

USP <797> AVAILABILITY

1

1.1 Where can I find the full text of <797>?

United States Pharmacopeial Convention (USP) publishes the *USP Compounding Compendium*.¹ It contains all the major compounding chapters:

- ▶ *USP General Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations*²
- ▶ *USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations*³
- ▶ *USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings*⁴
- ▶ *USP General Chapter <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*⁵ as well as all the other chapters that are referenced in those core compounding chapters.

Additionally, the General Notices that apply to compounding and compounding monographs are included. The *USP Compounding Compendium* is available through USP at www.usp.org as an annual subscription.

1.2 When did <797> become official?

<797> has been an official standard since 2004. It was revised in 2008. Several proposed revisions were published for public comments. The 2023 revision was published on November 1, 2022 with an official date of November 1, 2023.

1.3 Why is there a need for a chapter on sterile compounding? Is this all about the meningitis scare from 2012?

This is a focus on patient safety.⁶ It was first published in 2004, so <797> predates the meningitis tragedy of 2012. There were several issues of improper quality (strength as well as microbial contamination) that occurred in 1989 and 1990, prompting both a Food and Drug Administration (FDA) Alert and an ASHP Urgent Attention letter directed to sterile compounders.⁷ Those events and others led to the development of <797>.

1.4 Is <797> a guideline? A requirement?

<797> is a minimum standard. Regulators such as federal or state entities can make it a regulation by including it in their documents. Accreditation organizations, such as The Joint Commission, DNV Healthcare, the Accreditation Commission for Health Care, the Center for Improvement in Healthcare Quality, and others, can include it in their own standards.

1.5 How can <797> be a minimum standard if my state hasn't incorporated it into regulations?

USP is a standard-setting organization. Even if your state has not codified it into regulation, it is still a federal standard and can be used to inspect or survey your pharmacy.