

USP 797 Sterile Compounding Practice Test (Sample)

Study Guide



Everything you need from our exam experts!

This is a sample study guide. To access the full version with hundreds of questions,

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Table of Contents

Copyright	1
Table of Contents	2
Introduction	3
How to Use This Guide	4
Questions	6
Answers	9
Explanations	11
Next Steps	17

Introduction

Preparing for a certification exam can feel overwhelming, but with the right tools, it becomes an opportunity to build confidence, sharpen your skills, and move one step closer to your goals. At Examzify, we believe that effective exam preparation isn't just about memorization, it's about understanding the material, identifying knowledge gaps, and building the test-taking strategies that lead to success.

This guide was designed to help you do exactly that.

Whether you're preparing for a licensing exam, professional certification, or entry-level qualification, this book offers structured practice to reinforce key concepts. You'll find a wide range of multiple-choice questions, each followed by clear explanations to help you understand not just the right answer, but why it's correct.

The content in this guide is based on real-world exam objectives and aligned with the types of questions and topics commonly found on official tests. It's ideal for learners who want to:

- Practice answering questions under realistic conditions,
- Improve accuracy and speed,
- Review explanations to strengthen weak areas, and
- Approach the exam with greater confidence.

We recommend using this book not as a stand-alone study tool, but alongside other resources like flashcards, textbooks, or hands-on training. For best results, we recommend working through each question, reflecting on the explanation provided, and revisiting the topics that challenge you most.

Remember: successful test preparation isn't about getting every question right the first time, it's about learning from your mistakes and improving over time. Stay focused, trust the process, and know that every page you turn brings you closer to success.

Let's begin.

How to Use This Guide

This guide is designed to help you study more effectively and approach your exam with confidence. Whether you're reviewing for the first time or doing a final refresh, here's how to get the most out of your Examzify study guide:

1. Start with a Diagnostic Review

Skim through the questions to get a sense of what you know and what you need to focus on. Don't worry about getting everything right, your goal is to identify knowledge gaps early.

2. Study in Short, Focused Sessions

Break your study time into manageable blocks (e.g. 30 - 45 minutes). Review a handful of questions, reflect on the explanations, and take breaks to retain information better.

3. Learn from the Explanations

After answering a question, always read the explanation, even if you got it right. It reinforces key points, corrects misunderstandings, and teaches subtle distinctions between similar answers.

4. Track Your Progress

Use bookmarks or notes (if reading digitally) to mark difficult questions. Revisit these regularly and track improvements over time.

5. Simulate the Real Exam

Once you're comfortable, try taking a full set of questions without pausing. Set a timer and simulate test-day conditions to build confidence and time management skills.

6. Repeat and Review

Don't just study once, repetition builds retention. Re-attempt questions after a few days and revisit explanations to reinforce learning.

7. Use Other Tools

Pair this guide with other Examzify tools like flashcards, and digital practice tests to strengthen your preparation across formats.

There's no single right way to study, but consistent, thoughtful effort always wins. Use this guide flexibly — adapt the tips above to fit your pace and learning style. You've got this!

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Questions

- 1. What is the correct guideline regarding the temperature of Compounding Sterile Preparations (CSPs) during transit?**
 - A. CSPs can exceed the warmest temperature specified on the label.**
 - B. The temperature must be maintained at or below the warmest specified temperature on the label.**
 - C. Temperatures are not important during transport of CSPs.**
 - D. CSPs must be frozen during transit.**
- 2. What must patients and/or caregivers demonstrate under direct supervision when it comes to aseptic technique?**
 - A. The ability to make their own medications at home.**
 - B. Competency in aseptic technique.**
 - C. Ability to read the labels correctly.**
 - D. Understanding the ingredients of the CSP.**
- 3. What is essential for ensuring proper personnel training in safe sterile compounding?**
 - A. Implement regular competency evaluations and practical training sessions**
 - B. Using online training modules exclusively**
 - C. Relying on annual refresher courses only**
 - D. Allowing self-study on compounding protocols**
- 4. What is the focus of risk assessment in sterile compounding?**
 - A. To enhance product marketing**
 - B. To identify potential hazards and implement controls**
 - C. To increase production speed**
 - D. To track employee performance**
- 5. Which strategy is effective in preventing cross-contamination in sterile compounding?**
 - A. Using shared equipment**
 - B. Implementing proper waste disposal**
 - C. Designating specific areas for different procedures**
 - D. Conducting training once a year**

