

# USP 797 Sterile Compounding Practice Test (Sample)

## Study Guide



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**SAMPLE**

## **Questions**

- 1. When should gloves be changed during the compounding process?**
  - A. After one hour of use**
  - B. When they become contaminated or after a significant task change**
  - C. Only if torn**
  - D. Before starting new tasks only**
- 2. What is a critical factor in determining the potency of a compounded preparation?**
  - A. The color of the preparation**
  - B. The ingredients and their proportions used**
  - C. The fragrance added for patient appeal**
  - D. The packaging type chosen for distribution**
- 3. What is the expected outcome of applying USP 797 standards?**
  - A. Increased commercialization of compounded sterile products**
  - B. Lower rates of patient infections associated with sterile preparations**
  - C. Higher production rates in compounding pharmacies**
  - D. Decreased regulatory oversight for compounding facilities**
- 4. What does proper training in sterile compounding help staff to achieve?**
  - A. Increased profitability**
  - B. Better health benefits**
  - C. Compliance with industry standards**
  - D. Less supervision needed**
- 5. Should CSPs not immediately dispensed be refrigerated?**
  - A. Yes**
  - B. No**
  - C. Only if they contain hazardous materials**
  - D. Only if they are liquid**

- 6. For how long should the LAFW blowers run before starting compounding activities?**
- A. 15 minutes**
  - B. 30 minutes**
  - C. 45 minutes**
  - D. One hour**
- 7. What is the correct order of garbing for compounding sterile preparations?**
- A. Gloves, shoe covers, gown, face mask, hair cover**
  - B. Gown, face mask, hair cover, shoe covers, gloves**
  - C. Hair cover, gown, gloves, shoe covers, face mask**
  - D. Face mask, gloves, gown, hair cover, shoe covers**
- 8. What should the air quality be in an ante-area used for sterile compounding?**
- A. ISO Class 5**
  - B. ISO Class 6**
  - C. ISO Class 8 or better**
  - D. ISO Class 9**
- 9. Is formal documentation needed for adverse event reporting procedures?**
- A. No, it's not necessary**
  - B. Yes, it should be detailed in writing**
  - C. Yes, but only for severe cases**
  - D. Only for internal reviews**
- 10. How can contamination of a CSP be minimized during compounding?**
- A. By limiting the use of sterile gloves and gowns**
  - B. By ensuring aseptic technique and proper garbing**
  - C. By using non-sterile equipment in the process**
  - D. By compounding in a crowded area**

## **Answers**

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1. B
2. B
3. B
4. C
5. B
6. B
7. B
8. C
9. B
10. B

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## **Explanations**

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**1. When should gloves be changed during the compounding process?**

**A. After one hour of use**

**B. When they become contaminated or after a significant task change**

**C. Only if torn**

**D. Before starting new tasks only**

The correct answer emphasizes the importance of maintaining aseptic technique in the compounding process. Gloves should be changed when they become contaminated or after a significant task change to ensure that sterile products are not compromised. Contamination can occur even if it is not visible, and changing gloves helps prevent the transfer of pathogens or contaminants from one surface or task to another. In a sterile compounding environment, it is crucial to adhere to the highest standards of hygiene to safeguard patient safety. Significant task changes, such as moving from handling non-sterile items to sterile products, require a glove change to avoid any risk of contamination from previous tasks. Regular assessments of glove integrity and cleanliness throughout the compounding process help maintain a sterile environment and reduce the likelihood of infection.

**2. What is a critical factor in determining the potency of a compounded preparation?**

**A. The color of the preparation**

**B. The ingredients and their proportions used**

**C. The fragrance added for patient appeal**

**D. The packaging type chosen for distribution**

The potency of a compounded preparation is fundamentally determined by the ingredients used and their specific proportions. Active pharmaceutical ingredients (APIs) must be used in accurate amounts to ensure that the final compounded product delivers the intended therapeutic effect. If the dosage of an active ingredient is too low, it may not provide the necessary efficacy, and if it is too high, it could lead to toxicity or adverse effects. Therefore, precise measurement and proper formulation are crucial to maintaining the integrity and effectiveness of the compound. While factors such as the color of the preparation, fragrance, and packaging may contribute to patient acceptance and the overall presentation of the product, they do not influence the actual potency in terms of therapeutic effectiveness. These factors have a more aesthetic and marketing role rather than a scientific impact on the efficacy of the compounded medication.

