

BEYOND USE DATING FOR STERILE COMPOUNDING

Beyond Use Date (BUD) is very different from expiration date. USP Chapter 797 defines BUD as the date or time after which a compounded sterile preparation (CSP) may not be stored or transported and is calculated from the date or time of compounding. Expiration date is a manufacturer defined term based on very specific testing used for commercially available products. A CSP cannot be labeled with the term “expiration date” or any variance thereof. It must be labeled with a different phrase such as, “do not use after” or “use before” etc.

BUDs for CSPs depend on the stability of the compound and the sterility of the compound. Stability information may be found in literature (such as *Trissel’s Stability of Compounded Formulations*) or may be determined by performing a stability test on the CSP. A point in time potency test is not equivalent to a stability test. When determining BUDs the stability or the sterility may be the limiting factor.

If stable and in the absence of sterility testing, USP 797 limits BUDs of CSPs to the following, based on risk level:

Risk Level	Controlled Room Temperature	Cold Temperature	Frozen
Immediate Use	1 hour from start of compounding	NA	NA
Low – Segregated Compounding Area	12 hours or less from compounding	NA	NA
Low	48 hours	14 days	45 days
Medium	30 hours	9 days	45 days
High	24 hours	3 days	45 days

If the BUD is extended beyond the allowances by USP Chapter 797, a sterility test that complies with USP Chapter 71 must be performed regardless of the quantity compounded. For example, if a high risk sterile eye drop is compounded and a 14 day room temperature BUD is given, enough extra of the eye drop must be compounded to send for sterility testing.

Single Dose Containers (SDC) and Multiple Dose Containers (MDC)

SDC – vial, bag, bottle, syringe	Outside ISO 5 environment – one hour from time of puncture or opening
SDC – vial , bag, bottle, syringe	Inside ISO 5 environment – up to 6 hours from time of puncture or opening
SDC – ampule	Cannot be stored, any not used must be discarded immediately
MDC	Up to 28 days from time of puncture or opening unless otherwise specified by manufacturer

Pharmacy Bulk Package (PBP)

PBP is treated the same as SDC for vials, bags, bottles and syringes in that if opened outside an ISO 5 environment, the PBP can be used for 1 hour from the time of puncture/opening and if opened inside an ISO 5 environment, the PBP can be used for up to 6 hours from the time of puncture/opening. The entire contents of a PBP can be used to compound multiple medium risk CSPs which may be stored up to 9 days refrigerated or 45 days frozen.