Open Microphone Session on USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations

April 20, 2018
1:00 – 3:00 pm ET
NOTICE TO PARTICIPANTS:

- To minimize background noise, all lines will be muted upon joining the session.

- During the meeting, you may ask questions or make comments at any time by using the **Chat** function
  - Select the Chat icon on the upper right hand column of your WebEx view page
  - Use the text box at the bottom to enter your question
  - In the “Send” dropdown, select “Host”

- Questions will be collated for the Q&A portion of the WebEx.
NOTICE TO PARTICIPANTS:

Please note this session is currently being recorded and will be made available on USP’s website at http://www.usp.org/compounding/general-chapter-795

USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations

Millions of medications are compounded each year in the US to meet the unique needs of patients, including vulnerable populations such as seniors and children. Compounding provides tailored therapy to patients who may

Important Updates

- March 30, 2018 - The proposed <795> revision is now posted for public comment**

  Download the Proposed Revision to GC <795>

Submit Comments to the Proposed Revision to GC <795>

- April 20, 2018 - Open Microphone Session

Register for Open Microphone Webinar
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<td>Robert Shrewsbury, Ph.D.</td>
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| Question & Answer Session                            | **Moderator:** Jeanne Sun, PharmD  
**Panelist:**  
• Gigi Davidson, B.S. Pharm, DICVP  
• Robert Shrewsbury, Ph.D. |
USP Overview
Building foundations for a healthier world
Who we are

A healthier world needs a strong foundation—one that establishes quality, sets the bar for scientific rigor and technological progress, and epitomizes collaboration between industry, nonprofits, government and academia.

From the standards we create to the partnerships and conversations we foster, our scientists, advocates and network of experts are critical to constructing and reinforcing this foundation to ensure people stay healthy.
Mission

To improve global health through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods
200 years building quality foundations for a healthier world
Advocating for quality

USP is an organization of organizations, with 450+ members representing academia, health practitioners, manufacturers, governmental bodies, and consumer organizations.
800+
external experts
from industry, governments, nonprofits and academia
# The experts behind our standards

## 2015–2020 Council of Experts

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<td>B104 Antibiotics</td>
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# 2015 – 2020 Compounding Expert Committee

**Chair:** Gigi Davidson, B.S. Pharm, DICVP, NC State College of Veterinary Medicine  
**Vice Chair:** Connie Rae Sullivan, B.S. Pharm, National Home Infusion Association

<table>
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<tr>
<th>Member</th>
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<tbody>
<tr>
<td>Lisa Ashworth, B.S. Pharm</td>
<td>Children's Health System of Texas</td>
</tr>
<tr>
<td>Gus Bassani, Pharm.D.</td>
<td>PCCA</td>
</tr>
<tr>
<td>Edmund Elder, Ph.D., B.S. Pharm</td>
<td>University of Wisconsin-Madison</td>
</tr>
<tr>
<td>Ryan Forrey, Pharm.D., M.S.</td>
<td>Beckon Dickinson</td>
</tr>
<tr>
<td>Deborah Houston, Pharm.D.</td>
<td>Novant Health - Kernersville Medical Center</td>
</tr>
<tr>
<td>Brenda Jensen, M.A.</td>
<td>Compounding Consultants, LLC.</td>
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<tr>
<td>Patricia Kienle, MPA, B.S. Pharm</td>
<td>Cardinal Health</td>
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<tr>
<td>William Mixon, B.S. Pharm</td>
<td>The Compounding Pharmacy</td>
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<tr>
<td>John Musil, Pharm.D.</td>
<td>Avella, Inc</td>
</tr>
<tr>
<td>David Newton, Ph.D.</td>
<td>Shenandoah University (retired)</td>
</tr>
<tr>
<td>Alan Parr, Pharm.D., Ph.D.</td>
<td>BioCeutics, LLC</td>
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<tr>
<td>Abby Roth, B.Sc.</td>
<td>ClinicallQ</td>
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<tr>
<td>Robert Shrewsbury, Ph.D.</td>
<td>UNC Eshelman School of Pharmacy</td>
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<tr>
<td>James Wagner</td>
<td>Controlled Environment Consulting</td>
</tr>
<tr>
<td>Brenda Yuzdepski, B.S. Pharm</td>
<td>Saskatoon Medical Arts Pharmacy</td>
</tr>
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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

Stakeholder Implementation

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
Academics
Healthcare Industry
Regulatory Authorities
(Non-voting Liaisons)
Manufacturers

Stakeholders
USP actively seeks engagement with stakeholders throughout the standard-setting process through stakeholder meetings, advisory roundtables, and open-microphone webinars.

