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

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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

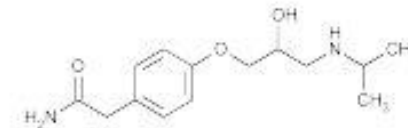
- contain formulations for specific preparations for which there is no suitable commercially available product.

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 RECORD	
Formula Name/Strength or Active/Storage Form: Captopril Compounded Oral Solution 0.75 mg/mL	Reference: USP Monograph
EMD: 7.8mg	Storage: Refrigerated
Quantity: 100 mL	
Ingredients:	Quantity Needed
Captopril Powder, USP	0.075 g
Vehicle for Oral Solution - q.s. 100 mL	
Equipment:	
Mortar	
1/2 oz Glass Mortar and Pestle	
100 mL Glass Vial/Container	
Rubber Spatula	
Procedure:	
Calculation, Not needed	
Mixing Instructions:	
1. Using the balance, weigh Captopril Powder, USP on a weigh paper with the metal spatula.	
2. Add 20 mL of vehicle for Oral Solution in a glass vial.	
3. Add Captopril Powder, USP and approximately 80 mL of vehicle for Oral Solution to mortar, and mix using the pestle. Continue adding the vehicle for Oral Solution to mortar in small quantities, allowed to combine and mix thoroughly after each addition.	
4. Transfer the contents of the mortar using a rubber spatula to a calibrated bottle and q.s. to volume with Vehicle for Oral Solution, and then mix well.	
Final Step: Tight light-resistant container	
Labeling: Captopril Compounded Oral Solution 0.75 mg/mL	
Labeling Requirements: Label to state beyond-use date	
Labeling Requirements: Label to indicate this is a compounded preparation	
Description: Clear Solution	
QC: Inspection per 8.1-8.4	

Master Formulation Records

COMPOUNDING RECORD				
Formula Name/Strength or Active/Storage Form: Captopril Compounded Oral Solution 0.75 mg/mL	Reference: USP Monograph			
EMD: 7.8mg	Storage: Refrigerated			
Quantity: 100 mL	Assigned BUD:			
Identify Compounded:	By or Lot Number:			
Storage Requirements:				
Chemical Name	Quantity	Vendor or Manufacturer	Lot Number	Expiration Date
Captopril Powder, USP	0.075 g			
Vehicle for Oral Solution	q.s. 100 mL			
Composed by:				
Description of final preparation: Clear solution				
QC: Inspection per 8.1-8.4	Visual inspection			
Supplied by:				
Supplied Label:				
Final check by:				

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



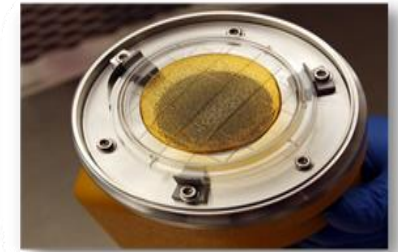
Personnel Qualifications



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 Hazardous Drugs in Healthcare Settings, 2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health



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



- ▶ Eye and face protection



- ▶ Disposable and impermeable gowns



- ▶ Respiratory protection



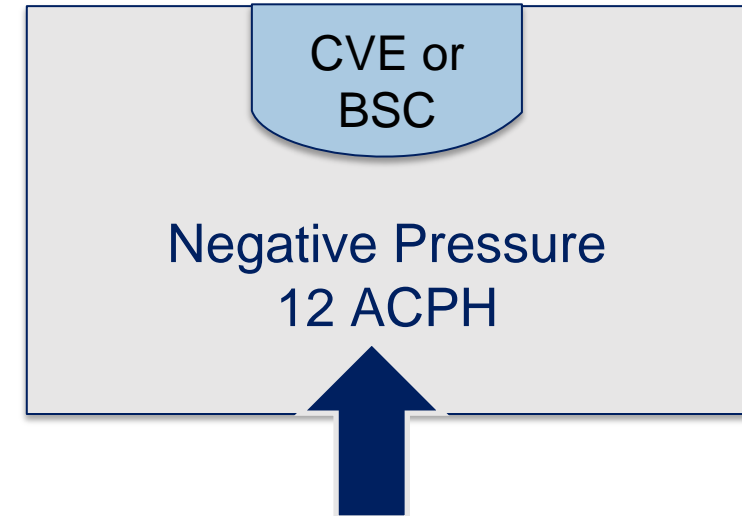
- ▶ Head and hair covers, shoe covers, sleeve covers

