



U.S. Pharmacopeia
The Standard of QualitySM

USP Compounding Backgrounder

What is compounding?

Compounding involves the preparation and mixing of one or more components according to a written prescription—specifically for individual patients and based on their unique needs. Compounding includes:

- Preparation of drugs or devices to fill a prescription order;
- Reconstitution of commercial products that may require the addition of one or more ingredients;
- Manipulation of commercial products that may require the addition of one or more ingredients; and
- Preparation of drugs or devices for the purposes of research, teaching, or chemical analysis.

Compounding is usually performed by a licensed practitioner or a trained professional under the guidance of a licensed practitioner.

Why is compounding important?

Not all medicines are commercially produced in large quantities by pharmaceutical manufacturers in the dosage forms required by specific patients. Pharmacists therefore compound prescription medications for many different reasons—examples include when there is a shortage of a marketed product, when a medication is not commercially available in a liquid form for treating a child, and when a patient may be allergic to preservatives or dyes contained in the product. Compounding is often performed for pediatric, geriatric, and other special populations, to include veterinary patients, who require patient-specific doses.

Do compounding standards exist?

Yes, there are standards for compounding. USP publishes standards for compounding in the *United States Pharmacopeia* and *National Formulary (USP–NF)*. These include standards for compounded preparations, which under federal law are the official standards for compounded preparations in the United States. This means that if a practitioner compounds a medicine included in the *USP–NF*, this product must comply with the *USP–NF* standards.

In addition to standards for compounded preparations, the *USP–NF* contains several general chapters that provide standards for compounding practices. They are:

- <795> *Pharmaceutical Compounding—Nonsterile Preparations*. This chapter provides procedures and requirements for nonsterile types of compounding.
- <797> *Pharmaceutical Compounding—Sterile Preparations*. This chapter provides procedures and requirements for compounding sterile preparations.
- <1075> *Good Compounding Practices*. This chapter provides guidance on applying good compounding practices for the preparation of compounded formulations for dispensing and/or administering to humans and/or animals.
- <1160> *Pharmaceutical Calculations in Prescription Compounding*. This chapter provides general guidance and assistance to pharmacists in performing the necessary calculations when preparing or compounding any pharmaceutical drug.
- <1163> *Quality Assurance in Pharmaceutical Compounding*. This chapter describes a quality assurance program as a system of steps and actions that must be taken to ensure the maintenance of proper standards in compounded preparations.

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How does USP set standards for compounding?

USP standards are developed through an open and transparent process that includes public involvement. The standards are approved by USP's Compounding Pharmacy and Sterile Compounding Expert Committees, which are part of USP's Council of Experts (a volunteer body that directs USP's scientific and standards-setting decisions). These standards are first published in USP's bimonthly *Pharmacopeial Forum*, the journal of standards development, for public comment. Comments are reviewed and considered by the Expert Committees.

Once the standard is approved, it is then published in *USP–NF*. The *USP–NF* revision process is continuous. Revisions, along with proposals for new standards, can be suggested by any health care practitioner, scientist, consumer, or organization and are considered and reviewed by the USP's Expert Committees on compounding.

What is the *USP Pharmacists' Pharmacopeia*?

USP released the first *USP Pharmacists' Pharmacopeia* for practicing pharmacists in June 2005, and a second edition in 2008. The compendium offers information on safely preparing, compounding, packaging, and storing medications. Combining relevant, official text from the *USP–NF* with authorized content developed by USP's Expert Committees, the *USP Pharmacists' Pharmacopeia* contains monographs and general chapters, as well as references for compounding specifications and general legal information.

The latest edition of the *USP Pharmacists' Pharmacopeia* includes:

- 129 official monographs from *USP–NF*, abridged for pharmacy practitioners;
- the newly revised General Chapter *Pharmaceutical Compounding—Sterile Preparations <797>*, along with 72 other relevant USP General Chapters;
- a comprehensive section on veterinary compounding;
- sections on food ingredients, flavorings, and colorings—all of which may be used in compounded preparations;
- information and resources to help reduce medication errors and enhance patient safety; and
- legal statutes and regulatory information applicable to pharmacy compounding.

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