USP Compounding Standards <795> and <797>

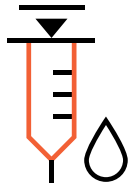
Lauren Grey Pearson, Pharm.D., MBA
Senior Scientist, Compounding
USP Healthcare Quality and Safety

November 13th, 2025

USP Overview

Six areas of collaboration

2025-2030 Council of Experts



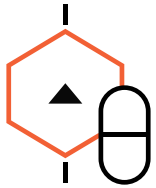
Biologics

Biologics – Therapeutic Peptides, Oligonucleotides, and Complex Carbohydrates
Rosario Lobrutto

Biologics – Therapeutic Proteins
Kenneth R. Miller

Biologics – Vaccines
Mark van Ooji

Biologics – Cell & Gene Therapies
Lili Belcastro



Small Molecules

Small Molecules – Therapeutic Areas 1
Mary Seibel

Small Molecules – Therapeutic Areas 2
Robert G. Buice Jr.

Small Molecules – Therapeutic Areas 3
Eric Kesslen

Small Molecules – Therapeutic Areas 4
Partha S. Mukherjee

Small Molecules – Therapeutic Areas 5
Justin Pennington

Small Molecules – Therapeutic Areas 6
Allan D. Bokser

Excipients

Excipient Monographs 1
Vivek S. Dave

Excipient Monographs 2
Barbara R. Serr

Excipient Chapters
Richard Creekmore

General Chapters

General Chapters – Dosage Forms
Kevin Warner

General Chapters – Chemical Analysis
Anthony C. Bevilacqua

General Chapters – Microbiology
Ed C. Tidswell

General Chapters – Packaging & Distribution
Renaud Janssen

General Chapters – Statistics
Charles Tan

General Chapters – Pharmaceutical Analysis Lifecycle & Data Science
Jaime Marach

General Chapters – Materials Physical Properties Characterization
Eloise Welfare

Healthcare Quality & Safety

Healthcare Safety, Quality, & Nomenclature
Melody Ryan

Compounding
Brenda Jensen

Healthcare Information & Technology
Leslie Lenert

Personalized Medicines
Sara L. Rogers

Dietary Supplements & Herbal Medicines, Food Ingredients

Botanical Dietary Supplements & Herbal Medicines
Thomas Brendler

Non-Botanical Dietary Supplements
Raimar Loebenberg

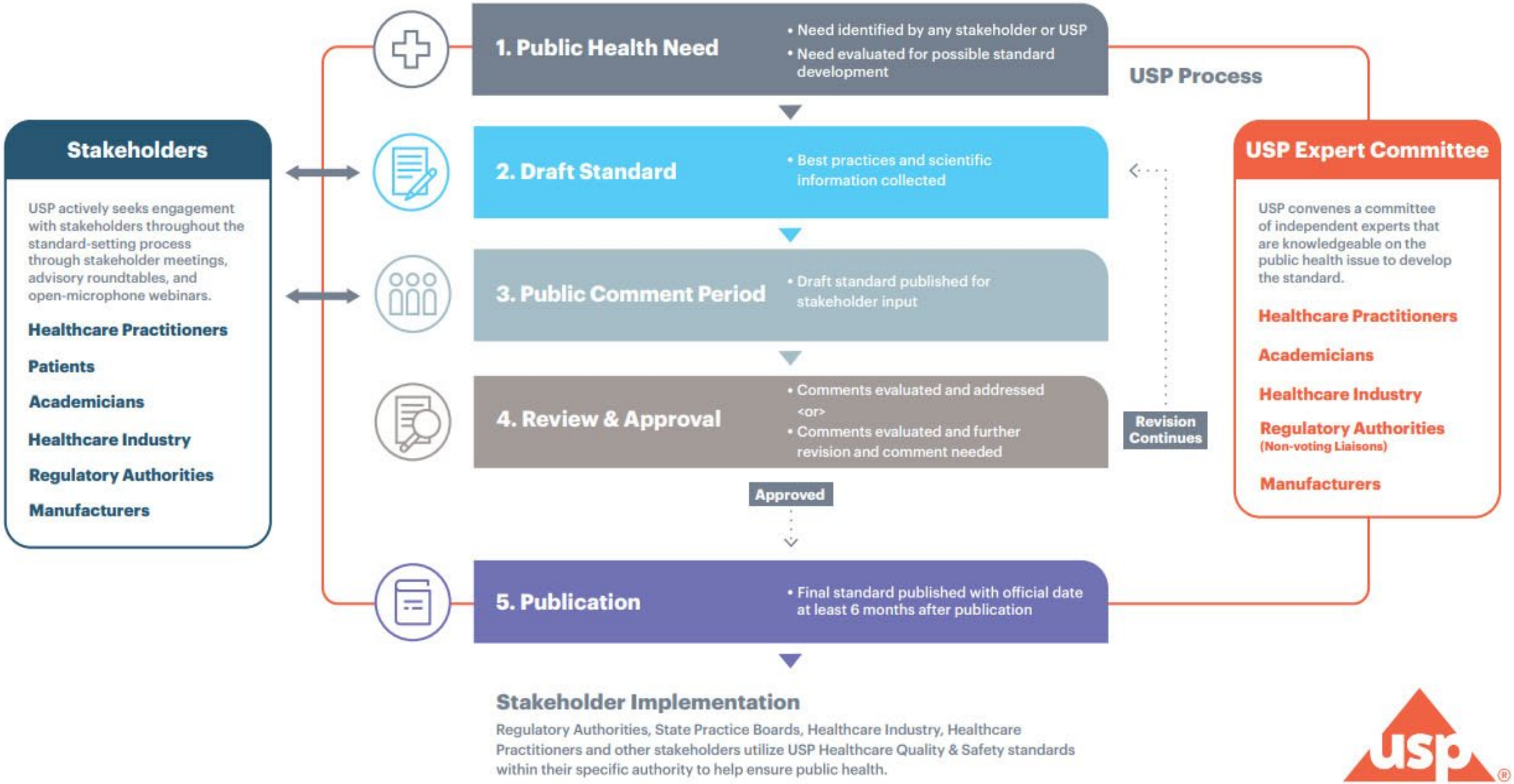
Dietary Supplements Admission, Evaluation, & Labeling
Amy L. Roe