- 6. What defines a Category 1 CSP?**
- A. A preparation that is intended for long-term storage**
 - B. A preparation that is for immediate use and does not require environmental controls or sterile compounded facilities**
 - C. A preparation that requires compounding to occur in a cleanroom**
 - D. A preparation that can only be compounded by a pharmacist**
- 7. What are the risks associated with using expired ingredients in compounding?**
- A. They may improve the compound's effectiveness**
 - B. They can lead to reduced efficacy and safety risks due to potential degradation or contamination**
 - C. They may have no effect on the final product**
 - D. They are strictly monitored by regulatory bodies**
- 8. In what situations should a compounding facility undergo a thorough re-evaluation?**
- A. When new marketing strategies are implemented**
 - B. Following significant alterations to procedures or after an adverse event**
 - C. When there is a change in managerial staff**
 - D. Upon routine inspections by the health department**
- 9. What is the main goal of maintaining proper airflow in the sterile compounding area?**
- A. To enhance comfort for the staff**
 - B. To reduce the risk of contamination by ensuring a continuous flow of filtered air**
 - C. To control temperature fluctuations**
 - D. To save on energy costs**
- 10. How often should personnel perform glove fingertip testing?**
- A. Only once before starting work**
 - B. At least annually for low- and medium-risk compounding; semi-annually for high-risk compounding**
 - C. Every month regardless of risk level**
 - D. Every week during the compounding process**

Answers

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

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Explanations

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1. What is the correct guideline regarding the temperature of Compounding Sterile Preparations (CSPs) during transit?

- A. CSPs can exceed the warmest temperature specified on the label.
- B. The temperature must be maintained at or below the warmest specified temperature on the label.**
- C. Temperatures are not important during transport of CSPs.
- D. CSPs must be frozen during transit.

Maintaining the temperature of Compounding Sterile Preparations (CSPs) during transit is critical to ensure their stability, efficacy, and safety for patient use. The correct guideline states that the temperature must be maintained at or below the warmest specified temperature on the label. This is necessary because exceeding this temperature can lead to degradation of the active ingredients, potentially compromising the effectiveness of the preparation and posing a risk to patient safety. CSP labels are accompanied by stability information that includes temperature limits based on scientific studies. Following these guidelines helps to ensure that the products remain within their validated storage conditions throughout the transportation process, thus upholding quality assurance and minimizing the risk of microbial contamination or loss of potency. Other choices misrepresent the importance of temperature control. Allowing CSPs to exceed labeled temperatures can damage the preparation, while stating that temperatures are not important during transport neglects the stringent standards set forth by the guidelines for compounding as well as patient safety. Lastly, freezing CSPs during transit is inappropriate for many formulations, as freezing can lead to changes in composition and loss of efficacy.

2. What must patients and/or caregivers demonstrate under direct supervision when it comes to aseptic technique?

- A. The ability to make their own medications at home.
- B. Competency in aseptic technique.**
- C. Ability to read the labels correctly.
- D. Understanding the ingredients of the CSP.

Patients and/or caregivers must demonstrate competency in aseptic technique under direct supervision because this skill is critical for ensuring the safety and effectiveness of compounded sterile preparations (CSPs). Aseptic technique involves a series of specific procedures that minimize the risk of contamination by pathogens during the preparation and administration of medications. Competency in this area means that individuals are not only familiar with the theoretical aspects of aseptic technique but can also perform the necessary steps correctly in practice. This includes practices such as properly washing hands, using sterile equipment, and maintaining an appropriate environment during the preparation process. Given the complexities involved in sterile compounding, it is essential that patients and caregivers can apply these techniques accurately to reduce the risk of infections and ensure the quality of the compounded medications they are handling. Other options, while they may contain relevant aspects of patient education, do not encompass the critical hands-on skill set needed for aseptic technique, which is vital for patient safety in the context of sterile compounding.

3. What is essential for ensuring proper personnel training in safe sterile compounding?

A. Implement regular competency evaluations and practical training sessions

B. Using online training modules exclusively

C. Relying on annual refresher courses only

D. Allowing self-study on compounding protocols

Implementing regular competency evaluations and practical training sessions is crucial for ensuring proper personnel training in safe sterile compounding because it establishes a structured approach to maintaining and enhancing the skills and knowledge of staff engaged in this critical area of pharmacy practice. Competency evaluations help to assess the understanding of both theoretical concepts and practical skills, ensuring that personnel can perform tasks to the established standards required by guidelines like USP 797. Practical training sessions allow for hands-on demonstrations and practice, enabling individuals to refine their techniques under supervision. This approach fosters an environment of continuous learning and improvement, which is essential for adapting to any updates in protocols or procedures that may arise in sterile compounding practices. Regular assessments can identify areas where personnel may require additional training or support, promoting a culture of safety and compliance in handling sterile products. Other training methods, such as online training modules or relying solely on annual refresher courses, may lack the interactive and evaluative aspects needed to comprehensively prepare individuals for the complexities of sterile compounding. Likewise, self-study may not provide the structured feedback necessary to ensure that all compounding protocols are understood and adhered to correctly. Thus, the combination of competency evaluations and practical training is fundamental for effective training in sterile compounding.