### 3. What is the expected outcome of applying USP 797 standards?

- A. Increased commercialization of compounded sterile products
- B. Lower rates of patient infections associated with sterile preparations**
- C. Higher production rates in compounding pharmacies
- D. Decreased regulatory oversight for compounding facilities

The application of USP 797 standards is fundamentally aimed at ensuring the safety and quality of compounded sterile preparations. One of the primary outcomes of adhering to these standards is the significant reduction in the rates of patient infections associated with these medications. By implementing stringent guidelines for the preparation, handling, and storage of sterile compounds, USP 797 establishes a framework that promotes aseptic techniques, proper environmental controls, and thorough training for compounding personnel. This focus on minimizing contamination risks directly leads to improved patient safety and healthcare outcomes. The standards emphasize the importance of maintaining a sterile environment, practicing proper hand hygiene, using appropriate PPE (personal protective equipment), and following detailed protocols for compounding procedures. As a result, the incidence of infection associated with compounded sterile drugs can be expected to decline significantly, benefitting patient health and enhancing the overall reputation of compounding pharmacies. In contrast, increasing commercialization of compounded sterile products, higher production rates, or decreasing regulatory oversight do not align with the primary intent of USP 797, which is to prioritize patient safety. Increased commercialization and higher production rates might actually introduce more risks if safety measures are compromised, while less regulatory oversight would undermine the very protections that USP 797 is designed to enforce.

### 4. What does proper training in sterile compounding help staff to achieve?

- A. Increased profitability
- B. Better health benefits
- C. Compliance with industry standards**
- D. Less supervision needed

Proper training in sterile compounding is essential for ensuring compliance with industry standards. This training equips staff with the knowledge and skills needed to adhere to the rigorous requirements set forth by organizations such as the United States Pharmacopeia (USP), particularly USP Chapter 797, which outlines practices to prevent contamination and ensure the safety and efficacy of compounded sterile preparations. When staff are well-trained, they understand the critical aspects of aseptic technique, proper cleaning and disinfection procedures, and the use of appropriate personal protective equipment. This understanding helps maintain a sterile environment, which is crucial in preventing infections and complications for patients receiving compounded medications. Compliance with industry standards not only safeguards patient health but also helps institutions avoid potential legal issues, fines, or harm to their reputation that can arise from non-compliance. Thus, a focus on proper training leads directly to a significant improvement in adherence to regulatory requirements and best practices in sterile compounding.

**5. Should CSPs not immediately dispensed be refrigerated?**

- A. Yes
- B. No**
- C. Only if they contain hazardous materials
- D. Only if they are liquid

The correct response to the question of whether compounded sterile preparations (CSPs) that are not immediately dispensed should be refrigerated is that they should not. According to USP 797 standards, the storage requirements for CSPs depend significantly on the intended use and the stability of the components within the preparation. If a CSP is not administered or dispensed immediately, it is typically stored at controlled room temperature unless otherwise recommended based on sterility assurance and stability guidelines. Refrigerating a CSP that does not require it might lead to undesirable effects such as precipitate formation, phase separation, or changes in potency, particularly for certain medications that have specific storage requirements. Each CSP should be evaluated based on its stability profile, and the storage conditions indicated in the manufacturer's guidelines should be closely adhered to, which usually includes room temperature if refrigeration is not specified. Therefore, it is essential to properly assess the requirements for different types of CSPs to ensure their effectiveness and safety prior to their administration.

**6. For how long should the LAFW blowers run before starting compounding activities?**

- A. 15 minutes
- B. 30 minutes**
- C. 45 minutes
- D. One hour

The correct duration for running the Laminar Airflow Workbench (LAFW) blowers before commencing compounding activities is 30 minutes. This timeframe is important because it allows for the establishment of unidirectional airflow, ensuring the workspace is adequately cleared of particles and contaminants. The 30-minute pre-operation run time supports the reduction of microbial load in the area where sterile products will be prepared. This practice is aligned with the guidelines outlined in USP 797, which emphasizes the importance of maintaining a sterile environment for compounding. Continual airflow helps to displace potentially harmful particles, thereby creating a safer workspace for both the compounder and the products being prepared. The flow of HEPA-filtered air also must reach optimal levels, which can take some time, making 30 minutes a reasonable and effective standard in practice. While other times such as 15 minutes, 45 minutes, or one hour may be suggested in various settings or by different institutions, the proper consensus within the professional community is that 30 minutes is the most effective and widely accepted practice based on aseptic technique and environmental safety standards.

