Open Forum Session

Revisions to USP General Chapter (797) Pharmaceutical Compounding – Sterile Preparations

November 8, 2022
2:00 PM - 4:00 PM ET
NOTICE TO PARTICIPANTS:

- Please note this session is currently being recorded and will be made available on the USP website

- Disclaimer
  - This open forum is for informational purposes only
# Agenda

## Session Overview

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<th>Welcome</th>
<th>Selma Mitiche, Senior Scientist II, Personalized Medicines</th>
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<td>• USP Overview</td>
<td>Brenda Jensen, Chair, Compounding Expert Committee</td>
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<td>• Background</td>
<td>Connie Sullivan, Chair, &lt;797&gt; Subcommittee</td>
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<tr>
<td>• Overview of Revised General Chapter &lt;797&gt; Pharmaceutical Compounding – Sterile Preparations</td>
<td></td>
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## Next Steps

Selma Mitiche, Senior Scientist II, Personalized Medicines

## Question & Answer Session

**Moderator:** Selma Mitiche, Senior Scientist II, Personalized Medicines

**Panelists:** Compounding Expert Committee
USP Overview
The 2020 – 2025 Council of Experts

Biologics

- Biologics Monographs 1: Peptides & Oligonucleotides
  - Michael De Felippis
- Biologics Monographs 2: Proteins
  - Wendy Saffell-Clemmer
- Biologics Monographs 3: Complex Biologics & Vaccines
  - Erdi Zbibakis
- Biologics Monographs 4: Antibiotics
  - Matthew Borar
- Biologics Monographs 5: Advanced Therapies
  - Mahraad Ali

Small Molecules

- Small Molecules 1
  - Mary Seibel
- Small Molecules 2
  - Justin Pennington
- Small Molecules 3
  - Eric Kesslen
- Small Molecules 4
  - Kim Huynh-Sa
- Small Molecules 5
  - Amy Kieran
- Over-the-Counter (OTC) Methods & Approaches
  - Raphael Ornaf

Excipients

- Simple Excipients
  - Eric Murison
- Complex Excipients
  - Otilia Koo
- Excipients Test Methods
  - Chris Moratca

General Chapters

- General Chapters - Dosage Forms
  - Martin Coffey
- General Chapters - Chemical Analysis
  - Nancy Lewen
- General Chapters - Microbiology
  - Donald Senger
- General Chapters - Packaging & Distribution
  - Renauld Janssen
- General Chapters - Measurement & Data Quality
  - Jane Weitzel
- General Chapters - Statistics
  - Charles Tan
- General Chapters - Physical Analysis
  - Xiaorong He

Healthcare Quality & Safety

- Nomenclature & Labeling
  - Stephanie Crawford
- Healthcare Safety & Quality
  - Melody Ryan
- Compounding
  - Branca Jensen
- Healthcare Information & Technology
  - Jeanne Tuttle

Dietary Supplements & Herbal Medicines

- Botanical Dietary Supplements & Herbal Medicines
  - Robin Murfes
- Non-botanical Dietary Supplements
  - Guido F. Pauli
- Dietary Supplements Admission
  - Evaluation & Labeling
  - Terrence Low Dog
- Food Ingredients
  - Jon DeVries
# 2020 – 2025 Compounding Expert Committee

**Chair:** Brenda Jensen, MBA, Owner and Compounding Pharmacy Consultant, Compounding Consultants, LLC  
**Vice Chair:** Robert Shrewsbury, Ph.D., Associate Professor, UNC Eshelman School of Pharmacy

