

### 13.1 Is a beyond-use date the same thing as an expiration date?

*No.* Manufacturers establish expiration dates for their products based on studies of the physical and chemical stability of their products, packaged in the dosage form marketed, when stored based on the requirements of the labeling. The beyond-use dates (BUDs) that compounders assign to preparations are much shorter because the validated testing is not done.

### 13.2 What BUDs are allowed by <795>?

*Stability information provided by USP monograph<sup>1</sup> or other peer-reviewed formulas can be used. In the absence of that information, the maximum BUDs for CNSPs are:*

Type of Preparation	BUD	Storage Temperature
Nonaqueous formulation	The shortest of the earliest expiration date of API or any component, or 6 months	
Water-containing topical/dermal and mucosal liquid and semisolid formulation	30 days	
Water-containing oral formulation	14 days	Controlled cold temperature

### 13.3 What is a USP monograph?

USP has over 150 compounding monographs available in the *USP-NF* or *Compounding Compendium*.<sup>1</sup> They are compounds that have undergone testing and may have BUDs that are longer than the chart above. To use the BUD stated in the monograph, the CNSP must be compounded as directed, using the same packaging, the same storage temperature, and completion of any required testing.

### 13.4 Can I use a USP monograph and extend the BUD beyond what's listed?

*No.*

### 13.5 What kind of specific stability data allows use of a longer BUD if there isn't a USP monograph?

*There are several things to consider:*

- ▶ A stability-indicating assay for the active pharmaceutical ingredient (API), CNSP, and container and closure used. (See *Strength and Stability Testing for Compounded Preparations*.<sup>32</sup>)
- ▶ If the preparation is an aqueous CNSP, an antimicrobial effectiveness test. See: <51> *Antimicrobial effectiveness testing*.<sup>33</sup>

### 13.6 Is there a maximum BUD even with studies that support a BUD longer than the defaults in <795>?

No, but consider the balance of patient need with safety.

### 13.7 I have published studies that have BUDs of 1 or 2 years. Can I use them?

You can use them, but consider the balance of patient need with safety.

### 13.8 I have published studies that show 100% of the compound remaining on Day 30. Can I extrapolate that information to use a longer BUD?

No, not without other information to support it. The authors may have stopped the study at Day 30, so that's all they can report. Perhaps the compound is stable longer, but you have no proof of that.

### 13.9 Is it always OK to use the default dates listed in <795>?

No. *Other factors may require you to use shorter times, including:*

- ▶ How the CNSP reacts over time
- ▶ The interaction of the container or closure with the CNSP
- ▶ Microbial growth. Even nonsterile preparations can be compromised by bacteria or fungus.

### 13.10 If I make a CNSP today, does the time for the BUD start today or tomorrow?

The BUD starts when you mix the CNSP.

### 13.11 Is there a particular type of container that the default BUDs are based on?

Yes. They are based on using tight, light-resistant containers. See <659> *Packaging and Storage Requirements*.<sup>34</sup>