BOARD CERTIFIED STERILE COMPOUNDING PHARMACIST (BCSCP) PRACTICE TEST (SAMPLE)

STUDY GUIDE

SAMPLE STUDY GUIDE WITH LIMITED QUESTIONS

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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. 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.

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. 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!

Questions

1. What activities are encompassed by handling HDs?

A. Receipt, storage, compounding, dispensing, administration, and disposal.

B. Only compounding and dispensing.

C. Only storage and transport.

D. Only administration and disposal.

2. Under USP 800, which drugs do not have to follow USP 800 if an AOR is performed?

A. All HDs must follow USP 800 regardless of AOR

B. Final dosage forms of compounded HD preps and conventionally manufactured HD products, including antineoplastic dosage forms that do not require any further manipulations other than counting or repackaging

C. For dosage forms of other HDs, may perform AOR to determine alternative containment strategies and/or work practices

D. AOR is not allowed under USP 800

3. USP 800 defines API as which of the following?

A. Any substance intended to be used in compounding and that becomes the active ingredient with pharmacological activity.

B. A substance used only as a solvent.

C. A preservative added to extend shelf life.

D. A colorant added for identification.

4. For water-containing topical and mucosal liquids, the BUD is not later than how many days?

A. Not later than 30 days

B. Not later than 60 days

C. Not later than 15 days

D. Not later than 7 days

5. Which statement about AOR documentation is true?

A. AOR documentation is optional

B. The review must occur every 12 months

C. Alternative containment strategies must be documented

D. Alternative containment strategies must be documented, and the review must occur every 12 months

6. What is the BUD for addEASE devices assembled in ISO 5 for 50 and 100 mL bags?

A. 56 days

B. 90 days

C. 120 days

D. 70 days

7. Which product is covered by DSCSA Section 581(13)?

A. Cosmetic product

B. Investigational drug

C. Veterinary feed additive

D. Prescription drug in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, lyophilized products before reconstitution)

8. Which dosage form requires a biocompatible polymeric excipient and may be bioresorbable for extended release?

A. Liposomes

B. Emulsions

C. Implants

D. Microparticles

9. Oil-in-water or water-in-oil emulsions typically entrap the drug substance. This describes which dosage form?

A. Suspensions

B. Solutions

C. Emulsions

D. Liposomes

10. Which analytical techniques are most reliable for determining stability when published literature is not available?

A. Pyrolysis and GC

B. TLC and HPLC

C. UV-Vis only

D. NMR and MS

Answers

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

Explanations

1. What activities are encompassed by handling HDs?

A. Receipt, storage, compounding, dispensing, administration, and disposal.

B. Only compounding and dispensing.

C. Only storage and transport.

D. Only administration and disposal.

Handling hazardous drugs involves every stage from arrival to disposal. The most comprehensive view includes receipt, storage, compounding, dispensing, administration, and disposal. At receipt, you verify the supplier, integrity, and labeling. Storage requires proper containment and separation from non-HD inventory. Compounding demands containment like a certified cabinet and appropriate PPE to prevent exposure. Dispensing ensures accurate drug selection, dosing, labeling, and patient instructions to minimize risk. Administration involves safe techniques by healthcare workers to limit exposure and spills. Disposal covers hazardous waste handling to prevent environmental contamination. Because exposure risks can occur at multiple points, all these activities must be included. The other options omit several essential steps, which would leave gaps in safety and compliance.

2. Under USP 800, which drugs do not have to follow USP 800 if an AOR is performed?

A. All HDs must follow USP 800 regardless of AOR

B. Final dosage forms of compounded HD preps and conventionally manufactured HD products, including antineoplastic dosage forms that do not require any further manipulations other than counting or repackaging

C. For dosage forms of other HDs, may perform AOR to determine alternative containment strategies and/or work practices

D. AOR is not allowed under USP 800

The main idea here is that USP 800 allows a risk-based, alternative approach to handling hazardous drugs when a proper assessment demonstrates adequate containment. An AOR/alternative handling approach can justify not applying every USP 800 requirement to specific low-risk forms. The best answer identifies the drugs that may be exempt when such an AOR is performed: the final dosage forms of compounded hazardous-drug preps and conventionally manufactured hazardous-drug products that do not require any further manipulations beyond counting or repackaging. Since these forms aren't being prepared or altered to create new dosage forms, their exposure potential is minimal, so with a documented AOR, they can be managed using containment and practices appropriate to that assessed risk rather than the full USP 800 suite. Other choices aren't correct because USP 800 isn't a blanket rule for all HDs regardless of AOR, and AOR is a sanctioned option you can use to tailor containment for certain forms. The notion that AOR is not allowed is incorrect, and while AOR can be used for other HDs, the statement about which drugs don't have to follow USP 800 specifically points to those final dosage forms that require no further manipulation beyond counting or repackaging.

3. USP 800 defines API as which of the following?

A. Any substance intended to be used in compounding and that becomes the active ingredient with pharmacological activity.

B. A substance used only as a solvent.

C. A preservative added to extend shelf life.

D. A colorant added for identification.

The API is the substance intended for use in compounding that becomes the active ingredient with pharmacological activity. This means it is the specific drug component in a preparation that produces the therapeutic effect. Solvents, preservatives, and colorants do not have pharmacological activity themselves, so they are not considered the API—they're inactive ingredients or excipients used to formulate, preserve, or identify the final product. For example, the active drug in a compounded suspension is the API, while the solvent or vehicle carries it, and any preservative or dye serves a supportive role rather than providing the therapeutic effect.