4. What is the focus of risk assessment in sterile compounding?

A. To enhance product marketing

B. To identify potential hazards and implement controls

C. To increase production speed

D. To track employee performance

In the context of sterile compounding, the primary focus of risk assessment is to identify potential hazards and implement controls to ensure the safety and quality of compounded sterile preparations. This process involves systematically evaluating every step of the compounding process to recognize factors that could compromise sterility or introduce contamination. Identifying potential hazards is crucial because it allows compounding personnel to understand where risks exist, whether they are environmental (like air quality), procedural (like compounding techniques), or related to equipment (like sterilization methods). Once these hazards are identified, appropriate controls can be established, such as implementing standard operating procedures, utilizing proper personal protective equipment, or enhancing facility designs. This focus on risk assessment aligns with the overarching goals of USP 797, which emphasizes the importance of maintaining safety and quality to protect patients who receive sterile compounded medications. By addressing potential risks proactively, the likelihood of contamination and adverse patient outcomes is significantly reduced, thereby enhancing the overall effectiveness of the compounding process.

5. Which strategy is effective in preventing cross-contamination in sterile compounding?
- A. Using shared equipment
 - B. Implementing proper waste disposal
 - C. Designating specific areas for different procedures**
 - D. Conducting training once a year

Designating specific areas for different procedures is an effective strategy in preventing cross-contamination in sterile compounding because it minimizes the risk of contaminants being transferred between different types of preparation activities. By allocating distinct spaces for specific tasks, such as compounding, dispensing, and waste management, the potential for cross-contact with allergens, microorganisms, or hazardous substances is significantly reduced. This spatial separation facilitates a controlled environment where sterility can be better maintained. Moreover, specific areas can be equipped with the appropriate tools, materials, and personal protective equipment tailored to the requirements of each procedure, further enhancing infection control measures. This organizational approach aligns with USP 797 guidelines, which emphasize the importance of maintaining a sterile environment and preventing contamination during the compounding process. Overall, segregating areas dedicated to certain tasks directly contributes to the safety and sterility of compounded medications.

6. What defines a Category 1 CSP?
- A. A preparation that is intended for long-term storage
 - B. A preparation that is for immediate use and does not require environmental controls or sterile compounded facilities**
 - C. A preparation that requires compounding to occur in a cleanroom
 - D. A preparation that can only be compounded by a pharmacist

A Category 1 Compounded Sterile Preparation (CSP) is specifically defined as a preparation that is for immediate use and does not require stringent environmental controls or the utilization of sterile compounding facilities. This means that Category 1 CSPs can be prepared in a manner that is more flexible than other categories, such as those requiring controlled environments or lengthy stability. The focus of Category 1 is on preparations that are made under conditions that maintain sterility due to the nature of their immediate use, which typically includes situations like emergency situations where rapid intervention is necessary. This classification allows for flexibility in compounding practices, recognizing that certain preparations can be made quickly and effectively without the more cumbersome requirements that other categories entail. Thus, it's vital for practitioners to understand that the primary feature defining a Category 1 CSP is indeed its immediacy and lack of requirement for strict environmental controls.

7. What are the risks associated with using expired ingredients in compounding?

- A. They may improve the compound's effectiveness
- B. They can lead to reduced efficacy and safety risks due to potential degradation or contamination**
- C. They may have no effect on the final product
- D. They are strictly monitored by regulatory bodies

Using expired ingredients in compounding carries significant risks primarily tied to the safety and efficacy of the final product. As time passes, the chemical composition of ingredients can change due to degradation, resulting in a loss of potency or effectiveness. This can render the compounded preparation less effective, which is particularly concerning in situations where precise therapeutic effects are crucial, such as in medications for critically ill patients. Additionally, expired ingredients are more susceptible to contamination. Microbial growth, chemical alterations, and changes in physical properties can pose serious safety risks. If a compounded preparation is made with an expired ingredient, it can lead to adverse reactions in patients or even therapeutic failures. The concept that expired ingredients might improve a compound's effectiveness or have no effect is misleading, as the risks associated with their use are well documented and recognized in the field of pharmacy. Furthermore, while regulatory bodies do monitor the use of pharmaceutical ingredients, using expired items can violate guidelines established to ensure patient safety and product integrity. Therefore, the emphasis on avoiding expired ingredients is crucial for maintaining the highest standards in sterile compounding.

