# BPS Sterile Compounding Practice Exam (Sample)

## Study Guide


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# Questions

1. **What is the consequence of using non-sterile water in the preparation of high risk CSPs?**

   **A. It maintains sterility of the product**

   **B. It causes contamination**

   **C. It prolongs shelf life**

   **D. It preserves the ingredients**

2. **What relative humidity should be maintained within a C-SCA?**

   **A. Above 60%**

   **B. Less than or equal to 60%**

   **C. Above 50%**

   **D. Exact 70%**

3. **In the context of compounded sterile preparations, why is it important to have documentation of the compounding procedure?**

   **A. To comply with state regulations only**

   **B. For marketing purposes**

   **C. To ensure consistency and accountability in the preparation**

   **D. To convince patients to use the service**

4. **At what temperature is depyrogenation achieved using dry heat?**

   **A. 200 degrees C**

   **B. 250 degrees C**

   **C. 300 degrees C**

   **D. 350 degrees C**

5. **What should be the maximum temperature for a Sterile Product Complex?**

   **A. 25 degrees C**

   **B. 20 degrees C**

   **C. 15 degrees C**

   **D. 10 degrees C**

**6. What is the recommended temperature and pressure for steam sterilization using an autoclave?**

- **A. 100 degrees C at 10 psi**
- **B. 121 degrees C at 15 psi**
- **C. 160 degrees C at 5 psi**
- **D. 250 degrees C at 20 psi**

**7. How can compounding accuracy be verified?**

- **A. By relying solely on the manufacturer's data**
- **B. Through review of labels and documentation of measurements**
- **C. Using visual inspections only**
- **D. By performing calculations without checks**

**8. Which of the following is a requirement for the immediate use provision?**

- **A. No more than two entries into one container**
- **B. Compounding process must exceed one hour**
- **C. Use of hazardous drugs is allowed**
- **D. Compounding can be done in a non-sterile environment**

**9. Which USP chapter is associated with sterilization and sterility assurance of compendial articles?**

- **A. USP 1211**
- **B. USP 797**
- **C. USP 71**
- **D. USP 85**

**10. Which chapter of USP deals primarily with radiopharmaceuticals?**

- **A. USP 797**
- **B. USP 823**
- **C. USP 800**
- **D. USP 999**

# Answers

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

# Explanations

## 1. What is the consequence of using non-sterile water in the preparation of high risk CSPs?

**A. It maintains sterility of the product**

**B. It causes contamination**

**C. It prolongs shelf life**

**D. It preserves the ingredients**

**Using non-sterile water in the preparation of high risk compounded sterile preparations (CSPs) leads to contamination of the product. High risk CSPs are defined as those that involve a greater chance of contamination due to factors such as the integration of non-sterile ingredients, being prepared in environments that do not meet sterile conditions, or utilizing non-sterile equipment. The primary goal in sterile compounding is to ensure that the final product is devoid of microorganisms that could cause harm to patients. When non-sterile water is introduced into the preparation process, it significantly increases the risk of microbial contamination, including bacteria, fungi, and other pathogens that could compromise patient safety. This risk is especially critical in patients who may have compromised immune systems, as they are more susceptible to infections from contaminated products. In high-risk situations, the utilization of sterile water is not just critical for the efficacy of the medication but also essential in ensuring that the final CSP is safe for patient administration. Thus, the use of non-sterile water is directly tied to the potential for contamination, highlighting its serious implications for patient health and the overall reliability of the compounded preparation.**

## 2. What relative humidity should be maintained within a C-SCA?

**A. Above 60%**

**B. Less than or equal to 60%**

**C. Above 50%**

**D. Exact 70%**

**Maintaining a relative humidity of less than or equal to 60% within a Compounding Sterile Aseptic Area (C-SCA) is critical for several reasons. High humidity levels can facilitate the growth of microorganisms and mold, which poses a significant risk to sterile compounding practices. Additionally, excessive moisture can affect the stability of certain substances, leading to degradation or contamination. The recommended humidity level helps ensure both environmental control and the integrity of compounded sterile preparations. By keeping the humidity at or below this level, it promotes a sterile environment conducive to safe medication preparation, minimizing the risk of contamination that could compromise patient safety.**

## 3. In the context of compounded sterile preparations, why is it important to have documentation of the compounding procedure?

