Updates on USP Compounding Standards <795>, <797>, and <800>

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District IV NABP Annual Meeting

Learning Objectives

- Describe the current status of:
  - <795> *Pharmaceutical Compounding – Nonsterile Preparations*
  - <797>*Pharmaceutical Compounding – Sterile Preparations* and
- Identify major elements in the revised <795> and <797>
- Review major elements in General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings*
- .

USP Standards for Compounding

USP provides 3 types of public standards for compounding

USP General Chapters

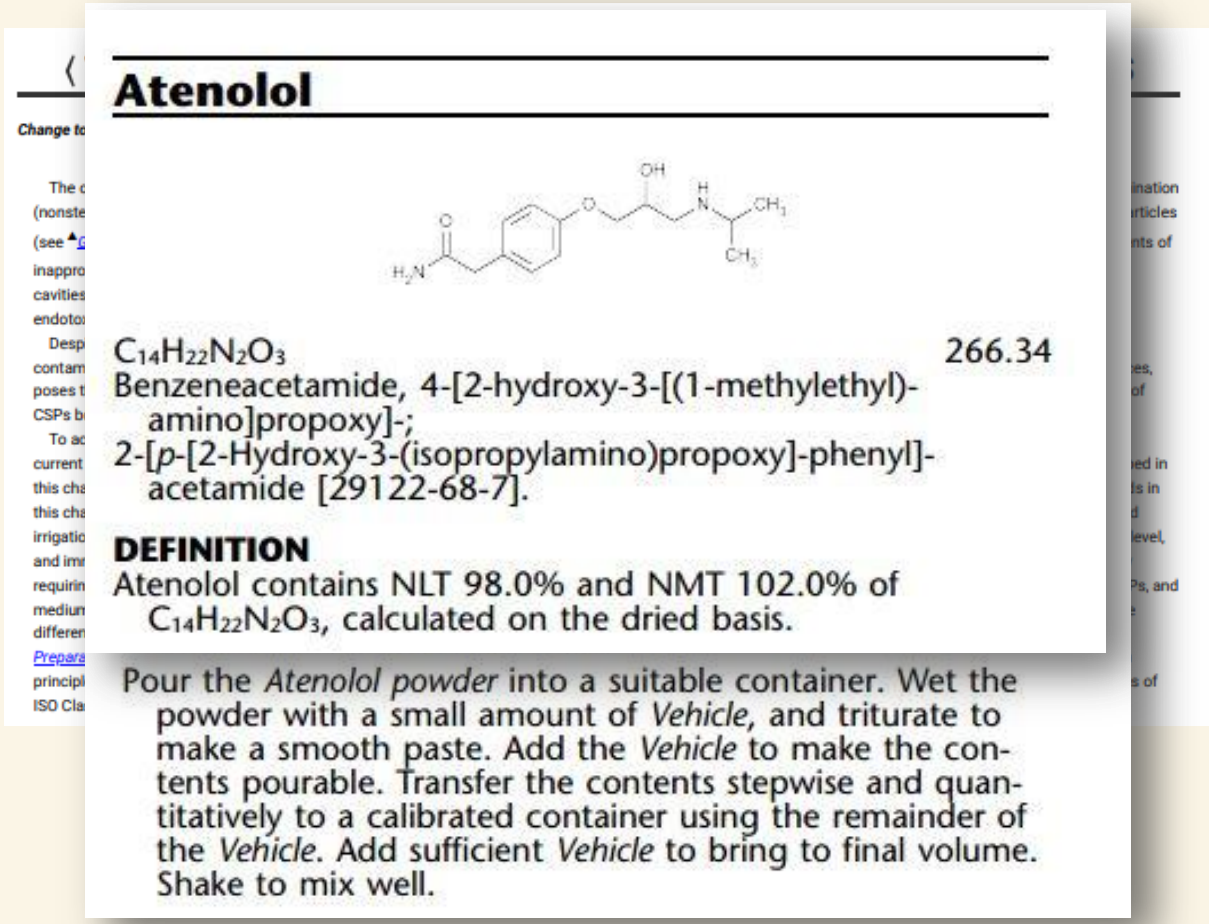
- establish practice standards to help ensure the quality of compounded preparations.

