

## USP Quality Standards for Compounding

USP is a scientific nonprofit organization that sets public standards for the identity, strength, quality, and purity of medicines. The first *United States Pharmacopeia (USP)* was published in 1820, and began as a “recipe” book to promote uniformity in the drugs prepared and dispensed by practitioners to their patients. USP’s commitment to help ensure the quality of compounded medicines is ongoing. USP standards are recognized in law and play a prominent role in federal and state compliance and enforcement activities.

### USP Helps Ensure the Quality of Compounded Medicines

USP provides three types of public standards for compounding that are developed by the USP Council of Experts and its [Compounding Expert Committee](#) to help ensure the quality of compounded medicines.

**(1) Monographs for Bulk Drug Substances and Other Ingredients** - These monographs provide standards for identity, quality, purity, strength, packaging, and labeling for bulk substances and other ingredients that may be used in compounded preparations.

**(2) Compounded Preparation Monographs** - Compounded preparation monographs contain formulations and quality standards for specific preparations. Compounded preparation monographs assist practitioners in compounding formulations for which there is no suitable commercially available product, and provide standards to ensure the quality of these medicines. These preparations may be used for pediatric, geriatric, and veterinary patients who may need a certain dosage form or strength of a medication or may have an allergy to an ingredient in an approved product. Currently, USP has over 175 monographs for compounded preparations (see <http://www.usp.org/usp-healthcare-professionals/compounding/compounding-monographs>).

**(3) General Chapters** - *USP* General Chapters serve as overviews and they outline information, procedures, or analytical methods that apply across all products or settings (e.g., compounding). There are currently six essential compounding General Chapters (see <http://www.usp.org/usp-healthcare-professionals/compounding/compounding-general-chapters>):

- <797> *Pharmaceutical Compounding—Sterile Preparations*
- <795> *Pharmaceutical Compounding—Nonsterile Preparation*
- <800> *Hazardous Drugs—Handling in Healthcare Settings*
- <1160> *Pharmaceutical Calculations in Pharmacy Practice*
- <1163> *Quality Assurance in Pharmaceutical Compounding*
- <1176> *Prescription Balances and Volumetric Apparatus Used in Compounding*

USP compounding standards support practitioners' adherence to widely acknowledged, scientifically sound procedures and practices, and facilitate consistency and quality in the medicines prepared for patients.

USP compounding standards are contained in the *United States Pharmacopeia and National Formulary (USP—NF)*, and also published in the *USP Compounding Compendium*.

### **Practitioners and Parties Responsible for Compounding Medicines are Required to Comply with USP's Chapters and Monographs**

USP standards—general chapters and monographs—contained in the *USP—NF* have long been recognized in various provisions of the federal Food, Drug and Cosmetic Act (FDCA) and play a prominent role in FDA compliance and enforcement.

#### **All Drugs**

Any drug that is recognized in the *USP—NF* must adhere to USP standards for identity, strength, quality, purity, packaging, and labeling or risk being deemed adulterated or misbranded. These provisions do not differentiate between manufactured and compounded medicines.

#### **Compounded Medicines**

The FDCA specifically references and mandates USP standards for compounding. USP standards for compounding were first recognized in Section 503A of the 1997 Food Drug Administration Modernization Act, which states that a compounder must use bulk drug substances and ingredients that comply with the standards of an applicable *USP—NF* monograph, if a monograph exists, and the USP chapter on pharmacy compounding.

More recently, Congress enacted the 2013 Drug Quality and Security Act (DQSA) to clarify FDA's authority over drug compounding, and reaffirmed USP's role under Section 503A. Following enactment of the DQSA, FDA provided further clarification of its views on the application of USP standards to pharmacy compounding through an FDA Guidance: [Pharmacy Compounding of Human Drug Products under Section 503A of the Federal Food, Drug, and Cosmetic Act](#).

This guidance states that compounded preparations by a licensed pharmacist or physician qualify for an exemption from requirements of a new drug application if they are compounded in compliance with the *USP* chapters on pharmacy compounding using bulk drug substances and ingredients that comply with the standards of an applicable *USP* or *NF* monograph, if one exists. The guidance specifically references General Chapter <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations*.

The guidance also notes that compounded preparations that qualify for the exemption from new drug application requirements under Section 503A must also still meet the remaining requirements of the FDCA. As set forth in the FDCA and pursuant to the guidance, this includes the requirement that a compounded medicine that is recognized in the *USP* or *NF* must meet the specified *USP–NF* standards for strength, quality, purity, packaging, and labeling.

In addition to the federal requirements, many states have specifically incorporated references to USP General Chapters in their laws and regulations. For example, according to the 2016 NABP Survey of Pharmacy Law, more than half of the U.S. State Boards of Pharmacy require compliance with <797>.

### **Additional Information**

For more information, sign up for the [Healthcare Quality Standards Update](#) to receive updates on healthcare related standards, or visit the [Compounding section](#) of our website.

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\* The Compounding Expert Committee is composed of 18 members representing a variety of disciplines including healthcare practitioners who have expertise in sterile and nonsterile compounding, veterinary compounding, aseptic technique, microbiology, environmental engineer, and analytical testing. Additionally, 10 government liaisons participate in the Compounding Expert Committee, including seven representatives from the FDA and three representatives from the Centers for Disease Control and Prevention.