Healthcare Practitioners
Patients
Academics
Healthcare Industry
Regulatory Authorities
Manufacturers
USP Timeline for General Chapter Revisions

- **4/20/18**
  - Public Comment <795>
  - March 30, 2018: Web pre-posting, *5/1 publication in Pharmacopeial Forum*
  - April 20, 2018: Open Microphone Session
  - July 31, 2018: Close of public comment

February 2016
- <800>: Publication USP-NF

July 27, 2018
- Web pre-posting, *9/4 publication in Pharmacopeial Forum*

Sept 5, 2018
- Open Microphone Session

Nov 30, 2018
- Close of public comment

June 1, 2019
- <795>: Intended Publication USP-NF

Dec 1, 2019
- <800>: Official Date

Note: The current version of General Chapters <795> and <797> published in USP-NF are official.
Overview of Revised General Chapter <795> *Pharmaceutical Compounding – Nonsterile Preparations*
Background

Chapter History

- First Published in USP 24–NF 19 (2000)
  - Revision from USP <1161> Pharmacy Compounding Practices

- Subsequent Revisions
  - Revised in USP 27–NF 22 (2004)
  - Revised in USP 34–NF 29 (2011)
    - Incorporated USP <1075> Good Compounding Practices

- Most Recent Revision Bulletin (Official Jan 1, 2014)
  - Removed the reference to sterile preparations in the section on Beyond-Use Dates (BUDs)
  - Clarified that the BUDs in <795> are specific for nonsterile preparations and do not apply to sterile preparations
Purpose of Current Revision

- To reflect new science and evidence based on updated guidance documents, best practices, and new learnings from investigations
- To respond to stakeholder input received throughout the cycle
- To clarify topics that are frequently queried and misconstrued
- To align with published <800> and revision efforts for <797>

Current <795> Served as a Template for Revision

- Many sections were “summary” statements and were expanded to add clarity and additional information
- Revision proposal was modeled after current revision efforts for <797>
Sections in the currently official <795> that have been omitted in the revision proposal

- Categories of Compounding
  - Criteria for Simple, Moderate, and Complex eliminated
- Patient Counseling
- Compounding for Animal Patients

Content in currently official <795> that have been developed into new sections

- Component Selection, Handling, and Storage
- Packaging and Drug Preparation Containers
- Compounding Documentation
- Compounding Controls
- Quality Control
Overview

Proposed Chapter Outline

1. INTRODUCTION AND SCOPE
2. PERSONNEL QUALIFICATIONS—TRAINING, EVALUATION, AND REQUALIFICATION
3. PERSONAL HYGIENE AND GARBING
4. BUILDINGS AND FACILITIES
5. CLEANING AND SANITIZING
6. EQUIPMENT AND COMPONENTS
7. SOPs AND MASTER FORMULATION AND COMPOUNDING RECORDS
8. RELEASE TESTING
9. LABELING
10. ESTABLISHING BEYOND-USE DATES
11. QUALITY ASSURANCE AND QUALITY CONTROL
12. CNSP HANDLING, PACKAGING, STORAGE, AND TRANSPORT
13. COMPLAINT HANDLING AND ADVERSE EVENT REPORTING
14. DOCUMENTATION
Glossary
APPENDIX
Section 1. Introduction And Scope

- **Scope**
  - Added information on types of Compounded Nonsterile Preparations (CNSP)

- **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 individual responsible and accountable for the performance and operation of the facility and personnel
Section 2. Personnel Qualifications—Training, Evaluation, And Requalification

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

Section 3. 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
Section 4. Buildings And Facilities
- Added requirement for a designated space for nonsterile compounding
- Area must be designed and controlled to provide well-lighted comfortable conditions for garbed personnel
- Surfaces in a compounding area must be cleanable and clean

Section 5. Cleaning And Sanitizing
- New table on minimum frequencies of cleaning and sanitizing surfaces in the nonsterile compounding areas, including
  - Floors
  - Walls
  - Ceilings
  - Storage Shelving
Section 6. Equipment And Components

- Any weighing, measuring, or other manipulation of an API or added substance in powder form that can generate airborne contamination from drug particles must occur inside a containment device (i.e., powder containment hood).
  - CVE must be cleaned
  - CVE must be certified annually

- Components
  - APIs must be manufactured by an FDA-registered facility
    - Each API must be accompanied by a valid COA
  - Ingredients other than APIs should be obtained from an FDA-registered facility
  - Packages of ingredients that lack vendor expiration must not be used after 1 year from the date of receipt
Section 7. SOPs and Master Formulation And Compounding Records.
- Boxes include required elements of Master Formulation Record and Compounding Record

Section 8. Release Testing
- Confirm CNSP and labeling match Compounding Records
- Visual inspections to determine if physical appearance is as expected
- Other tests to ensure quality (e.g. pH, assays)

