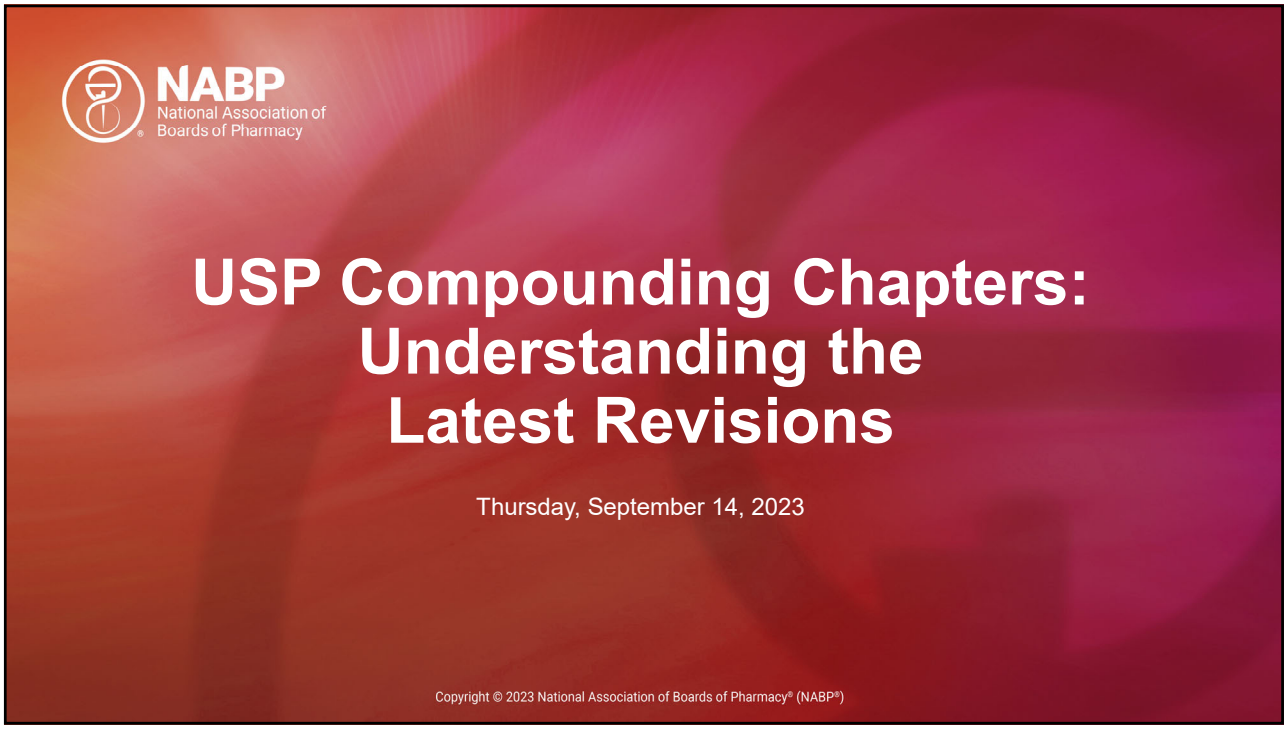

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Financial Disclosures

Our speaker Connie Sullivan declares that she does not have a current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of this continuing pharmacy education (CPE) activity within the past 24 months.

Our speakers Brenda Jensen and Gus Bassani declare that they do have a current affiliation or financial arrangement with ineligible companies as an owner of Compounding Consultants, LLC, and as an employee of PCCA, Inc, respectively.

Additionally, NABP staff involved in the planning of this activity do not have a current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of NABP's CPE Program within the past 24 months.

All relevant financial relationships have been mitigated.