**7. What is the correct order of garbing for compounding sterile preparations?**

- A. Gloves, shoe covers, gown, face mask, hair cover
- B. Gown, face mask, hair cover, shoe covers, gloves**
- C. Hair cover, gown, gloves, shoe covers, face mask
- D. Face mask, gloves, gown, hair cover, shoe covers

The correct order of garbing for compounding sterile preparations is essential to minimize contamination risk. In this order, personnel first don the hair cover to prevent contamination from hair and skin particles. Following this, the gown is put on, which serves as a protective barrier to ensure that clothing does not introduce contaminants to the sterile environment. The face mask is then worn to protect the sterile preparations from droplets and respiratory emissions. After securing the mask, shoe covers are put on to prevent any contaminants from footwear from entering the sterile compounding area. Finally, gloves are donned to provide an additional layer of protection for both the compounding personnel and the sterile products being prepared. This sequence is crucial because it ensures that contaminants are managed in a systematic way, contributing to the overall sterility of the compounding environment. Each piece of garb plays a unique role in protecting the sterile environment, and the order is designed to maintain hygiene throughout the garbing process.

**8. What should the air quality be in an ante-area used for sterile compounding?**

- A. ISO Class 5
- B. ISO Class 6
- C. ISO Class 8 or better**
- D. ISO Class 9

In the context of sterile compounding, the air quality in the ante-area is crucial for maintaining a controlled environment that minimizes the risk of contamination. An ante-area is the space where compounded sterile preparations (CSPs) are prepared before they enter the actual cleanroom or buffer area. ISO Class 8 or better is the standard specified for ante-areas in sterile compounding settings. This classification indicates acceptable levels of airborne particulate contamination, ensuring a safer environment for both staff and the preparations being made. The ISO Class 8 standard allows for a higher number of allowable particles per cubic meter compared to more stringent classes, which is appropriate since the ante-area typically does not directly involve the sterile preparation process but serves as a transition area to the more controlled atmosphere of the cleanroom. Maintaining this air quality standard in the ante-area supports contamination control by reducing the amount of particulates in the air, which can be a source of microbial contamination. Overall, having an ante-area designated as ISO Class 8 provides a balance between operational efficiency and necessary cleanliness, aligning with the goals of USP 797 to ensure patient safety in the final compounded product.

**9. Is formal documentation needed for adverse event reporting procedures?**

- A. No, it's not necessary
- B. Yes, it should be detailed in writing**
- C. Yes, but only for severe cases
- D. Only for internal reviews

Formal documentation for adverse event reporting procedures is essential for several reasons. Firstly, it ensures accountability and traceability in the handling of adverse events. When events are documented in writing, it allows for consistent and accurate reporting, which is crucial for identifying patterns or recurring issues that may require further investigation or intervention. Moreover, detailed written records provide a comprehensive overview of the event, including relevant details such as the nature of the adverse event, patient information, and the circumstances surrounding the occurrence. This information is vital for healthcare providers and regulatory bodies to assess the potential impact on patient safety and to improve practices moving forward. Additionally, having a written procedure facilitates staff training and ensures that all team members are aware of the proper steps to take in the event of an adverse outcome. This promotes a culture of safety and continuous quality improvement within the sterile compounding environment. In the context of the other options, while there may be differing levels of documentation proposed, such as only for severe cases or just for internal reviews, a comprehensive and formal approach in all scenarios is necessary to uphold the highest standards of patient care and regulatory compliance.

**10. How can contamination of a CSP be minimized during compounding?**

- A. By limiting the use of sterile gloves and gowns
- B. By ensuring aseptic technique and proper garbing**
- C. By using non-sterile equipment in the process
- D. By compounding in a crowded area

Minimizing contamination of a compounded sterile preparation (CSP) during compounding is critically important to ensure patient safety and the effectiveness of the medication. Ensuring aseptic technique and proper garbing is the most effective approach to achieve this. Aseptic technique refers to the practices designed to prevent contamination by pathogens and includes steps such as working in a clean environment, using sterilized equipment, and maintaining a sterile field. This technique requires strict adherence to protocols that limit exposure to microorganisms, including careful handling of sterile supplies and avoiding unnecessary movements that could disturb the sterile environment. Proper garbing involves wearing appropriate garments such as sterile gloves, gowns, masks, and hair covers, which serve to shield the CSP from potential contaminants that may arise from the compounding personnel. When these garments are worn correctly and are of the appropriate type, they help to provide a barrier between the person's skin, hair, and respiratory secretions, thereby minimizing the risk of contamination. In contrast, choices like limiting the use of sterile gloves and gowns would likely increase the risk of contamination, as would using non-sterile equipment or compounding in a crowded area. These practices would not align with the fundamental principles of sterility and would compromise the integrity of the compounded preparation.