<table>
<thead>
<tr>
<th>EC Member</th>
<th>Affiliation</th>
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<tbody>
<tr>
<td>Lisa Ashworth, B.S. Pharm.</td>
<td>Compounding Specialist and Clinical Pharmacist, Children’s Health System of Texas</td>
</tr>
<tr>
<td>Phil Ayers, Pharm.D.</td>
<td>Chief, Clinical Pharmacy Services, Mississippi Baptist Medical Center</td>
</tr>
<tr>
<td>Gus Bassani, Pharm.D.</td>
<td>Chief Scientific Officer, PCCA</td>
</tr>
<tr>
<td>Suzanne Blevins, B.Sc.</td>
<td>Laboratory Director, Aerobiology Laboratory</td>
</tr>
<tr>
<td>Brett Cordes, DVM</td>
<td>Veterinarian, Private Practice</td>
</tr>
<tr>
<td>Gigi Davidson, B.S. Pharm.</td>
<td>Veterinary Pharmacy Consultant, VetPharm Consulting, LLC</td>
</tr>
<tr>
<td>Edmund Elder, Ph.D., B.S. Pharm.</td>
<td>Director, Zeeh Pharmaceutical Experiment Station, University of Wisconsin-Madison</td>
</tr>
<tr>
<td>Kevin Hansen, Pharm.D., MS</td>
<td>Assistant Director of Pharmacy, Cone Health</td>
</tr>
<tr>
<td>Patricia Kienle, MPA, B.S. Pharm.</td>
<td>Director, Accreditation and Medication Safety, Cardinal Health</td>
</tr>
<tr>
<td>Vanessa Pinheiro, M.S., B.S. Pharm.</td>
<td>Pharmacist and Consultant, Medisca and LP3 Network</td>
</tr>
<tr>
<td>Elizabeth Rebello, M.D., B.S. Pharm.</td>
<td>Professor and Anesthesiologist, University of Texas MD Anderson Cancer Center</td>
</tr>
<tr>
<td>Rick Rhoads, Pharm.D.</td>
<td>Director of Compounding, University Compounding Pharmacy</td>
</tr>
<tr>
<td>Connie Sullivan, B.S. Pharm.</td>
<td>President and CEO, National Home Infusion Association</td>
</tr>
</tbody>
</table>
How we work

1. Public Health Need
   - Need identified by any stakeholder or USP
   - Need evaluated for possible standard development

2. Draft Standard
   - Best practices and scientific information collected

3. Public Comment Period
   - Draft standard published for stakeholder input

4. Review & Approval
   - Comments evaluated and addressed
   - Comments evaluated and further revision and comment needed

5. Publication
   - Final standard published with official date at least 6 months after publication

Stakeholders
- USP actively seeks engagement with stakeholders throughout the standard-setting process through stakeholder meetings, advisory roundtables, and open-microphone webinars.
- Healthcare Practitioners
- Patients
- Academicians
- Healthcare Industry
- Regulatory Authorities
- Manufacturers

USP Process

USP Expert Committee
- USP convenes a committee of independent experts that are knowledgeable on the public health issue to develop the standard.
- Healthcare Practitioners
- Academicians
- Healthcare Industry
- Regulatory Authorities (Non-voting Liaisons)
- Manufacturers

Stakeholder Implementation
History of 〈797〉

- **First Sterile Compounding Standard**
  - 〈1206〉 *Sterile Drug Products for Home Use* (1995)

- **General Chapter 〈797〉**
  - Published in USP27-NF22 (2004)
    - Incorporated 〈1206〉
  - Revised in USP USP31-NF26 2S (2008)
History of Revisions

2010
USP begins process to revise (795) & (797)

2015
Proposed revisions to (797) published in PF. Received >8,000 comments

2018
Revised (795) published in PF. Draft received >4,000 comments

June 2019
Revised (795) & (797) published in USP-NF

July 2019
USP received appeals

August 2019
USP CMP EC denied appeals

September 2019
USP received second appeals. Chapters postponed.

January 2020
Appeals Panel public hearings

March 2020
Appeals Panel issued decision remanding chapters to CMP EC

September 2021
Proposed revised (795) & (797) published in PF. Proposed revisions receive >1,000 comments

November 2022
Revised (795) & (797) published in USP-NF
Approach to Revisions

- **Stakeholder Engagement**
  - Reviewed feedback, including PF public comments and issues raised in the appeals
  - Held stakeholder semi-structured interviews (May 2020)
  - Roundtable session (July 28, 2020)
  - Open forum (September 15, 2020)

- Identified key stakeholder engagement discussion topics as a framework

- Also had general considerations throughout the review process
  - Scientifically robust, risk-based approach to assigning BUDs
  - Physical and chemical stability considerations
  - Sterility assurance
  - Operational implications
  - Balancing the need for patient access to cost-effective CSPs with rigorous quality standards
  - Implications on regulatory oversight and enforcement
Overview of Revised General Chapter 〈797〉 Pharmaceutical Compounding – Sterile Preparations
To address the information raised in the appeals and from stakeholder engagement sessions