**A. To comply with state regulations only**

**B. For marketing purposes**

**C. To ensure consistency and accountability in the preparation**

**D. To convince patients to use the service**

**Documenting the compounding procedure is crucial because it ensures consistency and accountability in the preparation of compounded sterile products. Proper documentation provides a clear record of each step taken during the compounding process, including ingredient sources, equipment used, and the specific techniques employed. This allows compounding pharmacists to replicate the process reliably, which is vital in maintaining the product's quality and effectiveness. Additionally, documentation is a key component in quality assurance and regulatory compliance. It facilitates tracking the preparation history of a compound, which is essential in case of any issues that may arise, such as product recalls or adverse events. In terms of accountability, detailed records help to establish who performed each stage of compounding, which is important for both quality control and professional responsibility. Other options, while they may have some relevance, do not capture the comprehensive role that proper documentation plays in guaranteeing the safety, quality, and regulatory adherence of compounded sterile preparations.**

## 4. At what temperature is depyrogenation achieved using dry heat?

**A. 200 degrees C**

**B. 250 degrees C**

**C. 300 degrees C**

**D. 350 degrees C**

**Depyrogenation using dry heat is effectively achieved at a temperature of 250 degrees Celsius. This temperature is high enough to ensure that pyrogens, which are heat-stable substances often produced by microorganisms, are destroyed. The process involves exposing the items to this temperature for a specific duration to ensure that all pyrogens are eliminated, thereby ensuring the sterility and safety of the compounded sterile products. The choice of 250 degrees Celsius aligns with scientific guidelines and practices established for depyrogenation in a sterile compounding environment. It is recognized as a standard temperature that balances efficacy with safety, ensuring that materials remain intact while effectively achieving the desired sterilization. Higher temperatures might not provide additional benefits for depyrogenation and could risk damaging certain materials, while lower temperatures would not be sufficient to achieve the required level of efficacy in pyrogen removal.**

## 5. What should be the maximum temperature for a Sterile Product Complex?

**A. 25 degrees C**

**B. 20 degrees C**

**C. 15 degrees C**

**D. 10 degrees C**

**The maximum temperature for a Sterile Product Complex is critical for ensuring the stability and safety of compounded sterile preparations. Temperature affects the chemical stability of drugs and can impact sterility. A maximum temperature of 20 degrees Celsius is generally established as suitable for many sterile products. This temperature limit helps to reduce the risk of degradation and maintain the effectiveness of the active ingredients. Maintaining this temperature ensures that the compound's potency remains intact while also reducing the potential for microbial growth, which is crucial in sterile compounding environments. In sterile compounding, exceeding the recommended temperature can result in the alteration of the product's properties and efficacy, thereby posing risks to patient safety. The other temperature options are lower than 20 degrees Celsius, but there needs to be a balance between stability and practicality in handling and storage conditions. Setting the maximum temperature at 20 degrees allows for a safe yet practical environment within which sterile products can be prepared and stored effectively.**

## 6. What is the recommended temperature and pressure for steam sterilization using an autoclave?

**A. 100 degrees C at 10 psi**

**B. 121 degrees C at 15 psi**

**C. 160 degrees C at 5 psi**

**D. 250 degrees C at 20 psi**

**The recommended temperature and pressure for steam sterilization using an autoclave is 121 degrees Celsius at 15 psi. This combination is widely recognized as effective for achieving sterility in healthcare and pharmaceutical settings. The reason this specific temperature and pressure are effective stems from their ability to destroy a broad range of microorganisms, including bacteria, viruses, and spores, through the application of saturated steam. At 121 degrees Celsius, the heat penetrates materials effectively, and the pressure of 15 psi helps to maintain the integrity of the steam, ensuring that it reaches all surfaces of the items being sterilized. Other combinations of temperature and pressure, while they may involve higher temperatures or different pressures, do not meet the criteria established for effective sterilization within the recommended guidelines. For instance, lower temperatures, like those in the first option, do not provide sufficient energy to inactivate most pathogens. Higher temperatures, such as those in the last option, while capable of sterilizing, are not standard for autoclaving as they can viably compromise materials that may not withstand such extreme conditions. Thus, the 121 degrees Celsius at 15 psi is recognized as the optimal set point for reliable steam sterilization in a variety of clinical and laboratory settings.**