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NABP National Association of Boards of Pharmacy

USP Compounding Chapters: Understanding the Latest Revisions

Brenda Jensen, CPhT, CNMT, MBA
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USP Compounding Expert Committee;
President & Chief Executive Officer,
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Welcome

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Revisions to USP Compounding Standards ⟨795⟩ and ⟨797⟩

September 14th, 2023

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Learning Objectives

1. Identify key aspects of the revisions to *USP* ⟨795⟩ *Pharmaceutical Compounding – Nonsterile Preparations* and *USP* ⟨797⟩ *Pharmaceutical Compounding – Sterile Preparations*
2. Discuss the next steps for the revised USP compounding chapters
3. Describe subjects of the revised USP compounding chapters that were previously unclear to readers
4. Explain how to apply the revised USP compounding chapters

6

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Assessment Questions

1. When do USP standards become official?

A. As soon as they are published in the *Pharmacopeial Forum*

B. Generally, six months after being published in the *Pharmacopeial Forum*

C. As soon as they are published in the *USP–NF*

D. Generally, six months after being published in the *USP–NF*

7

7

Assessment Questions

2. The current official version of USP ⟨797⟩ was last revised in

A. 2008

B. 2015

C. 2019

D. 2022

8

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Assessment Questions

3. Category 1 compounded sterile preparations (CSPs) in USP ⟨797⟩ are restricted to

A. Sterile to sterile compounding only

B. CSPs that are assigned a BUD of no more than 6 hours when stored at room temperature

C. CSPs that are assigned a BUD of no more than 24 hours when stored under refrigeration

D. Non-hazardous CSPs only

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USP Overview

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The 2020 – 2025 Council of Experts

Biologics	Small Molecules	Excipients	General Chapters	Healthcare Quality & Safety	Dietary Supplements & Herbal Medicines, Food Ingredients
Biologics Monographs 1–Peptides & Oligonucleotides *Michael De Felippis*	**Small Molecules 1** *Mary Selbel*	**Simple Excipients** *Eric Munson*	**General Chapters–Dosage Forms** *Martin Coffey*	**Nomenclature & Labeling** *Stephanie Crawford*	**Botanical Dietary Supplements & Herbal Medicines** *Robin Merles*
Biologics Monographs 2–Proteins *Wendy Saffell-Clemmer*	**Small Molecules 2** *Justin Pennington*	**Complex Excipients** *Otilia Koo*	**General Chapters–Chemical Analysis** *Nancy Lewen*	**Healthcare Safety & Quality** *Melody Ryan*	**Non-botanical Dietary Supplements** *Guido F Pauli*
Biologics Monographs 3–Complex Biologics & Vaccines *Earl Zablackis*	**Small Molecules 3** *Eric Kesslen*	**Excipients Test Methods** *Chris Moreton*	**General Chapters–Microbiology**	**Compounding** *Brenda Jensen*	**Dietary Supplements Admission Evaluation & Labeling** *Tiersons Low Dog*
Biologics Monographs 4–Antibiotics *Matthew Borer*	**Small Molecules 4** *Kim Huynh-Ba*		**General Chapters–Packaging & Distribution** *Renaud Janssen*	**Healthcare Information & Technology** *Jeanne Tuttle*	**Food Ingredients** *Jon DeVries*
Biologics Monographs 5–Advanced Therapies *Mehrshid Alal*	**Small Molecules 5** *Amy Karren*		**General Chapters–Measurement & Data Quality** *Jane Weitzel*		
	Over-the-Counter (OTC) Methods & Approaches *Raphael Omaf*		**General Chapters–Statistics** *Charles Tan*		
			General Chapters–Physical Analysis *Xiaorong He*		

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2020 – 2025 Compounding Expert Committee