USP Compounded Preparation Monographs

- contain formulations for specific preparations for which there is no suitable commercially available product.

USP Monographs for Bulk Substances and Other Ingredients

- provide standards for identity, quality, purity, strength, packaging and labeling for bulk substances and other ingredients that may be used in compounded preparations.



Atenolol

$C_{14}H_{22}N_2O_3$ 266.34

Benzeneacetamide, 4-[2-hydroxy-3-[(1-methylethyl)-amino]propoxy]-;
2-[*p*-[2-Hydroxy-3-(isopropylamino)propoxy]-phenyl]-acetamide [29122-68-7].

DEFINITION

Atenolol contains NLT 98.0% and NMT 102.0% of $C_{14}H_{22}N_2O_3$, calculated on the dried basis.

Pour the *Atenolol powder* into a suitable container. Wet the powder with a small amount of *Vehicle*, and triturate to make a smooth paste. Add the *Vehicle* to make the contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container using the remainder of the *Vehicle*. Add sufficient *Vehicle* to bring to final volume. Shake to mix well.

Compounding General Chapters

USP standards help promote public health, protect patients and healthcare workers, and address public health challenges.

- <795> *Pharmaceutical Compounding – Nonsterile Preparations*
- <797> *Pharmaceutical Compounding – Sterile Preparations*
- <800> *Hazardous Drugs – Handling in Healthcare Settings*
- <825> *Radiopharmaceuticals – Preparation, Compounding, Dispensing, And Repackaging*

- <1163> *Quality Assurance in Pharmaceutical Compounding*
- <1160> *Pharmaceutical Calculations in Prescription Compounding*
- <1168> *Compounding for Phase I Investigational Studies*
- <1176> *Prescription Balances & Volumetric Apparatus*

Status of USP Compounding Standards

- On June 1, 2019, USP published revisions to **General Chapter <795>** for nonsterile compounding and **General Chapter <797>** for sterile compounding, as well as new chapter <825> for preparation, compounding, dispensing, and repackaging of radiopharmaceuticals
- After publication of the revised and new compounding standards, USP received **appeals** on certain provisions in <795>, <797>, and <825>.
  - The responsible Expert Committees considered the information raised in the appeals and issued decisions on the appeals
- As part of the formal USP appeals process, appellants had the opportunity to request further review by an appointed Panel, and **USP has received four such requests.**

Status of USP Compounding Standards

- In light of these appeals, and in accordance with our Bylaws, **USP postponed the official dates of <795>, <797>, and <825> until further notice.** The decisions on the appeals to <795>, <797>, and <825> do not foreclose the possibility of future revisions to these chapters.
- **General Chapter <800> is not subject to any pending appeals and will become official on December 1, 2019.** During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable.

Overview of Revisions to <795> *Pharmaceutical Compounding – Nonsterile Preparations*

Official date postponed until further notice

Major Elements of <795>

Pharmaceutical Compounding – Nonsterile Preparations

Scope

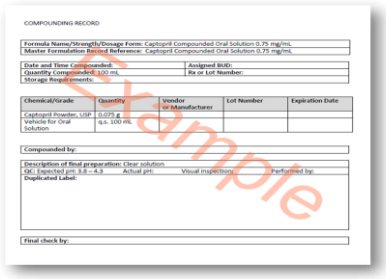
Personnel

Compounding Facilities

Component Selection, Handling and Storage

Stability Criteria and Beyond-Use Dating

Master Formulation Records



Compounding Records

Quality Assurance and Quality Control

Overview of Revisions to <797> *Pharmaceutical Compounding – Sterile Preparations*

Official date postponed until further notice

Major Elements of <797>

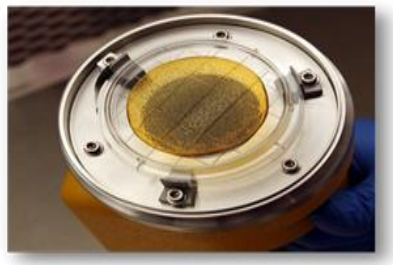
Pharmaceutical Compounding – Sterile Preparations