## 7. How can compounding accuracy be verified?

**A. By relying solely on the manufacturer's data**

**B. Through review of labels and documentation of measurements**

**C. Using visual inspections only**

**D. By performing calculations without checks**

**Verifying compounding accuracy is crucial to ensure the safety and efficacy of compounded sterile preparations. The correct approach involves thorough review of labels and documentation of measurements. This process helps confirm that the right ingredients and quantities are used according to the compounding recipe or formula. The review of labels ensures that the correct components have been chosen for the specific preparation, while documentation of measurements provides a systematic way to track what has been compounded. This creates a reliable record that can be referenced if questions arise about the compounding process, facilitating accountability and traceability. On the other hand, relying solely on manufacturer data does not take into account the specific context of the compounding procedure and may lead to inaccuracies if the data doesn't reflect the compounding environment or equipment used. Meanwhile, visual inspections can help identify certain discrepancies but are insufficient as a standalone method, as they might miss subtler issues related to measurement precision. Lastly, performing calculations without checks exposes the process to human error, which can lead to significant compounding inaccuracies. This makes a review of labels and measurements a comprehensive and necessary practice for ensuring accurate compounding.**

## 8. Which of the following is a requirement for the immediate use provision?

**A. No more than two entries into one container**

**B. Compounding process must exceed one hour**

**C. Use of hazardous drugs is allowed**

**D. Compounding can be done in a non-sterile environment**

**The immediate use provision is designed to allow for the preparation of sterile compounds in situations where the need for rapid administration is critical, such as in emergencies. One of the key requirements of this provision is that there should be no more than two entries into one container. This restriction helps minimize the risk of contamination, ensuring the compounded preparation remains sterile while facilitating its use in urgent situations. The other options present requirements or scenarios that are not aligned with the immediate use provision. For instance, allowing a compounding process to exceed one hour is counter to the intention of immediate use, which focuses on prompt delivery and use. Furthermore, hazardous drugs typically require stricter handling and compounding standards due to their significant risks, which is not consistent with immediate use scenarios. Lastly, compounding in a non-sterile environment would not maintain the necessary sterility for immediate use, which must occur under appropriate conditions to prevent contamination. Therefore, the correct answer emphasizes the critical limit on container entries to uphold safety and sterility in urgent compounding situations.**

## 9. Which USP chapter is associated with sterilization and sterility assurance of compendial articles?

**A. USP 1211**

**B. USP 797**

**C. USP 71**

**D. USP 85**

**The chapter that focuses on sterilization and sterility assurance of compendial articles is USP 1211. This chapter provides guidance specifically on the various methods of sterilization, including their effectiveness and the importance of validating sterilization processes to ensure the sterility of pharmaceutical products. It discusses different sterilization techniques, such as moist heat sterilization, dry heat sterilization, and others, highlighting their application in manufacturing processes where sterility must be assured. This chapter is crucial for professionals involved in sterile compounding and pharmaceutical manufacturing, as it outlines standards and practices to ensure that products are free from viable microorganisms. Understanding and adhering to the principles set forth in this chapter is essential for maintaining the integrity and safety of sterile products. While other USP chapters mentioned may also relate to sterile compounding, they serve different purposes. For example, USP 797 primarily deals with the sterile compounding environment and procedures but does not focus explicitly on sterilization processes used or sterility assurance as USP 1211 does. Thus, USP 1211 is the appropriate reference for sterilization and sterility assurance in the context of compendial articles.**

## 10. Which chapter of USP deals primarily with radiopharmaceuticals?

**A. USP 797**

**B. USP 823**

**C. USP 800**

**D. USP 999**

**The correct answer is USP 823 because this chapter specifically addresses the handling and compounding of radiopharmaceuticals, which are drugs that emit radiation and are used primarily for diagnostic or therapeutic purposes in nuclear medicine. USP 823 outlines the standards and requirements for the preparation of these highly specialized compounds, ensuring safety, quality, and efficacy in the handling of radioactive materials. This chapter also provides guidelines for various aspects, including personnel qualifications, environmental controls, and equipment requirements tailored to the unique challenges posed by working with radiopharmaceuticals. Given the complexity and potential hazards associated with radioactivity, these guidelines are critical in a sterile compounding environment to protect both patients and healthcare professionals. Other chapters mentioned, like USP 797 or USP 800, focus on sterile compounding and hazardous drugs, respectively, but do not specifically address the unique considerations for radiopharmaceuticals. USP 999, while a real designation, does not pertain to any established standards related to radiopharmaceuticals or sterile compounding. Therefore, USP 823 serves as the appropriate regulatory framework for handling radiopharmaceuticals in a compounding setting.**