

FAQs FOR USP CHAPTER 795 NONSTERILE COMPOUNDING

1. Is reconstituting an antibiotic considered nonsterile compounding?

A: Yes, this is considered simple compounding. However, when following manufacturer's directions, such as reconstituting an antibiotic, mixing Benzaclin, or making Tamiflu suspension when it is unavailable, does not require any additional documentation. Therefore, there will be no compound record or training documentation.

2. Does a pharmacist have to have documented training for nonsterile compounding?

A: Yes, USP Chapter 795 requires documented training for all employees who compound or supervise compounding. Some pharmacists may have had a nonsterile compounding lab in pharmacy school, but documented training for the specific types of compounding being performed at the pharmacy is required. The documented training may be from a third party. Documented training may be one pharmacist training another pharmacist.

3. What is training?

A: Training must include:

- A.** read and be familiar with USP Chapter 795;
- B.** read and be familiar with each procedure related to the compounding the person will be performing or supervising;
- C.** demonstration of the compounding procedures to the trainee;
- D.** the trainee will repeat the observed compounding procedures under the supervision of the trainer;
- E.** documentation this person has been trained; and
- F.** signature of trainer that this person has been trained.

4. How is training documented?

A: One example:

- A.** Have each person participating in compounding sign a log that USP Chapter 795 has been read (the Chapter is about 7 pages).
- B.** Have each person participating in compounding sign a log that he/she has read each compounding procedure.
- C.** Have the trainee watch the trainer compound the preparation(s).
- D.** Have the trainee compound the preparation(s) while the trainer is watching.

- E.** Document the observed training on the compound record(s) used for the training with the trainer signing the compound record.
- F.** The observed portion of training must be done for each type of preparation being compounded: creams, suspensions, solutions, troches, etc.

5. How frequently must training be done?

A: Training is required to be completed before the person compounds or supervises compounding. It is to be ongoing. If a new preparation is to be compounded, there must be documentation of training for the new preparation. It is recommended compounding personnel be evaluated annually.

6. Why can't the expiration date of the commercially available products being used in the compound, be used for the Beyond Use Date (BUD)?

A: The commercially available products have an expiration date that is specific to that product in that container. When compounding, the commercially available products are being manipulated and the expiration date no longer applies. If the expiration date of the manufacturer product is shorter than the USP Chapter 795 BUDs, the expiration date must be used.

The following BUDs apply if there is no testing or documentation to extend the BUD and the expiration date of any component used is longer:

- A. Oral aqueous preparations: 14 days, refrigerated
- B. Topical, dermal or mucosal aqueous preparations: 30 days, room temperature
- C. Nonaqueous preparations: 6 months, room temperature