Food Ingredients
James Brooks

2025 – 2030 Compounding Expert Committee

EC Member	Affiliation
Brenda Jensen, CPhT, CNMT, MBA (*Chair*)	Owner and Compounding Pharmacy Consultant, Compounding Consultants, LLC
Lisa D. Ashworth, B.S. Pharm., R.Ph., BCSCP, FACA	Independent Pharmacy Consultant, Ashworth Consultants
Paul Baker, Pharm.D., BCSCP, R.Ph.	Assistant Director of Quality and Regulatory Compliance, Massachusetts General Hospital
Gigi Davidson, B.S. Pharm., DICVP, FACVP, FSVHP	Veterinary Pharmacy Consultant, VetPharm Consulting, LLC
Edmund Elder, Ph.D., B.S. Pharm., R.Ph.	Emeritus Research Services Director, University of Wisconsin-Madison
Glen Gard, CPhT-Adv, CSPT, FNHIA	Senior Director of Sterile Compounding and Pharmacy Compliance, Option Care Health
Kevin Hansen, Pharm.D., M.S., BCSCP	Senior Director, Pharmacy Compounding Services, Premier Inc.
Jessica Hawkins, Pharm.D., BCPS, BCSCP	Sterile Compounding Pharmacy Program Manager, Lexington VA Healthcare System
Kathleen Kane, Pharm.D., BCSCP, DPLA	Assistant Director of Pharmacy, University of Chicago Medical Center
Deborah Larison, Pharm.D., CPh	Chief Operation Officer/Chief Compliance Officer, Paul's Pharmacy
Diego Marro, Ph.D., Pharm.D.	Owner and Compounding Pharmacist, Farmacia Marro
Melissa Messick, Pharm.D.	Inpatient Sterile Products Manager, Penn State Health Milton S Hershey Medical Center
Vanessa Pinheiro, M.S., B.S. Pharm.	Manager, Compounding Services, Development & Consulting, Medisca; Program Facilitator, LP3 Network
Hudson Polonini, Ph.D., M.Sc., B.S. Pharm.	Global R&D Manager, Fagron
Kelley Reece, Pharm.D., BCSCP	Pharmacy Quality and Regulatory Manager, MD Anderson Cancer Center
Rick Rhoads, Pharm.D.	Director of Compounding, University Compounding Pharmacy
George Smith, Pharm.D., BCPS, BCSCP	System Sterile Compounding Services Specialist, Prisma Health
K. Mark Wiencek, Ph.D.	Principal Microbiologist, Contec, Inc.

How We Work


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
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
<or>
• Comments evaluated and further revision and comment needed
Revision Continues
Approved
5. Publication
• Final standard published with official date at least 6 months after publication
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
Regulatory Authorities, State Practice Boards, Healthcare Industry, Healthcare Practitioners and other stakeholders utilize USP Healthcare Quality & Safety standards within their specific authority to help ensure public health.

