MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

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

USP <797> GENERAL GUIDELINES FOR ASSIGNING BEYOND-USE DATE LIMITS

USP Chapter <797> distinguishes three categories of CSPs: Category 1, Category 2, and Category 3, primarily based on the state of environmental control under which they are compounded, the probability for microbial growth during the time they will be stored, and the time period within which they must be used.

1. Category 1 CSPs: compounded under the least controlled environmental conditions.
2. Category 2 CSPs: require more environmental controls and testing than Category 1 CSPs.
3. Category 3 CSPs: undergo sterility testing, supplemented by endotoxin testing when applicable, and have more requirements than Category 2 CSPs for personnel qualification, use of sterile garb, use of sporicidal disinfectants, frequency of environmental monitoring, and stability determination.

Table 1: Compounded Sterile Preparations – The Longest Permitted BUDs Established for Category 1 CSPs

Beyond-Use Date Limits and Storage Conditions	
Controlled Room Temperature (20°C-25°C)	Refrigerated (2°C-8°C)
≤ 12 hours	≤ 24 hours

- Category 1 CSPs may require additional testing. Refer to relevant section(s) in USP <797> for additional information to consider.

Table 2: Compounded Sterile Preparations – The Longest Permitted BUDs Established for Category 2 CSPs

Preparation Characteristics		Storage Temperature		
Compounding Method	Sterility Testing Performed and Passed	Controlled Room Temperature (20°C-25°C)	Refrigerated (2°C-8°C)	Frozen (-25°C to -10°C)
Aseptically Processed Compounded Sterile Preparations (CSPs)	NO	Prepared from one or more non-sterile starting component(s) BUD: 1 day	Prepared from one or more non-sterile starting component(s) BUD: 4 days	Prepared from one or more non-sterile starting component(s) BUD: 45 days
		Prepared from only sterile starting component(s) BUD: 4 days	Prepared from only sterile starting component(s) BUD: 10 days	Prepared from only sterile starting component(s) BUD: 45 days
	YES	30 days	45 days	60 days
Terminally Sterilized Compounded Sterile Preparations (CSPs)	NO	14 days	28 days	45 days
	YES	45 days	60 days	90 days

- Category 2 CSPs may require additional testing that includes, but is not limited to, testing for bacterial endotoxins and Antimicrobial Effectiveness Testing <51>. Refer to relevant section(s) in USP <797> for additional information to consider.

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Table 3: Compounded Sterile Preparations – The Longest Permitted BUDs Established for Category 3 CSPs

Preparation Characteristics	Storage Temperature		
Compounding Method	Controlled Room Temperature (20°C-25°C)	Refrigerated (2°C-8°C)	Frozen (-25°C to -10°C)
Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs	60 days	90 days	120 days
Terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPS	90 days	120 days	180 ys

- The BUD assigned to a Category 3 CSP **must** be supported by stability data obtained using a stability-indicating analytical method that is able to distinguish the active ingredient from its degradants and impurities (e.g., by forced degradation studies) and quantify the amount of the active ingredient.
- Category 3 CSPs may require additional testing that includes, but is not limited to, testing for bacterial endotoxins and Antimicrobial Effectiveness Testing <51>. Refer to relevant section(s) in USP <797> for additional information to consider.

Note: Medisca assigns Beyond-Use Date Limits for all 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 BUD section in the currently official version of USP-NF 2023, Issue 1 takes precedence.

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 copoundingservices@medisca.net or call 1-866-333-7811.

REFERENCES

1. USP <797>. *United States Pharmacopeia /National Formulary 2023.* Rockville, MD. US Pharmacopeial Convention, Inc. 2023.