EC Member	Affiliation
Brenda Jensen, CPhT, CNMT, MBA (*Chair*)	Owner and Compounding Pharmacy Consultant, Compounding Consultants, LLC
Vanessa Pinheiro, M.S., B.S. Pharm. (*Vice Chair*)	Pharmacist and Consultant, Medisca and LP3 Network
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Kevin Hansen, Pharm.D., MS, BCSCP	Director of 503B Programs, Premier, Inc.
Patricia Kienle, MPA, B.S. Pharm., R.Ph., BCSCP, FASHP	Director, Accreditation and Medication Safety, Cardinal Health
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Robert Shrewsbury, Ph.D.	Associate Professor, UNC Eshelman School of Pharmacy
Connie Sullivan, B.S. Pharm.	President and CEO, National Home Infusion Association
Alan Parr, Pharm.D., Ph.D. (*Advisor*)	Director of Biopharmaceutics, BioCeutics, LLC
Brenda Yuzdepski, B.S. Pharm. (*Advisor*)	Owner and CEO, Medical Arts Pharmacy

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Implementation Date

- Currently official chapter versions
  - ⟨795⟩ last revised in 2014
  - ⟨797⟩ last revised in 2008
- Revised chapters
  - The revised chapters published in November 2022 will become official on **November 1, 2023**
  - To allow for increased flexibility and engagement for adoption
  - USP encourages early implementation of these revised standards

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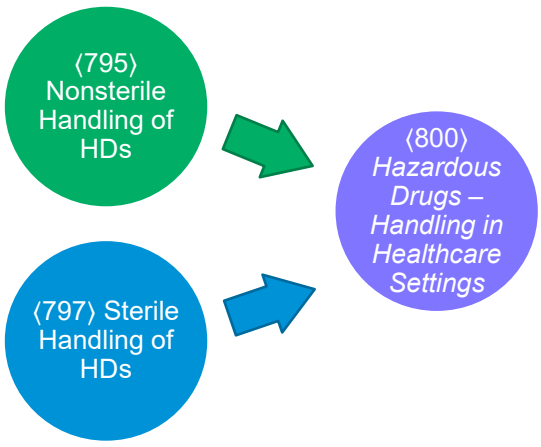
Hazardous Drugs

- Provisions have been removed for handling of hazardous drugs
  - Compounded hazardous drugs are subject to ⟨800⟩
- ⟨800⟩ is out of scope for today's session



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Overview of Revised General Chapter ⟨795⟩ *Pharmaceutical Compounding – Nonsterile Preparations*

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Scope of ⟨795⟩

- Practices not subject to the requirements in ⟨795⟩
  - Nonsterile radiopharmaceuticals
  - Reconstitution
  - Repackaging
  - Splitting tablets
  - Administration

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Flavoring

- Nonsterile compounding is defined as combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation
- Adding components (such as flavors) not stipulated in the labeling to conventionally manufactured products is compounding as defined in ⟨795⟩ and has been within the scope of ⟨795⟩ since the chapter was first published in 2004
- Flavors are organic chemicals with reactive functional groups including acids, alcohols, aldehydes, amides, amines, esters, ketones, and lactams
- The effect of adding these substances, even in very small quantities or concentrations, to conventionally manufactured products is unpredictable due to the potential for a variety of chemical reactions

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⟨795⟩ Establishing Beyond-Use Dates

- Terminology
  - Expiration Date applies to conventionally manufactured drug products
  - BUD applies to CNSPs calculated in terms of hours, days, or months
- Parameters to consider
  - Water activity (a_w)
  - Chemical and physical stability
  - Compatibility of container closure system
  - Degradation of container closure system
  - Potential for microbial proliferation
  - Deviations from essential compounding steps and procedures

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⟨795⟩ Establishing Beyond-Use Dates

2008 Currently Official Chapter	Revised Chapter
Water-containing oral formulations = **14 days** Water-containing topical/dermal and mucosal liquids and semisolid formulations = **30 days** Nonaqueous formulations = **6 months**	Nonpreserved aqueous dosage forms ($a_w \geq 0.60$) = **14 days** Preserved aqueous dosage forms ($a_w \geq 0.60$) = **35 days** Oral liquids (nonaqueous) ($a_w < 0.60$) = **90 days** Other nonaqueous dosage forms ($a_w < 0.60$) = **180 days**