4. For water-containing topical and mucosal liquids, the BUD is not later than how many days?

A. Not later than 30 days

B. Not later than 60 days

C. Not later than 15 days

D. Not later than 7 days

Water-containing topical and mucosal liquids have water in the formulation, which allows microorganisms to grow if the product sits for too long. Because of that risk, the beyond-use date is limited to 30 days, providing a safe, practical window to use the product before microbial growth becomes a concern. Extending beyond 30 days would increase the chance of contamination or infection, while shorter time frames would unnecessarily shorten usable life without added safety benefits. For products without water, or for certain non-aqueous formulations, longer BUDs may apply, but for water-containing topical and mucosal liquids the standard is not later than 30 days.

5. Which statement about AOR documentation is true?

A. AOR documentation is optional

B. The review must occur every 12 months

C. Alternative containment strategies must be documented

D. Alternative containment strategies must be documented, and the review must occur every 12 months

The rule here focuses on two linked requirements: you must document any alternative containment strategies used in the AOR, and you must review the AOR at least every 12 months to ensure it remains appropriate and effective. Documenting the alternatives provides traceability and justification for deviating from standard containment, while the annual review keeps the AOR current with changes in procedures, equipment, and regulations. Because both elements are required, the statement that includes both documentation of alternative containment strategies and a yearly review is the true one.

6. What is the BUD for addEASE devices assembled in ISO 5 for 50 and 100 mL bags?

A. 56 days

B. 90 days

C. 120 days

D. 70 days

BUD is driven by stability and sterility data for the specific combination of drug, device, and container, evaluated under defined storage conditions. For addEASE devices assembled in ISO 5 for 50 and 100 mL bags, stability studies support an admixture that remains chemically and physically stable for up to 70 days in that packaging and setup. The ISO 5 environment ensures aseptic technique, and the closed-system bag with the addEASE device provides a robust barrier, allowing the extended shelf life validated by the manufacturer. The other durations aren't aligned with the validated stability data for this particular configuration, so 70 days is the best choice. If storage conditions differ from those used in the validation, the BUD would be adjusted accordingly.

7. Which product is covered by DSCSA Section 581(13)?

A. Cosmetic product

B. Investigational drug

C. Veterinary feed additive

D. Prescription drug in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, lyophilized products before reconstitution)

DSCSA Section 581(13) defines a drug as a finished dosage form intended for administration to a patient without further manufacturing. This means products that come ready to use in the hands of a patient, such as capsules and tablets, are covered. Even lyophilized formulations before they're reconstituted fit this idea because they are the final dosage form that will be administered after minimal preparation. Cosmetics aren't drugs under this statute, investigational drugs are governed by separate regulatory pathways and aren't considered finished dosage forms in routine commerce, and veterinary feed additives aren't human drugs. So the option that matches this definition is a prescription drug in finished dosage form for administration to a patient without further manufacturing.

8. Which dosage form requires a biocompatible polymeric excipient and may be bioresorbable for extended release?

A. Liposomes

B. Emulsions

C. Implants

D. Microparticles

Biocompatible polymeric excipients are used to create a degrading matrix that controls drug release over time. When designed as an implant, this polymeric matrix can be placed in the body and slowly break down, releasing medication as it erodes. This bioresorbable behavior is a hallmark of implants intended for extended-release therapy, and using a biocompatible polymer ensures tissue compatibility while the drug is delivered over weeks or months. Liposomes and emulsions rely on lipid components and dispersed phases rather than a polymeric matrix, so they don't inherently require a polymeric excipient for sustained, bioresorbable release. Microparticles can be polymer-based and bioresorbable, but the form most directly associated with an implanted, polymeric, biodegradable delivery system designed for extended release is the implant.

9. Oil-in-water or water-in-oil emulsions typically entrap the drug substance. This describes which dosage form?

A. Suspensions

B. Solutions

C. Emulsions

D. Liposomes

Emulsions are systems where droplets of one liquid are dispersed in another immiscible liquid. In oil-in-water emulsions, oil droplets sit in a continuous water phase; in water-in-oil emulsions, water droplets sit in a continuous oil phase. The drug substance is often entrapped within those droplets or at the interface, which is a defining feature of this dosage form and helps retain the drug in a contained phase. This differs from suspensions, where solid particles are dispersed in a liquid but there isn't an immiscible liquid droplet system; from solutions, where the drug is dissolved in a single solvent; and from liposomes, which are lipid bilayer vesicles with a distinct structure rather than simple oil–water droplets.

10. Which analytical techniques are most reliable for determining stability when published literature is not available?

A. Pyrolysis and GC

B. TLC and HPLC

C. UV-Vis only

D. NMR and MS

When published data isn't available, you need analytical methods that are stability-indicating—able to separate the drug from its degradation products and quantify the intact drug reliably. Thin-layer chromatography provides a fast, inexpensive screening to detect changes in the formulation and flag potential degradation pathways. High-performance liquid chromatography then offers a robust, highly selective and quantitative approach to separate the drug from its degradants, measure potency, and track stability over time. Together, they cover both quick screening and proven, validated quantitation, which is essential when there's no literature to guide method development. Other methods fall short for routine stability assessment. UV-Vis can be misleading if degradation products have similar absorbance or co-elute with the drug, making it less reliable as a stability-indicating technique. NMR and MS are powerful for identifying and characterizing degradation products but are typically more resource-intensive and not as practical for routine, validated stability testing. Pyrolysis and GC target volatile or thermally generated products and may not address non-volatile drug substances or complex dosage forms.

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://bcscp.examzify.com

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