Section 9. Labeling
- Requirements for *labels* (labeling on immediate container)
- Requirements for *labeling* (all matter on container or in package or wrapper)
Section 10. 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
- Chemical and physical stability
- Compatibility of container-closure system
- Degradation of container-closure system
- Potential for microbial proliferation
Section 10. Establishing Beyond-Use Dates

- Maximum BUD by Type of Preparation in the **Absence** of CNSP-Specific Stability Information

<table>
<thead>
<tr>
<th>Type of Preparation</th>
<th>BUDs (days)</th>
<th>Storage Temperaturea</th>
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<tbody>
<tr>
<td>Solid dosage forms</td>
<td>180</td>
<td>Controlled room temperature</td>
</tr>
<tr>
<td>Preserved aqueous dosage forms</td>
<td>30</td>
<td>Controlled room temperature</td>
</tr>
<tr>
<td>Non-preserved aqueous dosage forms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aw &gt; 0.6</td>
<td>14</td>
<td>Refrigerator</td>
</tr>
<tr>
<td>Nonaqueous dosage forms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aw ≤ 0.6</td>
<td>90</td>
<td>Controlled room temperature</td>
</tr>
</tbody>
</table>
Section 10. Establishing Beyond-Use Dates

- **In the Presence** of CNSP-Specific Stability Information
  - BUD may be extended up to maximum of 180 days
  - Stability-indicating assay for the specific API, CNSP, and container–closure that will be used
  - Must first be tested for antimicrobial effectiveness at the end of the proposed BUD

- **Shorter BUDs May be Required**
  - If ingredients have an earlier expiration date
  - If components have a earlier expiration date or BUD
  - If ingredients are known to be susceptible to decomposition
Section 11. Quality Assurance and Quality Control

- Quality Assurance = set of written processes that, at a minimum, verifies, monitors, and reviews the adequacy of the compounding process
- Quality Control = observation of techniques and activities that demonstrate that requirements are met

Section 12. CNSP Handling, Packaging, Storage, And Transport

Section 13. Complaint Handling And Adverse Event Reporting

- SOPs for complaint receipt, acknowledgement, and handling
- Review of adverse events

Section 14. Documentation
Submitting Comments
USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations

Millions of medications are compounded each year in the US to meet the unique needs of patient, including vulnerable populations such as seniors and children. Compounding provides tailored therapy to patients who may

Important Updates

- March 30, 2018 - The proposed <795> revision is now posted for public comment**

Download the Proposed Revision to GC <795>  Submit Comments to the Proposed Revision to GC <795>
<795> Public Comment Form

Public Comments requested through an electronic form
Public Comment Form

Please enter your contact information

- First Name
- Last Name
- Degree
- Email
- Phone Number
- Title
- Organization
- Address 1
- Address 2
- City
- State
- Zip/Postal Code
- Country
USP prefers that you provide specific comments on the proposed revision of <795> Pharmaceutical Compounding – Nonsterile Preparations with the relevant section/line numbers. The revision proposal is available at www.uspnf.com/notices/general-chapter-795-proposed-revisions with the line numbers printed on the left margin.

Please select all of the section(s) in the proposed revision to <795> for which you have comments. You will be prompted to enter comments for each section(s) you select.

If you have general comments on the chapter that do not have a corresponding section/line number, please select "General Comments" below.

[Note – If you would like to submit your comment in a PDF or word document, please email the document to CompoundingSL@usp.org]

**General Comments**

1. **Introduction and Scope**

2. **Personnel Qualifications—Training, Evaluation, and Requalification**

3. **Personal Hygiene and Garbing**
Please select the subsection(s) of 1. Introduction and Scope for which you'd like to offer comments

1. Introduction and Scope

1.1 Scope
Please enter the line numbers your comment refers to in Section 1.1 Scope

28, 59

Please enter specific changes requested for Section 1.1 Scope

Line 28 - Comment ABC
Line 59 - Comment XYZ

Please enter the rationale for the specific changes requested for Section 1.1 Scope
Thank you for using this electronic form to submit your comments on USP’s proposed revision for General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations. Please click the right arrow to complete this survey. You will receive an email from USP within 5-7 business days confirming receipt of your comments. If you have any questions, please email CompoundingSL@usp.org.
Timeline and Next Steps
Note: The current version of General Chapters <795> and <797> published in USP-NF are official.
Next Steps

- Stakeholders submit comments using the electronic form
  - Compounding Expert Committee will review all comments
  - Comments will be addressed through commentary posted on the USP website

- Sign up for to received updates on USP Healthcare Quality and Safety Standards
  - [https://www.usp.org/hqs-signup-form](https://www.usp.org/hqs-signup-form)
Question & Answer Session

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Panelist:
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Thank You

Empowering a healthy tomorrow
Stay Connected

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