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⟨795⟩ Establishing Beyond-Use Dates

- *Table 4. BUD Limit by Type of Preparation in the **Absence** of a USP–NF Compounded Preparation Monograph or CNSP-Specific Stability Information* [a]

Type of Preparation	BUD (days)	Storage Temperature [b]
Aqueous Dosage Forms ($a_w \geq 0.60$)		
Nonpreserved aqueous dosage forms [c]	14	Refrigerator
Preserved aqueous dosage forms [c]	35	Controlled room temperature or refrigerator
Nonaqueous Dosage Forms ($a_w < 0.60$)		
Oral liquids (nonaqueous) [d]	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms [e]	180	Controlled room temperature or refrigerator

a A shorter BUD must be assigned when the physical and chemical stability of the CNSP is less than the BUD limit stated in the table (see *10.4 CNSPs Requiring Shorter BUDs*).
b See *Packaging and Storage Requirements* ⟨659⟩.
c An aqueous preparation is one that has an a_w of ≥ 0.6 (e.g., emulsions, gels, creams, solutions, sprays, or suspensions).
d A nonaqueous oral liquid is one that has an a_w of < 0.6 .
e Other nonaqueous dosage forms that have an a_w of < 0.6 (e.g., capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges).

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⟨795⟩ Establishing Beyond-Use Dates

Nonaqueous Dosage Forms: $a_w < 0.6$			Aqueous Dosage Forms: $a_w \geq 0.6$		
Dosage Form	Description	a_w	Dosage Form	Description	a_w
Animal treat	Animal treat (oil flavor)	0.507	Animal treat	Animal treat with 15%–18% aqueous flavor	0.716
Capsule (oil filled)	Olive oil encapsulated	0.468	Cream	Cream vehicle (oil in water emulsion, petrolatum free)	0.968
Capsule (powder filled)	Powder base encapsulated	0.435	Cream	Emollient cream (petrolatum and mineral oil)	0.984
Gel (glycol based)	Propylene glycol, ethoxy diglycol, or hydroxypropyl cellulose gel	0.056	Cream	Cream (oil in water emulsion with natural oils)	0.989
Lollipop (sorbitol based)	Sorbitol-based lollipop	0.460	Foam	Foaming surfactant solution	0.983
Ointment	Hydrophilic petrolatum	0.396	Gel (water based)	Alcohol-free aqueous gel	0.990
Ointment	Polyethylene and mineral oil gel base	0.459	Gel (water based)	Hydroxypropyl methylcellulose (HPMC) gel	1.000
Oral solution (glycol based)	20% Polyethylene glycol and 80% propylene glycol	0.009	Lotion	Lotion (oil in water emulsion)	0.986
Oral solution (oil based)	Medium chain triglycerides oil	0.338	Nasal spray	Nasal spray	0.991
Oral suspension (fixed oil)	Fixed oil with thickener	0.403	Oral solution (water based)	Low-sucrose syrup vehicle	0.906
Powder for inhalation	Encapsulated powder for inhalation	0.402	Oral solution (water based)	90% Water and 10% glycerin	0.958
Stick	Lip balm	0.181	Oral suspension (water based)	Oral suspension base	0.992
Suppository	Polyethylene glycol base	0.374	Rinse	Polymer gel with 30% water	0.960
Suppository	Fatty acid base	0.385	Shampoo	Shampoo	0.976
Tablet (compressed)	Compressed tablet	0.465	Simple syrup	Simple syrup	0.831
Tablet (triturate)	Tablet triturate (lactose and/or sucrose)	0.427	-	-	-
Troche or lozenge (gelatin based)	Gelatin troche or lozenge with NMT 3% aqueous flavor	0.332	-	-	-
Troche or lozenge (glycol based)	Polyethylene glycol troche or lozenge with NMT 3% aqueous flavor	0.571	-	-	-