To address areas requiring further clarification

To align revisions with:
- 〈795〉 *Pharmaceutical Compounding – Nonsterile Preparations*
- 〈800〉 *Hazardous Drugs – Handling in Healthcare Settings*
1. Introduction and Scope
2. Personnel Training and Evaluation
3. Personal Hygiene and Garbing
4. Facilities and Engineering Controls
5. Certification and Recertification
6. Microbiological Air and Surface Monitoring
7. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA
8. Introducing Items into the SEC and PEC
9. Equipment, Supplies, and Components
10. Sterilization and Depyrogenation
11. Master Formulation and Compounding Records
12. Release Inspections and Testing
13. Labeling
14. Establishing Beyond-Use Dates
15. Use of Conventionally Manufactured Products as Components
16. Use of CSPs as Components
17. SOPs
18. Quality Assurance and Quality Control
19. CSP Handling, Storage, Packaging, Shipping, and Transport
20. Documentation
21. Compounding Allergenic Extracts
   ▸ Glossary
Serve as the minimum standards for the preparation of compounded sterile preparations (CSPs) for human and animal drugs

To minimize harm, including death, from:
- Microbial contamination (nonsterility)
- Excessive bacterial endotoxins
- Variability from the intended strength of correct ingredients
- Physical and chemical incompatibilities
- Chemical and physical contaminants
- Use of ingredients of inappropriate quality

Requires aseptic techniques, processes, and procedures when preparing any sterile medication to minimize:
- Contact with nonsterile surfaces
- Introduction of particulate matter or biological fluids
- Mix-ups with other products or CSPs
Sterile compounding is defined as:
- Combining
- Admixing
- Diluting
- Pooling
- Reconstituting
- Repackaging
- Otherwise altering a drug or bulk drug substance to create a sterile preparation
Scope

- Removes provisions for handling of hazardous drugs
  - Compounded sterile hazardous drugs are subject to \(800\)

- Removes provisions for radiopharmaceuticals
  - Compounding radiopharmaceuticals are subject to \(825\)
  Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging
Alternative Technologies

- The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited as long as they are noninferior to those described herein and validated for the intended purpose (e.g., Validation of Alternative Microbiological Methods (1223) and Validation of Compendial Procedures (1225)).
# 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.
Preparation Per Approved Labeling

- Clarifies that compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the product’s manufacturer.

- Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer’s approved labeling is out of scope of this chapter only 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.

- Proprietary bag and vial systems
  - Docking and activation in accordance with the manufacturer’s labeling for immediate administration to an individual patient is not considered compounding and may be performed outside of an ISO Class 5 environment.
  - Docking for future activation and administration is considered compounding and must be performed in accordance with this chapter, with the exception of 14. Establishing Beyond-Use Dates. BUDs for proprietary bag and vial systems must not be longer than those specified in the manufacturer’s labeling.
Categories of CSPs

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

**Category 1 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

**Category 2 CSPs**
- Must be prepared in a cleanroom suite
- May be assigned a BUD of > 12 hours at controlled room temperature or > 24 hours if refrigerated

**Category 3 CSPs**
- 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
## Revisions

### Assigning Longer BUDs than in the Chapter*

<table>
<thead>
<tr>
<th>2008 Last Official Chapter</th>
<th>2015 Revision Proposed in PF</th>
<th>2018 Revision Proposed in PF</th>
<th>2019 Revision Published in <em>USP-NF</em> (subsequently remanded)</th>
<th>Revised Chapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUDs could be assigned up to the duration indicated by appropriate information sources for the same or similar formulations and by personal experience</td>
<td>The ability to assign longer BUDs was not described</td>
<td>BUDs could be assigned up to a maximum of 90 days if supported by stability data</td>
<td>BUDs could only be assigned up to the limits described in the chapter</td>
<td>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</td>
</tr>
</tbody>
</table>

* 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.
## Personnel Qualifications