History of ⟨795⟩

- **First Nonsterile Compounding Standard**
  - *USP* ⟨1161⟩ *Pharmacy Compounding Practices* **(1996)**
- **General Chapter ⟨795⟩**
  - Published in USP 24–NF 19 **(2000)**
  - Revised in USP 27–NF 22 **(2004)**
  - Revised in USP 34–NF 29 **(2011)**
    - Incorporated *USP* ⟨1075⟩ *Good Compounding Practices*
  - Revision Bulletin **(2014)**
    - Clarified that the BUDs in ⟨795⟩ are specific for nonsterile preparations and do not apply to sterile preparations

History of ⟨797⟩

- **First Sterile Compounding Standard**
  - ⟨1074⟩ *Dispensing Practices for Sterile Drug Products Intended for Home Use* **(1992)**
  - ⟨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)**

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

⟨795⟩ Overview

Introduction and Scope

- Scope
  - Added information on types of compounded nonsterile preparations (CNSPs)
- Hazardous Drugs
  - Removed all information on handling of hazardous drugs and added references to General Chapter ⟨800⟩ *Hazardous Drugs – Handling in Healthcare Settings*
- Affected Personnel and Settings
  - Added roles and responsibility of the designated person
    - Designated person = One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs

⟨795⟩ Overview

Personnel Training and Evaluation

- Added guidance on training and core competencies
- Included steps in training procedures

Personal Hygiene and Garbing

- Added Box on Hand Hygiene Procedures
- Included description of garb and glove requirements
  - Gloves are required for all compounding activities
  - Other garb must be used as appropriate for the type of compounding

⟨795⟩ Overview

Buildings and Facilities

- Added requirement for a designated area for nonsterile compounding
- Area must be well lit and be maintained in a clean, orderly, sanitary condition and in a good state of repair

Cleaning and Sanitizing

- New table on minimum frequencies for cleaning and sanitizing surfaces in nonsterile compounding areas, including:
  - Work surfaces
  - Floors
  - Walls
  - Ceilings
  - Storage Shelving

⟨795⟩ Overview

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

⟨795⟩ Overview

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).

⟨795⟩ Overview

Nonaqueous Dosage Forms: $a_w < 0.6$		
Dosage Form	Description	a_w
Animal treat	Animal treat (oil flavor)	0.507
Capsule (oil filled)	Olive oil encapsulated	0.468
Capsule (powder filled)	Powder base encapsulated	0.435
Gel (glycol based)	Propylene glycol, ethoxy diglycol, or hydroxypropyl cellulose gel	0.056
Lollipop (sorbitol based)	Sorbitol-based lollipop	0.460
Ointment	Hydrophilic petrolatum	0.396
Ointment	Polyethylene and mineral oil gel base	0.459
Oral solution (glycol based)	20% Polyethylene glycol and 80% propylene glycol	0.009
Oral solution (oil based)	Medium chain triglycerides oil	0.338
Oral suspension (fixed oil)	Fixed oil with thickener	0.403
Powder for inhalation	Encapsulated powder for inhalation	0.402
Stick	Lip balm	0.181
Suppository	Polyethylene glycol base	0.374
Suppository	Fatty acid base	0.385
Tablet (compressed)	Compressed tablet	0.465
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

Aqueous Dosage Forms: $a_w \geq 0.6$		
Dosage Form	Description	a_w
Animal treat	Animal treat with 15%–18% aqueous flavor	0.716
Cream	Cream vehicle (oil in water emulsion, petrolatum free)	0.968
Cream	Emollient cream (petrolatum and mineral oil)	0.984
Cream	Cream (oil in water emulsion with natural oils)	0.989
Foam	Foaming surfactant solution	0.983
Gel (water based)	Alcohol-free aqueous gel	0.990
Gel (water based)	Hydroxypropyl methylcellulose (HPMC) gel	1.000
Lotion	Lotion (oil in water emulsion)	0.986
Nasal spray	Nasal spray	0.991
Oral solution (water based)	Low-sucrose syrup vehicle	0.906
Oral solution (water based)	90% Water and 10% glycerin	0.958
Oral suspension (water based)	Oral suspension base	0.992
Rinse	Polymer gel with 30% water	0.960
Shampoo	Shampoo	0.976
Simple syrup	Simple syrup	0.831
-	-	-
-	-	-
-	-	-

