



# New United States Pharmacopeia (USP) Guidelines

Effective November 1, 2023

## What does this mean and how will it affect veterinary professionals?

As of November 1, 2023, new USP guidelines are limiting beyond-use dates (BUDs) on drugs compounded at all 503A compounding pharmacies.

The new USP guidelines limit the ability of 503A compounding pharmacies to extend BUDs. At Stokes Pharmacy, our traditional 503A compounding pharmacy, we have invested substantial time and resources into stability studies to meet passing criteria as per USP for extended dating on BUDs where possible but these are limited. Studies are done on a per drug/strength/base/container and are valid at that pharmacy only unless sharing formulas and methods.

Epicur Pharma's manufactured **503B medications** are not required to follow the requirements of USP <795> or <797>. Instead, they **use longer/proven expiration dates** validated by the current Good Manufacturing Practice (cGMP) regulations enforced by the FDA and will continue to have an **expiration of up to 365 days**. Stability studies for increasing BUD at pharmacies are not the same or even close to what is required by the FDA.

Take a deeper dive into the difference between beyond-use dates and expiration dates!

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as featured in



For a list of Epicur Pharma's manufactured 503B drugs, go to [epicurpharma.com](https://epicurpharma.com).

# Guidance with your Office Orders

For the drugs compounded at Stokes Pharmacy where the dating is significantly reduced, we can help! Both our direct to office team and our iFill online ordering platform will:

- Share new BUDs with you
- Provide alternative options to help guide your purchasing decisions
- Clearly differentiate our 503A compounded medications (Stokes Pharmacy) from our 503B manufactured medications (Epicur Pharma)



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## USP <797> (Sterile)

The categories listed in the revised USP <797> are 1 through 3, with category 3 preparations\* requiring stability data to support the beyond-use date (BUD) stated in USP <797>.

## Sterile Compounded Preparation BUDs by Method and Category

	Aseptically Processed			Terminally Sterilized*		
	Category 2: No sterility test	Category 2: Sterility test Required Before Shipping	Category 3*: Sterility test Required Before Shipping	Category 2: No Sterility Test	Category 2: Sterility test Required Before Shipping	Category 3*: Sterility test Required Before Shipping
<b>Controlled Room Temperature</b>	1 day	30 days minus time for testing <sup>1</sup>	60 days minus time for testing <sup>1</sup>	14 days	45 days minus time for testing <sup>1</sup>	90 days minus time for testing <sup>1</sup>
<b>Refrigerated</b>	4 days	45 days minus time for testing <sup>1</sup>	90 days minus time for testing <sup>1</sup>	28 days	60 days minus time for testing <sup>1</sup>	120 days minus time for testing <sup>1</sup>
<b>Frozen</b>	45 days	60 days minus time for testing <sup>1</sup>	120 days minus time for testing <sup>1</sup>	45 days	90 days minus time for testing <sup>1</sup>	180 days minus time for testing <sup>1</sup>

*Note: Category 1 is 12-24 hours and is not pertinent to compounding pharmacies.*

*1-Sterility testing takes a minimum of 14 days. \*Not every product can be terminally sterilized.*



# When it's time to place an order for your hospital, be assured, Stokes Pharmacy will do its best to provide alternative choices.

Following are some examples of how Stokes Pharmacy plans to handle medications affected by short dating (starting early 2024 but some as early as 11/1/23):

Stokes Drug Impacted	New Dating Per USP	Recommendation	Facility*	Dating on Recommended Drug
Acetylcysteine 2.5% Ophthalmic Solution	4 days refrigerated	Acetylcysteine 5% Ophthalmic Solution (Category 3 - Refrigerated)	Stokes	BUD of 90 days minus testing <sup>1</sup>
Cidofovir 1% Ophthalmic Solution	4 days refrigerated	Cidofovir 0.5% Ophthalmic Solution	Epicur	365 days from date manufactured
Flurbiprofen 0.03% Ophthalmic Ointment	1 day controlled room temperature	Flurbiprofen 0.04% Ophthalmic Solution	Epicur	365 days from date manufactured
Tacrolimus AQ 0.05% Ophthalmic Suspension	4 days refrigerated	Tacrolimus AQ 0.03% or 0.1% Ophthalmic Suspension	Epicur	365 days from date manufactured
Tacrolimus MCT 0.2% Ophthalmic Solution	4 days refrigerated	Tacrolimus MCT 0.3% Ophthalmic Solution or AQ 0.1% Ophthalmic Suspension	Epicur	365 days from date manufactured
Voriconazole 1% Ophthalmic Ointment	1 day controlled room temperature	Voriconazole 1% Ophthalmic Solution (Category 3 - Refrigerated)	Stokes	BUD of 90 days minus testing <sup>1</sup>
EDTA 2% Ophthalmic Ointment	1 day controlled room temperature	EDTA 2% Ophthalmic Solution or Gel (coming in 2024)	Epicur	365 days from date manufactured
EDTA 3% Ophthalmic Solution	4 days refrigerated (ships when made) or 45 days minus testing (Category 2) <sup>1</sup>	EDTA 2% Ophthalmic Solution	Epicur	365 days from date manufactured
Nalbuphine 1.2% Ophthalmic Solution	4 days refrigerated or 45 days minus testing (category 2) <sup>1</sup>	No alternative	N/A	N/A

\*Epicur Pharma drugs are manufactured in an FDA Registered 503B Facility. Stokes Pharmacy drugs are compounded in a 503A pharmacy; 1-Sterility testing takes a minimum of 14 days

When you're looking for a compounded medication, consider Epicur Pharma's manufactured medications. Both you and the pet owner will benefit from longer expiration dates and the order will ship the same business day.

**Please call us with any questions. We are here to help!**