<table>
<thead>
<tr>
<th>Category</th>
<th>2008 Last Official Chapter</th>
<th>2015 Revision Proposal</th>
<th>2018 Revision Proposal</th>
<th>2019 Remanded Chapter</th>
<th>Revised Chapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual observation of hand hygiene and garbing</td>
<td>Annually</td>
<td>Every 3 months</td>
<td>Every 6 months</td>
<td>Every 6 months</td>
<td><strong>Category 1 &amp; 2:</strong> Every 6 months <strong>Category 3:</strong> Every 3 months for personnel who compound Category 3 CSPs</td>
</tr>
<tr>
<td>Gloved fingertip and thumb sampling</td>
<td><strong>Low/Medium-Risk CSPs:</strong> Annually <strong>High-Risk CSPs:</strong> Semi-annually</td>
<td>Every 3 months</td>
<td>Every 6 months</td>
<td>Every 6 months</td>
<td><strong>Category 1 &amp; 2:</strong> Every 6 months <strong>Category 3:</strong> Every 3 months for personnel who compound Category 3 CSPs as part of garbing competency and aseptic competency</td>
</tr>
<tr>
<td>Media-fill testing</td>
<td><strong>Low/Medium-Risk CSPs:</strong> Annually <strong>High-Risk CSPs:</strong> Semi-annually</td>
<td>Every 3 months</td>
<td>Every 6 months</td>
<td>Every 6 months</td>
<td><strong>Category 1 &amp; 2:</strong> Every 6 months <strong>Category 3:</strong> Every 3 months for personnel who compound Category 3 CSPs</td>
</tr>
</tbody>
</table>
### Minimum Garbing Requirements

<table>
<thead>
<tr>
<th>2008 Last Official Chapter</th>
<th>2015 Revision Proposal</th>
<th>2018 Revision Proposal</th>
<th>2019 Remanded Chapter</th>
<th>Revised Chapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Gown</td>
<td>Determined based on:</td>
<td>• Gown</td>
<td>• Gown</td>
<td>• Low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gown or coverall)</td>
</tr>
<tr>
<td>• Dedicated shoes or shoe covers</td>
<td>• Category</td>
<td>• Disposable covers for shoes</td>
<td>• Disposable covers for shoes</td>
<td>• Low-lint covers for shoes</td>
</tr>
<tr>
<td>• Head and facial hair covers</td>
<td>• Type of PEC</td>
<td>• Disposable covers for shoes</td>
<td>• Disposable covers for head and facial hair</td>
<td>• Low-lint cover for head that covers the hair and ears, and if applicable, cover for facial hair</td>
</tr>
<tr>
<td>• Face masks</td>
<td>Included:</td>
<td>• Face mask</td>
<td>• Face mask</td>
<td>• Low-lint face mask</td>
</tr>
<tr>
<td>• Sterile gloves</td>
<td>• Gown or coveralls</td>
<td>• Sterile gloves</td>
<td>• Sterile gloves</td>
<td>• Sterile powder-free gloves</td>
</tr>
<tr>
<td></td>
<td>• Disposable covers for shoes</td>
<td>If using RABS → disposable gloves inside of gauntlet gloves</td>
<td>If using RABS → disposable gloves inside of gauntlet gloves</td>
<td>If using a RABS, (i.e., a CAI or CACI), disposable gloves should be worn inside the gloves attached to the RABS sleeves. Sterile gloves must be worn over the gloves attached to the RABS sleeve</td>
</tr>
</tbody>
</table>
### Revised Chapter – Category 3

If the facility compounds Category 3 CSPs, additional garbing requirements must be continuously met in the buffer room in which Category 3 CSPs are prepared. The following additional garbing requirements must be followed in the buffer room where Category 3 CSPs are prepared for all personnel regardless of whether Category 3 CSPs are compounded on a given day:

1. Do not allow any exposed skin in the buffer room. (i.e., face and neck must be covered).
2. All low-lint outer garb must be sterile, including the use of sterile sleeves over gauntlet sleeves when a RABS is used.
3. Disposable garbing items must not be reused, and laundered garb must not be reused without being laundered and resterilized with a validated cycle.
4. The facility’s SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment.
Minimum PEC Placement

Category 1 CSPs

ISO Class 5 PEC

Unclassified SCA

Category 2 or 3 CSPs

ISO Class 5 PEC

Anteroom (ISO Class 8)

Buffer Room (ISO Class 7)

“Clean Side”

“Dirty Side”

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## Microbiological Air and Surface Monitoring

<table>
<thead>
<tr>
<th></th>
<th>2008 Last Official Chapter</th>
<th>2015 Revision Proposal</th>
<th>2018 Revision Proposal</th>
<th>2019 Remanded Chapter</th>
<th>Revised Chapter</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Viable air</strong></td>
<td>Every 6 months</td>
<td>Monthly</td>
<td>Every 6 months</td>
<td>Every 6 months</td>
<td><strong>Category 1 &amp; 2:</strong> Every 6 months</td>
</tr>
<tr>
<td><strong>sampling</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Category 3:</strong> Monthly</td>
</tr>
<tr>
<td><strong>Surface</strong></td>
<td>Periodically</td>
<td>Monthly</td>
<td>Monthly</td>
<td>Monthly</td>
<td><strong>Category 1 &amp; 2:</strong> Monthly</td>
</tr>
<tr>
<td><strong>sampling</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Category 3:</strong> <strong>Weekly</strong></td>
</tr>
</tbody>
</table>
Frequencies specified for separate activities
- Cleaning
- Disinfecting
- Applying a sporicidal disinfectant

Cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads)
- Must be low-lint
- Should be disposable
- Reusable cleaning tools must be dedicated for use
Cleaning, disinfecting and sporicidal agents used within the PEC must be sterile.