Scope

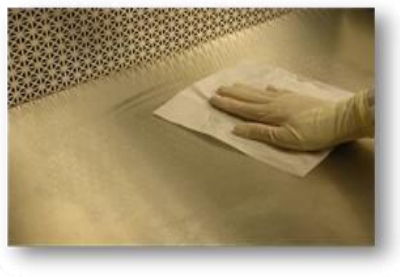
Personnel Qualifications

Personal Hygiene and Garbing

Facilities and Engineering Controls



Microbiological Monitoring

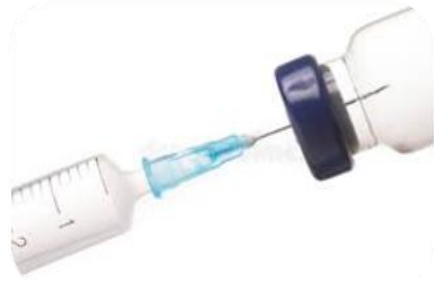


Cleaning and Disinfecting

Sterilization and Depyrogenation

Release Testing

Establishing Beyond-Use Dates



Compounding Allergenic Extracts

Review concepts in <800> *Hazardous Drugs – Handling in Healthcare Settings*

Official December 1, 2019

(During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable.)

Major Elements of <800>

List of HDs

Types of Exposures

Personnel Responsibilities

Facilities & Engineering Controls

Environmental Quality & Control

PPE

Compounding

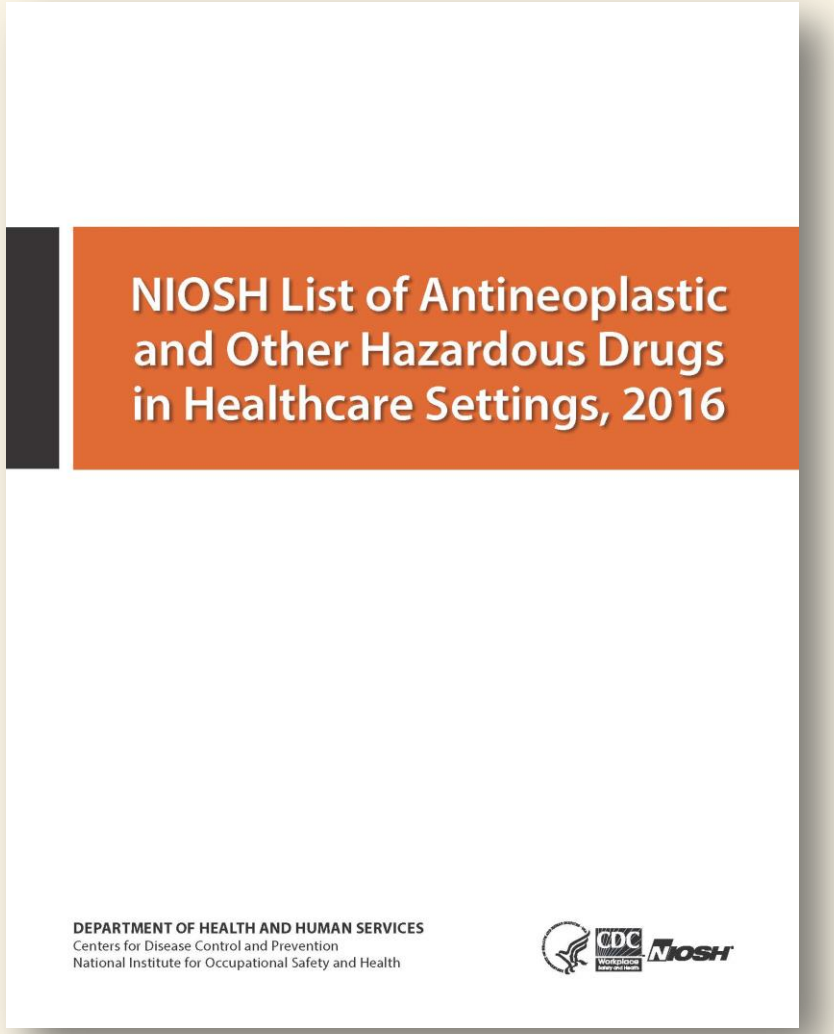
Deactivation, Decontamination, & Cleaning

Medical Surveillance

Hazardous Drugs (HD)