Nonsterile Compounding

Controlled, physically separated environments



	Nonsterile
C-PEC	<ul style="list-style-type: none">Externally vented (preferred) or redundant HEPA filtered
C-SEC	<ul style="list-style-type: none">Externally ventedNegative pressure (0.01-0.03" w.c.)12 ACPH

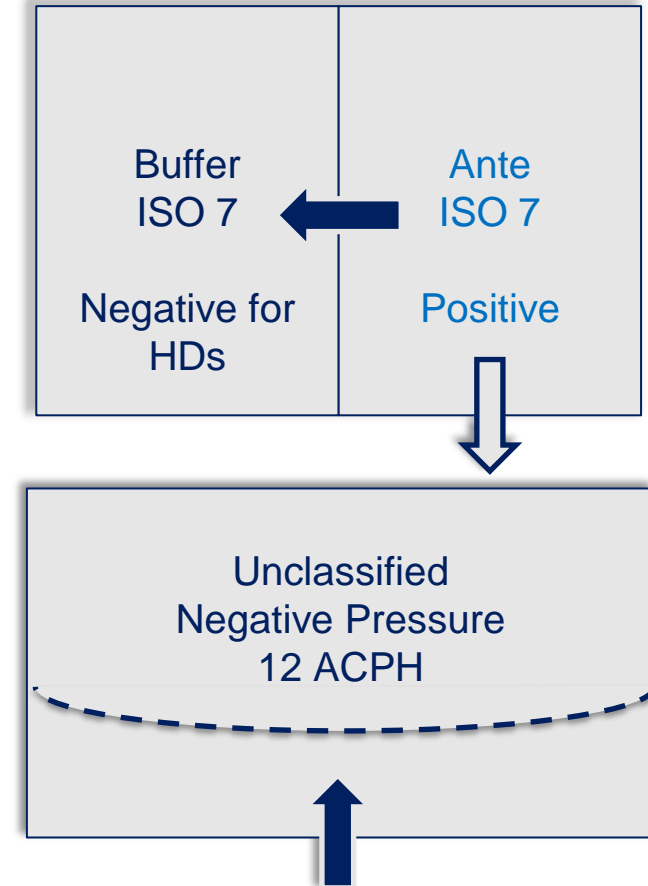


Sterile Compounding

Controlled, physically separated environments



	Sterile
C-PEC	<ul style="list-style-type: none">Externally vented, ISO Class 5
C-SEC	ISO Class 7 Cleanroom suite
	<ul style="list-style-type: none">Externally ventedNegative pressure30 ACPH
	Unclassified C-SCA
	<ul style="list-style-type: none">Externally ventedNegative 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





General

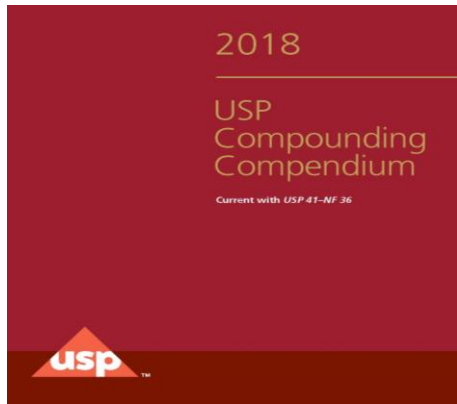
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Compounding

- [<795> *Pharmaceutical Compounding – Nonsterile Preparations*](#)
- [<797> *Pharmaceutical Compounding – Sterile Preparations*](#)



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

KNOW YOUR EXPOSURE TO HAZARDOUS DRUGS
Help minimize your risk with the USP <800> HazRx™ mobile app

WHAT IS THE EXPOSURE?

More than **8 million** US healthcare workers are exposed to hazardous drugs every year¹

More than **12 billion** doses of hazardous drugs are handled by US providers each year²

Drugs are classified as **hazardous** when they possess any of **these characteristics**:¹

- Impact or damage DNA/genes
- Cause cancer
- Contribute to infertility
- Impact a developing embryo or fetus
- Cause developmental abnormalities
- Cause organ damage
- Have a similar structure or function to drugs that are determined to be hazardous

General

- [USP Web Page \(HQS\)](#)
- [Compounding Updates](#)
- [HQS Newsletter](#)
- [Compounding Compendium](#)
- [USP Education](#)

Compounding

- [<795> Pharmaceutical Compounding – Nonsterile Preparations](#)
- [<797> Pharmaceutical Compounding – Sterile Preparations](#)

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2020-2025



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