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Addendum to the Assignment of Beyond-Use Dates for Non-Sterile Preparations

USP <795> GENERAL GUIDELINES FOR ASSIGNING BEYOND-USE DATE LIMITS

Type of Preparation	Dosage Form Specification Examples	Beyond-Use Date	Storage Temperature
For Non-Preserved Aqueous Dosage Form	$a_w \geq 0.6$ (e.g. emulsions, gels, creams, solutions, sprays or suspensions)	14 Days	Refrigerator
For Preserved Aqueous Dosage Form	$a_w \geq 0.6$ (e.g. emulsions, gels, creams, solutions, sprays or suspensions)	35 Days	Controlled Room Temperature or Refrigerator
For Non-Aqueous Oral Liquids	A non-aqueous oral liquid is one that has an $a_w < 0.6$ (e.g. fixed oils)	90 Days	Controlled Room Temperature or Refrigerator
Other Non-Aqueous Dosage Forms	(e.g. capsules, tablets, granules, powders, non-aqueous topicals, suppositories, and troches)	180 Days	Controlled Room Temperature or Refrigerator

Note: Medisca assigns Beyond-Use Date Limits for all non-sterile preparations based on the current USP BUD guidelines *at the time of formulation*. In the event that a particular formula's BUD does not match the current USP guidelines, the above table from USP-NF 2023, Issue 1 takes precedence.*

*Medisca has chosen to execute an early adoption of the revised standards of USP-NF 2023 (to be official 11/01/2023). Please check with your local regulatory body to confirm which standards are applicable to your practice.

Medisca currently has a Formula Beyond-Use Date Databank. This databank lists several formulas that have undergone R&D stability-indicating studies to establish the evidence-based extended BUD. The suggested BUD for a specific formula is based on the **exact** execution of the indicated ingredient list, quantities and procedures listed within this formulation. In the case of a R&D Bracketed BUD study, the studied concentration range will be listed and any concentration compounded at or between these strengths may apply the suggested BUD based on the exact execution of the indicated ingredient list, procedures and quantities listed within this formulation.

For exceptional cases, certain formulations may be assigned a lower BUD than what is indicated within the USP guidelines due to specific stability information surrounding the formulation in question. In such instances, the assigned BUD within the formulation stands.

If additional information and/or clarification is required, please e-mail our Compounding Support Services Department at compounding@medisca.com or call 1-866-333-7811.

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REFERENCES

1.	USP <795>. <i>United States Pharmacopeia /National Formulary 2023</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2023.
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