Any drug identified by ≥ 1 of the following criteria:

- Carcinogenicity
- Teratogenicity or other developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria



NIOSH List of Antineoplastic and Other HDs

Table 1	• **Antineoplastic drugs**
Table 2	• **Non-antineoplastic drugs**
Table 3	• Non-antineoplastic drugs with **adverse reproductive effects**

Containment Requirements

HDs that must follow all the requirements:

- Any HD API
- Any antineoplastic requiring manipulation

HDs eligible for an assessment of risk include:

- Final dosage forms of antineoplastics that do not require any further manipulation
- Dosage forms of other HDs

Assessment of Risk

- Considerations
  - Type of Hazardous Drug
  - Dosage Form
  - Risk of Exposure
  - Packaging
  - Manipulation

Personal Protective Equipment (PPE)

- ASTM powder-free chemotherapy gloves

- Disposable and impermeable gowns

- Head and hair covers, shoe covers, sleeve covers

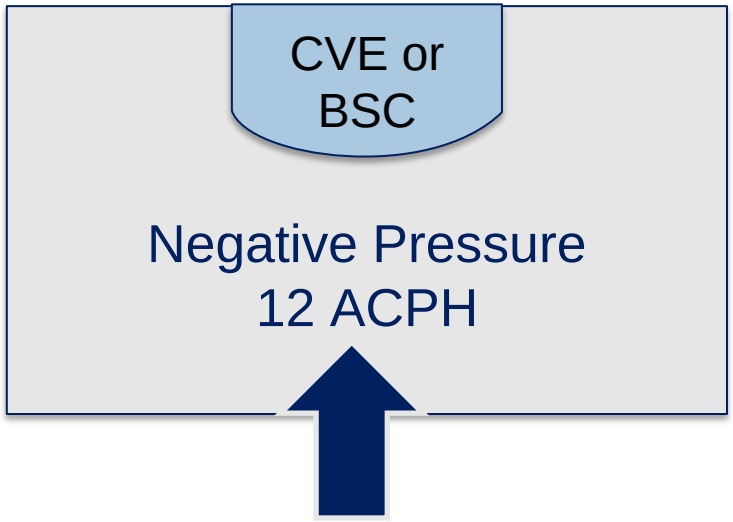
- Eye and face protection

- Respiratory protection

Nonsterile Compounding

Controlled, physically separated environments

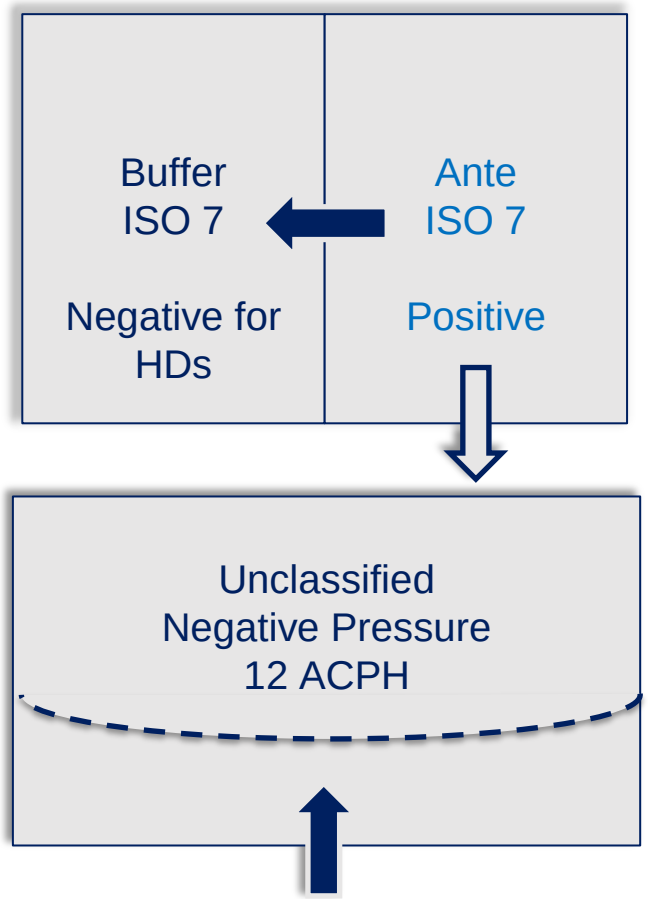
	Nonsterile
C-PEC	• Externally vented (preferred) or redundant HEPA filtered
C-SEC	• Externally vented • Negative pressure (0.01-0.03” w.c.) • 12 ACPH