8. In what situations should a compounding facility undergo a thorough re-evaluation?

- A. When new marketing strategies are implemented
- B. Following significant alterations to procedures or after an adverse event**
- C. When there is a change in managerial staff
- D. Upon routine inspections by the health department

A thorough re-evaluation of a compounding facility is crucial following significant alterations to procedures or after an adverse event. This process ensures that any changes made to the compounding practices are safe, effective, and compliant with established standards. When procedures are altered, it may affect sterility, accuracy, or the overall quality of compounded products. Similarly, after an adverse event, such as a contamination issue or patient harm, a comprehensive evaluation is necessary to identify the root causes, implement corrective actions, and prevent future occurrences. Such evaluations help in not only maintaining compliance with USP 797 requirements but also in safeguarding patient health. While changes in marketing strategies, managerial staffing, or routine inspections may warrant adjustments or reviews, they do not inherently necessitate a full re-evaluation of the compounding processes and safety measures in the same critical way as the significant procedural changes or adverse events would.

9. What is the main goal of maintaining proper airflow in the sterile compounding area?

- A. To enhance comfort for the staff**
- B. To reduce the risk of contamination by ensuring a continuous flow of filtered air**
- C. To control temperature fluctuations**
- D. To save on energy costs**

Maintaining proper airflow in the sterile compounding area is critical to reducing the risk of contamination. The primary purpose of airflow management, particularly through the use of laminar airflow hoods or cleanrooms, is to ensure a continuous flow of filtered air that minimizes the presence of airborne particles and microorganisms. This controlled environment helps prevent contaminants from settling on the sterile products being prepared, ensuring that the compounded medications maintain their sterility throughout the compounding process. Effective airflow is essential for creating a sterile environment, where the integrity and safety of the compounded products are prioritized. The filtered air flows from clean areas toward less clean areas, effectively pushing contaminants away from the critical work surfaces and ensuring that the environment meets the strict standards outlined in USP 797. While other factors such as staff comfort, temperature control, and energy costs may be relevant in a broader context, the primary goal of airflow management in the sterile compounding area is to safeguard against contamination, thereby protecting patient health and safety.

10. How often should personnel perform glove fingertip testing?

- A. Only once before starting work**
- B. At least annually for low- and medium-risk compounding; semi-annually for high-risk compounding**
- C. Every month regardless of risk level**
- D. Every week during the compounding process**

Glove fingertip testing is an essential component of ensuring aseptic technique in sterile compounding. This testing is performed to assess the effectiveness of an individual's hand hygiene and glove usage, which are critical for preventing contamination of sterile products. The correct response indicates that personnel should undergo glove fingertip testing at least annually for low- and medium-risk compounding, and semi-annually for high-risk compounding. This frequency is aligned with the standards set by USP 797, which emphasizes the need for regular competency evaluations in order to maintain a healthcare worker's ability to perform sterile compounding safely. This approach allows for adequate monitoring and feedback: annual testing for lower-risk environments reflects that personnel need to demonstrate their competency less frequently, while more frequent testing for higher-risk environments acknowledges the greater potential for risk and the need for consistent performance. This balance ensures ongoing vigilance and adherence to aseptic techniques, which is crucial when handling sterile preparations. In contrast, testing only once before starting work would not allow for the monitoring of competency over time and could lead to outdated practices. Testing every month or every week, regardless of risk level, could create unnecessary burden and may not be practical or warranted, as the standards acknowledge that more intensive monitoring is required only in high-risk

Next Steps

Congratulations on reaching the final section of this guide. You've taken a meaningful step toward passing your certification exam and advancing your career.

As you continue preparing, remember that consistent practice, review, and self-reflection are key to success. Make time to revisit difficult topics, simulate exam conditions, and track your progress along the way.

If you need help, have suggestions, or want to share feedback, we'd love to hear from you. Reach out to our team at hello@examzify.com.

Or visit your dedicated course page for more study tools and resources:

<https://usps797sterilecompounding.examzify.com>

We wish you the very best on your exam journey. You've got this!