Cleaning and disinfecting supplies used in the PEC must be sterile with the exception of tool handles and holders, which must be cleaned and disinfected prior to use in a PEC.

Reusable cleaning tools must be made of cleanable materials (e.g., handles should not be made of wood or any other porous material) and must be cleaned and disinfected before and after each use.
Master Formulation and Compounding Records

**Master Formulation Record**

- Required for
  - All CSPs prepared from nonsterile ingredient(s)
  - CSPs prepared for more than one patient

**Compounding Record**

- Required for
  - All Category 1, Category 2, and Category 3 CSPs
  - Immediate-use CSPs prepared for more than one patient
  - May be in the form of a prescription or medication order or label
  - May be stored electronically through an ACD, workflow management system, or other similar equipment
    - As long as it is retrievable and contains the required information
Release Inspections and Testing

Visual Inspection

Sterility Testing

- Required for **Category 2** CSPs assigned a BUD that requires sterility testing, and for all **Category 3** CSPs

- The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units

- If the number of CSPs to be compounded in a single batch is less than the number of CSPs needed for testing as specified in *USP (71)*, *Table 3*, additional units must be compounded to perform sterility testing
  - If between 1 and 39 CSPs, test a number of units equal to 10% of CSPs prepared
  - If >40 CSPs, test based on *USP (71)*, *Table 3*

- If an alternative method is used for sterility testing, the method must be validated (see *1223*) and demonstrated to be suitable for that CSP formulation
Release Inspections and Testing

Bacterial Endotoxins Testing

- **Required for**
  - *Category 2* injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing
  - *Category 3* injectable CSPs compounded from one or more nonsterile component(s)

- **Category 2** CSPs assigned a BUD that does not require sterility testing, but compounded from one or more nonsterile component(s) **should** be tested
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
### Category 1 CSP BUD Limits

<table>
<thead>
<tr>
<th>Storage Conditions</th>
<th>Controlled Room Temperature (20°–25°)</th>
<th>Refrigerator (2°–8°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 12 hours</td>
<td>≤ 24 hours</td>
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</tr>
</tbody>
</table>

#### 2008 Last official ⟨797⟩

- Low-Risk Level CSP in SCA 12 hours
### Category 2 CSP BUD Limits

<table>
<thead>
<tr>
<th>Preparation Characteristics</th>
<th>Storage Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compounding Method</td>
<td>Controlled Room Temperature (20°–25°)</td>
</tr>
<tr>
<td>Aseptically processed CSPs</td>
<td>Prepared from one or more nonsterile starting component(s): 1 day</td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

#### 2008 Last official (797)

- **High-Risk Level CSPs**
  - 1 day
  - 3 days
  - 45 days
## Category 2 CSP BUD Limits

<table>
<thead>
<tr>
<th>Preparation Characteristics</th>
<th>Storage Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compounding Method</td>
<td>Controlled Room Temperature (20°–25°)</td>
</tr>
<tr>
<td>Aseptically processed CSPs</td>
<td>Prepared from only sterile starting components: 4 days</td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

### 2008 Last official ⟨797⟩

<table>
<thead>
<tr>
<th></th>
<th>Medium-Risk Level CSPs</th>
<th>Low-Risk Level CSPs</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUD Limits</td>
<td>30 hours</td>
<td>48 hours</td>
</tr>
<tr>
<td></td>
<td>9 days</td>
<td>14 days</td>
</tr>
<tr>
<td></td>
<td>45 days</td>
<td>45 days</td>
</tr>
</tbody>
</table>
### Category 2 CSP BUD Limits