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⟨795⟩ Establishing Beyond-Use Dates

- In the **Presence** of CNSP-Specific Stability Information
  - BUD may be extended up to a maximum of 180 days
  - Stability-indicating analytical method for the API(s), CNSP formulation, and material of composition of the container closure that will be used
  - An aqueous CNSP must be tested for ⟨51⟩ antimicrobial effectiveness at the end of the BUD
    - Bracketing can be utilized to provide flexibility
  - If compounding from a *USP–NF* compounded preparation monograph, the BUD must not exceed the BUD specified in the monograph
- Shorter BUDs may be required
  - If components have an earlier expiration date or BUD
  - If ingredients are known to be susceptible to decomposition

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Overview of Revised General Chapter ⟨797⟩ *Pharmaceutical Compounding – Sterile Preparations*

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Scope of ⟨797⟩

- Radiopharmaceuticals
  - Compounding of radiopharmaceuticals is subject to the requirements in ⟨825⟩ *Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*
- Administration
  - Administration of medication is out of scope of ⟨797⟩
- Preparation Per Approved Labeling
  - Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is out of scope of ⟨797⟩ if:
    - The product is prepared as a single dose for an individual patient; and
    - The approved labeling includes information for the diluent, the resultant strength, the container closure system, and storage time

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⟨797⟩ Immediate-Use CSPs

Immediate-Use CSPs

Requirements for Immediate-Use CSPs
Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.
Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.
The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability and compatibility studies).
The preparation involves not more than 3 different sterile products.
Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.
Administration begins within 4 hours following the start of preparation. If administration has not begun within 4 hours following the start of preparation, it must be promptly, appropriately, and safely discarded.
Unless directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the 4-hour time period within which administration must begin.

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⟨797⟩ Revisions

Categories of CSPs

- High-Risk
- Medium-Risk
- Low-Risk
- Low-Risk with 12 Hour BUD

Category 1 CSPs	Category 2 CSPs	Category 3 CSPs
• Must be prepared in a PEC that may be located in an unclassified segregated compounding area • Assigned a BUD of ≤ 12 hours at controlled room temperature or ≤ 24 hours when refrigerated	• Must be prepared in a cleanroom suite • May be assigned a BUD of > 12 hours at controlled room temperature or > 24 hours if refrigerated	• Have additional requirements that must be met at all times • May be assigned a BUD longer than established for Category 2 CSPs, up to 180 days

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⟨797⟩ Revisions

Assigning Longer BUDs than in the Chapter*

2008 Last Official Chapter	2015 Revision Proposed in *PF*	2018 Revision Proposed in *PF*	2019 Revision Published in *USP-NF* (subsequently remanded)	Revised Chapter
BUDs could be assigned up to the duration indicated by appropriate information sources for the same or similar formulations and by personal experience	The ability to assign longer BUDs was not described	BUDs could be assigned up to a maximum of 90 days if supported by stability data	BUDs could only be assigned up to the limits described in the chapter	Category 3 describes the requirements a compounding site must ensure at all times for assigning longer BUDs than those established for Category 2 CSPs, up to a maximum of 180 days

* If there is a compounded preparation monograph for a particular CSP formulation, the BUD in the monograph can be assigned if the CSP is prepared according to the monograph and all monograph requirements are met, including sterility testing.

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⟨797⟩ Establishing Beyond-Use Dates

Quality factors

- Chemical and physical stability properties of the drug and/or its formulation
- Materials of composition of the container closure system and compatibility of the container closure system with the final preparation (e.g., leachables, interactions, adsorption, and storage conditions)

Sterility factors

- Conditions of the environment in which the CSP is prepared
  - Cleanroom suite or SCA
- Aseptic processing and sterilization method
- Starting components
  - Sterile or nonsterile starting ingredients
- Whether or not sterility testing is performed
- Storage conditions
  - Packaging and temperature

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⟨797⟩ Establishing Beyond-Use Dates

