or compounding aseptic containment isolator provides both product protection and personnel protection through negative pressure and HEPA-filtered exhaust, making them appropriate for hazardous drug compounding.

3. B — Buffer room positive to anteroom
The buffer room must maintain positive pressure relative to the anteroom to prevent less clean air from entering the cleanest compounding area, protecting the sterile compounding environment.

4. A — HEPA filter
HEPA (High Efficiency Particulate Air) filters remove 99.97% of particles 0.3 microns or larger, creating the ISO Class 5 environment required for sterile compounding.

5. D — ISO Class 8
ISO Class 8 is the minimum classification for anterooms, providing a transitional environment between unclassified areas and the ISO Class 7 buffer room.

6. C — Viable air sampling
Viable air sampling uses collection media to capture and culture living microorganisms from the air, allowing detection and quantification of microbial contamination.

7. B — Clean, disinfect, and retest the area
When environmental monitoring results exceed action levels, the area must be cleaned, disinfected, and retested to ensure it returns to acceptable microbial limits before resuming compounding.

8. A — Class II Type A
Class II Type A biological safety cabinets provide protection for both personnel and product, recirculating HEPA-filtered air back into the laboratory after removing particulates and potential contaminants.

9. D — At least every six months
According to USP standards, non-viable particle sampling in ISO Class 5 environments must be performed at least every six months to verify air quality certification and proper HEPA filter function.

10. A — To allow limited low-risk compounding when a full cleanroom is not available
A segregated compounding area contains ISO Class 5 primary engineering controls in a room that does not meet ISO Class 7 or 8 requirements, limited to compounding low-risk CSPs with 12-hour or less beyond use dates.

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11. B — Negative pressure relative to surrounding areas
Containment segregated compounding areas for hazardous drugs must maintain negative pressure relative to surrounding areas to prevent hazardous drug vapors or particles from escaping into adjacent spaces.

12. A — 30 air changes per hour
ISO Class 7 buffer rooms require a minimum of 30 air changes per hour to maintain proper air quality and particulate removal necessary for supporting sterile compounding operations.

13. D — Gloved fingertip sampling
Gloved fingertip sampling evaluates whether personnel are maintaining proper aseptic technique during compounding by testing for microbial contamination on gloved fingers after compounding activities.

14. C — Compounding aseptic isolator
Compounding aseptic isolators and compounding aseptic containment isolators are barrier systems with glove ports that provide a completely enclosed ISO Class 5 environment, separating the operator from the compounding area.

15. B — Temperature and pressure differentials
Temperature and pressure differentials must be continuously monitored in controlled environments to ensure they remain within specified tolerances for maintaining proper air quality and preventing contamination.

16. A — To prevent introduction of contaminants and microorganisms
Food and drink introduce particulates, microorganisms, and potential contaminants that can compromise the controlled environment and sterility of compounded preparations.

17. D — Direction of HEPA-filtered airflow
In a horizontal LAFW, HEPA-filtered air flows from the back toward the operator, while in a vertical LAFW, air flows downward from the top. Vertical flow provides better personnel protection and is preferred for hazardous compounding.

18. C — Document the result, corrective actions, and retest outcomes
All out-of-specification results must be thoroughly documented with corrective actions taken, investigation findings, and retesting results to maintain compliance and ensure patient safety.

19. B — Negative pressure with externally vented exhaust
A compounding aseptic containment isolator operates under negative pressure with externally vented HEPA-filtered exhaust to provide personnel and environmental protection when handling hazardous drugs.

20. A — 60% relative humidity
Humidity in buffer rooms should typically be maintained at or below 60% relative humidity to prevent microbial growth, condensation, and degradation of compounded preparations while maintaining comfort and equipment function.

21. D — Concentrated potassium chloride
Concentrated potassium chloride is a high-alert medication that can cause serious harm if administered incorrectly, requiring special labeling and handling procedures during compounding.

22. C — Small dose changes can cause significant blood glucose alterations
Insulin has a narrow therapeutic index because small changes in dose can result in significant blood glucose fluctuations, potentially causing hypoglycemia or hyperglycemia with serious clinical consequences.

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23. B — The drug is photosensitive and degrades with light exposure
Amphotericin B is photosensitive and degrades when exposed to light, requiring light-protected containers or amber bags to maintain potency and stability throughout its beyond-use date.

24. A — Hazard classification and risk statements
The hazard classification section of the Safety Data Sheet identifies physical, health, and environmental hazards, which directly determine the type and level of PPE required for safe handling during compounding.

25. D — Dextrose 5% in water
Phenytoin sodium is only compatible with normal saline (0.9% sodium chloride). When mixed with dextrose-containing solutions, it precipitates due to decreased pH and reduced solubility.

26. C — 10 mEq per 100 mL
Package inserts typically specify that potassium chloride for peripheral administration should not exceed 10 mEq per 100 mL (or 0.1 mEq/mL) to prevent venous irritation and phlebitis.

27. B — Chemotherapy agents
Chemotherapy agents are antineoplastic drugs that can cause cellular damage and require special handling with closed system transfer devices, negative pressure techniques, and appropriate PPE to protect personnel.

28. A — Polyvinyl chloride (PVC) bags
Paclitaxel contains Cremophor EL, which can leach DEHP (di-2-ethylhexyl phthalate) from PVC containers and tubing. Non-DEHP or non-PVC materials such as glass, polyolefin, or DEHP-free bags must be used.

29. D — Red man syndrome with flushing and hypotension
Red man syndrome is a histamine-related reaction characterized by flushing, rash, and hypotension that occurs with rapid vancomycin infusion. Package inserts specify infusion times of at least 60 minutes to minimize this risk.

30. C — Chemical incompatibility with calcium ions causing degradation
Ampicillin sodium is incompatible with lactated Ringer's solution because the calcium ions in the solution can interact with the beta-lactam ring, leading to degradation and loss of potency.

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