<table>
<thead>
<tr>
<th>Compounding Method</th>
<th>Sterility Testing Performed &amp; Passed</th>
<th>Controlled Room Temperature (20°–25°)</th>
<th>Refrigerator (2°–8°)</th>
<th>Freezer (−25° to −10°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aseptically processed CSPs</td>
<td>No</td>
<td>Prepared from one or more nonsterile starting component(s): 1 day</td>
<td>Prepared from one or more nonsterile starting component(s): 4 days</td>
<td>Prepared from one or more nonsterile starting component(s): 45 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prepared from only sterile starting components: 4 days</td>
<td>Prepared from only sterile starting components: 10 days</td>
<td>Prepared from only sterile starting components: 45 days</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>30 days</td>
<td>45 days</td>
<td>60 days</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>14 days</td>
<td>28 days</td>
<td>45 days</td>
</tr>
<tr>
<td>Terminally sterilized CSPs</td>
<td>No</td>
<td>45 days</td>
<td>60 days</td>
<td>90 days</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>45 days</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Category 3 CSP BUD Limits

<table>
<thead>
<tr>
<th>Compounding Method</th>
<th>Controlled Room Temperature (20°–25°)</th>
<th>Refrigerator (2°–8°)</th>
<th>Freezer (-25°–10°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs</td>
<td>60 days</td>
<td>90 days</td>
<td>120 days</td>
</tr>
<tr>
<td>Terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPs</td>
<td>90 days</td>
<td>120 days</td>
<td>180 days</td>
</tr>
</tbody>
</table>
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
Revisions

Multiple-Dose CSPs

- A multiple-dose CSP must be prepared as a Category 2 or Category 3 CSP
- For preserved aqueous multiple-dose CSPs, antimicrobial effectiveness testing must be passed in accordance with USP 〈51〉
- Time within which multiple-dose preserved CSPs must be used:
  - Whichever is shorter:
    - BUD limit assigned based on if CSP is compounded as Category 2 or Category 3
    - Up to 28 days after container is initially entered or punctured, if supported by 〈51〉 testing
- Time within which multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs must be used:
  - BUD limit assigned based on if CSP is compounded as Category 2 or Category 3, and
  - Discarded 24 hours after first opening if stored at room temperature, or 72 hours if refrigerated
Next Steps
Next Steps

- The Compounding Expert Committee decided to delay the implementation of the ⟨797⟩ revision until November 1, 2023

- USP Compounding Workshop
  - February 7, 2023, 8:00 AM – 5:30 PM ET
  - February 8, 2023, 8:00 AM – 3:30 PM ET

- 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](https://www.usp.org/hqs-signup-form)

- Attend the Compounding Expert Committee's Official Meetings
  - [https://www.usp.org/events-training/search?type%5B0%5D=event_types%3AExpert%20Committee/Panel%20Meeting](https://www.usp.org/events-training/search?type%5B0%5D=event_types%3AExpert%20Committee/Panel%20Meeting)
Question and Answer Session
## 2020 – 2025 Compounding Expert Committee

<table>
<thead>
<tr>
<th>EC Member</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Associate Professor, UNC Eshelman School of Pharmacy</td>
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<td>Lisa Ashworth, B.S. Pharm.</td>
<td>Compounding Specialist and Clinical Pharmacist, Children’s Health System of Texas</td>
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<td>Phil Ayers, Pharm.D.</td>
<td>Chief, Clinical Pharmacy Services, Mississippi Baptist Medical Center</td>
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<tr>
<td>Gus Bassani, Pharm.D.</td>
<td>Chief Scientific Officer, PCCA</td>
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<tr>
<td>Suzanne Blevins, B.Sc.</td>
<td>Laboratory Director, Aerobiology Laboratory</td>
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<td>Brett Cordes, DVM</td>
<td>Veterinarian, Private Practice</td>
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<td>Pharmacist and Consultant, Medisca and LP3 Network</td>
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<td>Professor and Anesthesiologist, University of Texas MD Anderson Cancer Center</td>
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<td>Rick Rhoads, Pharm.D.</td>
<td>Director of Compounding, University Compounding Pharmacy</td>
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<td>Connie Sullivan, B.S. Pharm.</td>
<td>President and CEO, National Home Infusion Association</td>
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<tr>
<td>Alan Parr, Pharm.D., Ph.D. (advisor)</td>
<td>Director of Biopharmaceuticals, BioCeutics, LLC</td>
</tr>
<tr>
<td>Brenda Yuzdepski, B.S. Pharm. (advisor)</td>
<td>Owner and CEO, Medical Arts Pharmacy</td>
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Thank You

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