Category 1 CSP BUD Limits

Storage Conditions	
Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)
≤ 12 hours	≤ 24 hours

2008 Last official ⟨797⟩

Low-Risk Level CSP in SCA	12 hours

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⟨797⟩ Establishing Beyond-Use Dates

Category 2 CSP BUD Limits

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed & Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (−25° to −10°)
Aseptically processed CSPs	No	Prepared from one or more nonsterile starting component(s): 1 day	Prepared from one or more nonsterile starting component(s): 4 days	Prepared from one or more nonsterile starting component(s): 45 days

2008 Last official ⟨797⟩

High-Risk Level CSPs	1 day	3 days	45 days

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⟨797⟩ Establishing Beyond-Use Dates

Category 2 CSP BUD Limits

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed & Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (−25° to −10°)
Aseptically processed CSPs	No	Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 10 days	Prepared from only sterile starting components: 45 days

2008 Last official ⟨797⟩

Medium-Risk Level CSPs	30 hours	9 days	45 days
Low-Risk Level CSPs	48 hours	14 days	45 days

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⟨797⟩ Establishing Beyond-Use Dates

Category 2 CSP BUD Limits

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed & Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (−25° to −10°)
Aseptically processed CSPs	No	Prepared from one or more nonsterile starting component(s): 1 day	Prepared from one or more nonsterile starting component(s): 4 days	Prepared from one or more nonsterile starting component(s): 45 days
		Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 10 days	Prepared from only sterile starting components: 45 days
	Yes	30 days	45 days	60 days
Terminally sterilized CSPs	No	14 days	28 days	45 days
	Yes	45 days	60 days	90 days

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⟨797⟩ Establishing Beyond-Use Dates

Category 3 CSP BUD Limits

Preparation Characteristics	Storage Conditions		
Compounding Method	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (-25°–10°)
Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs	60 days	90 days	120 days
Terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPs	90 days	120 days	180 days

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⟨797⟩ Revisions

Additional Requirements for Category 3 CSPs

- Category 3 CSPs undergo sterility testing, supplemented by endotoxin testing when applicable, and have more requirements than Category 2 CSPs for
  - Personnel qualification
  - Use of sterile garb
  - Frequency of applying sporicidal disinfectants
  - Frequency of environmental monitoring
  - Stability determination
- The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units

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Next Steps

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Next Steps

- The Compounding Expert Committee decided to delay the implementation of the revised chapters until November 1, 2023
- Sign up for updates to ⟨795⟩, ⟨797⟩, and other topics related to USP Healthcare Quality and Safety Standards
  - https://www.usp.org/hqs-signup-form
- Attend the Compounding Expert Committee's Official Meetings
  - https://callforcandidates.usp.org/node/32481
- Sign up for USP Education on-demand and live courses

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Assessment Questions

1. When do USP standards become official?

A. As soon as they are published in the *Pharmacopeial Forum*

B. Generally, six months after being published in the *Pharmacopeial Forum*

C. As soon as they are published in the *USP–NF*

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Assessment Questions

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A. 2008

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C. 2019

D. 2022

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Assessment Questions

3. Category 1 compounded sterile preparations (CSPs) in USP ⟨797⟩ are restricted to

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B. CSPs that are assigned a BUD of no more than 6 hours when stored at room temperature

C. CSPs that are assigned a BUD of no more than 24 hours when stored under refrigeration

D. Non-hazardous CSPs only

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Discussion

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Brenda Yuzdepski, B.S. Pharm. (*Advisor*)	Owner and CEO, Medical Arts Pharmacy

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Thank You

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2. Click on the "Live CPE" tab
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4. Enter the session code provided at the end of the webinar
5. Complete the course and speaker evaluations
6. Select the appropriate credit (pharmacist or pharmacy technician)
7. Enter your NABP e-Profile ID and date of birth and certify that the information is correct
8. Click the claim button

Claims must be submitted by noon on November 13, 2023.

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