⟨795⟩ Overview

Establishing Beyond-Use Dates

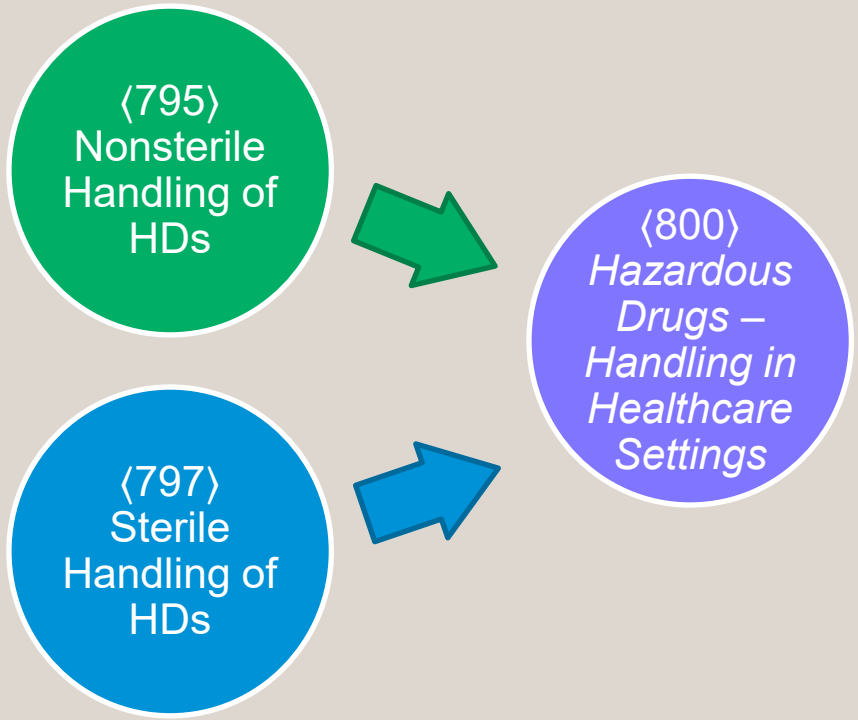
- In the **Presence** of CNSP-Specific Stability Information
  - BUD may be extended up to a maximum of 180 days
  - Stability-indicating analytical method for the API(s), CNSP formulation, and material of composition of the container closure that will be used
  - An aqueous CNSP must be tested for ⟨51⟩ 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

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

⟨797⟩ Overview

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*

⟨797⟩ Overview

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.

⟨797⟩ Overview

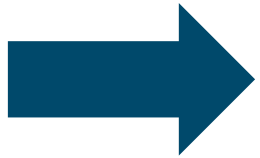
Preparation Per Approved Labeling

- 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

⟨797⟩ Overview

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

⟨797⟩ Overview

Personnel Qualifications

	2008 Last Official Chapter	2015 Revision Proposal	2018 Revision Proposal	2019 Remanded Chapter	Revised Chapter
Visual observation of hand hygiene and garbing	Annually	Every 3 months	Every 6 months	Every 6 months	**Category 1 & 2:** Every 6 months **Category 3:** Every 3 months for personnel who compound Category 3 CSPs
Gloved fingertip and thumb sampling	**Low/Medium-Risk CSPs:** Annually **High-Risk CSPs:** Semi-annually	Every 3 months	Every 6 months	Every 6 months	**Category 1 & 2:** Every 6 months **Category 3:** Every 3 months for personnel who compound Category 3 CSPs as part of garbing competency and aseptic competency
Media-fill testing	**Low/Medium-Risk CSPs:** Annually **High-Risk CSPs:** Semi-annually	Every 3 months	Every 6 months	Every 6 months	**Category 1 & 2:** Every 6 months **Category 3:** Every 3 months for personnel who compound Category 3 CSPs

⟨797⟩ Overview

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

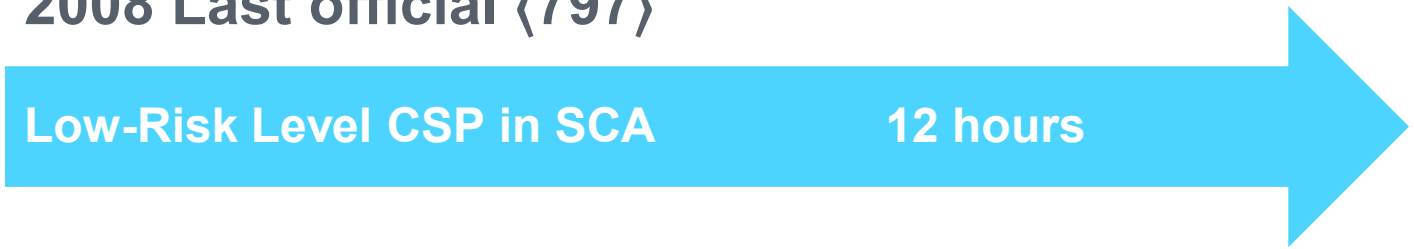
- Conditions of the environment in which the CSP is prepared
  - Cleanroom suite or SCA
- Aseptic processing and sterilization method
- Starting components
  - Sterile or nonsterile starting ingredients
- Whether or not sterility testing is performed
- Storage conditions
  - Packaging and temperature

⟨797⟩ Overview

Category 1 CSP BUD Limits

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

2008 Last official ⟨797⟩



⟨797⟩ Overview

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

⟨797⟩ Overview

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**

⟨797⟩ Overview

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

⟨797⟩ Overview

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

⟨797⟩ Overview

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

Next Steps

Next Steps

- The revised chapters became official on 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://www.usp.org/about/volunteer-experts/expert-committee-meetings

Thank You

The standard of trust

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Email questions to CompoundingSL@USP.org

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