Sterile Compounding

Controlled, physically separated environments

	Sterile
C-PEC	• Externally vented, ISO Class 5
C-SEC	ISO Class 7 Cleanroom suite
	• Externally vented • Negative pressure • 30 ACPH
	Unclassified C-SCA
	• Externally vented • Negative pressure (0.01-0.03” w.c.) • 12 ACPH



Dispensing

- Dispensing Final Dosage Forms
  - HDs that only require counting and repackaging may be dispensed without any further requirements for containment
- Clean equipment
  - Should be dedicated for use with HDs
  - Should be decontaminated after every use
- Antineoplastic HDs must not be placed in automated counting or packaging machines

USP Resources

General

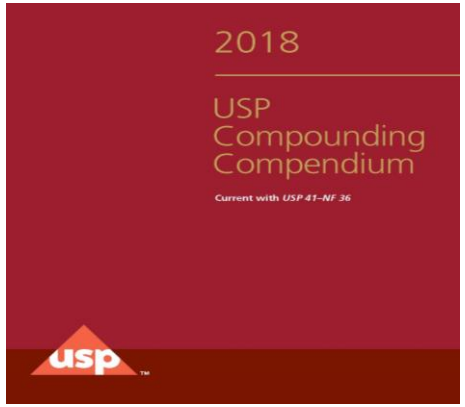
- USP Web Page
- USP Updates
- Compounding Compendium
- USP Education

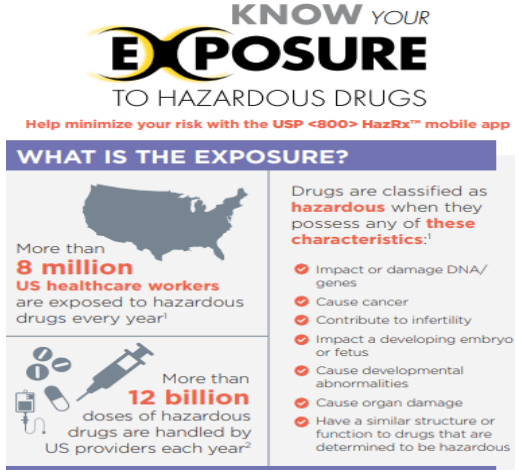
<800>

- Complimentary download <800>
- <800> FAQs
- HazRx™ Mobile App
- Infographic

Compounding

- <795> *Pharmaceutical Compounding – Nonsterile Preparations*
- <797> *Pharmaceutical Compounding – Sterile Preparations*





Stay informed signup for updates:
http://www.usp.org/hqs-signup-form

USP Resources

General

- USP Web Page (HQS)
- Compounding Updates
- HQS Newsletter
- Compounding Compendium
- USP Education

Compounding

- <795> Pharmaceutical Compounding – Nonsterile Preparations
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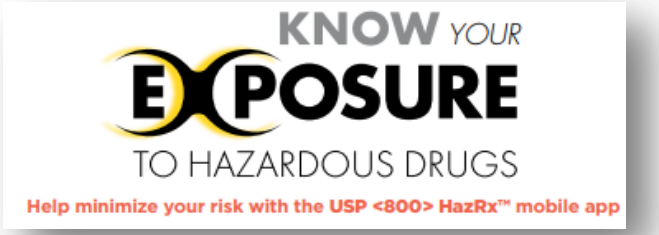

Call for Candidates

2020-2025

Central to USP's achievements are the contributions of countless professionals, who volunteer their time and knowledge in USP's Council of Experts and Expert Committees and Panels.

Our Call for Candidates is now open.

Join other motivated colleagues to help us set the standards that make it possible for 2 billion people around the world to have access to quality medicines, foods and dietary supplements.

Contact us at USPVolunteers@usp.org

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Sign up for updates

http://www.usp.org/hqs-signup-form

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Questions

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Thank You

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