

# USP <797> AVAILABILITY

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

United States Pharmacopeial Convention (USP) publishes the *USP Compounding Compendium*.<sup>1</sup> It contains all the major compounding chapters: *USP General Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations*,<sup>2</sup> *USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations*,<sup>3</sup> *USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings*,<sup>4</sup> and *USP General Chapter <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*<sup>5</sup> 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](http://www.usp.org) as an annual subscription.

Your subscription allows you to download updates throughout your subscription year. Be sure to do that each February, June, and November so you have the most current versions of existing chapters and any new General Notices, General Chapters, or monographs that were completed in the prior months.

## 1.2 When did <797> become official?

<797> has been an official standard since 2004. It was revised in 2008. A proposed revision was published in 2019 but was appealed and returned to the USP Compounding Expert Committee to evaluate and/or revise.<sup>6</sup>

## 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. 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.<sup>7</sup> 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-GL Healthcare, the Pharmacy Compounding Accreditation Boards, 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.