



U.S. Pharmacopeia  
The Standard of Quality™

## Equine Deaths in Florida: Compounding Standards Frequently Asked Questions

Compounding is an integral part of pharmacy practice and is an essential component of health care—for both humans and animals. The U.S. Pharmacopeial (USP) Convention takes an active role in supporting the public's access to customized therapy by setting national standards and guidelines for compounding both sterile and nonsterile medications. This work is guided by two USP Expert Committees: the Compounding Pharmacy and Sterile Compounding Expert Committees.

### 1. What is compounding, and how is it different from just filling a prescription?

Medicines can be compounded (mixed together) to meet the needs of a specific patient, or to provide access to a drug that has gone off the market or is otherwise unavailable. A trained pharmacist mixes carefully measured components together according to a “recipe” to form the desired medication.

### 2. What do USP's standards for compounding actually designate?

USP develops standards for compounding both sterile and nonsterile preparations that are included in our official publications of standards, the *U.S.*

*Pharmacopeia–National Formulary (USP–NF)*. These standards include:

- A. Written standards for individual medicines that may be compounded, which can be used every day by pharmacists to prepare medications for patients requiring customized drug therapy; and
- B. General Chapters that describe overall good compounding practices. General Chapters differ from individual standards in that they describe tests and procedures common to multiple standards.

Specifically, the USP General Chapters related to compounding are General Chapter <795> *Pharmaceutical Compounding – Nonsterile Preparations* and General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations*. General Chapter <795> provides compounding pharmacists with guidance on applying good compounding practices in the preparation of nonsterile compounded formulations for dispensing and/or administration to humans or animals. This chapter and related written standards on formulation help define what constitutes good compounding practices. The chapter also provides general information to enhance the compounding professional's ability to extemporaneously compound preparations that are of acceptable strength, quality, and purity.

General Chapter <797> focuses on sterile preparations, describing conditions and practices to prevent harm or death in patients that could result from 1) microbial contamination (nonsterility), 2) excessive bacterial endotoxins, 3) variability in the intended strength of correct ingredients that exceeds stated limits, 4) unintended chemical and physical contaminants, and 5) ingredients of poor quality in compounded sterile preparations.

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**3. Do USP's compounding standards apply to veterinary as well as human medicine compounding?**

Yes.

**4. Is it correct that a USP standard states that a batch of more than 25 identical units requiring sterile preparation is required to be tested by a third party? If so, in this case of the equine deaths in Florida where there were 21, did this meet the USP requirement?**

This requirement is found in General Chapter <797> under the section titled "Finished Preparation Release Checks and Tests, Sterility Testing." It only applies to *high-risk* compounded sterile preparations, which are defined clearly in the *USP-NF*. The designation as "high risk" is based on a number of factors including use of nonsterile ingredients and environmental factors such as air quality.

Note that this 25 units requirement refers to sterility, *not* potency or concentration of ingredients, which initially seems to have been the problem in the recent case of equine deaths.

**5. Did the pharmacy in question appear to follow USP compounding standards?**

We do not know all the details of this particular situation, so we cannot comment. It should also be noted that USP does not enforce its standards; that is left to regulatory authorities.

**6. How are compounding pharmacies regulated?**

All pharmacies and pharmacists are licensed and strictly regulated at the state level. Compounding is a core component of pharmacy and has always been regulated by state boards of pharmacy.

The Food and Drug Administration (FDA) also has an important role to play in making sure that ingredients used in compounding are safe and are manufactured by FDA-registered and -inspected facilities.

**7. Are pharmacies required by law to follow USP's compounding standards?**

Compounded preparations that are recognized in official standards (those published in the *USP-NF*) must adhere to these standards for identity, quality, purity, and strength, as well as packaging and labeling. Additionally, the FDA recognizes General Chapters <795> and <797> to be official and enforceable.