

Exhibit 3-41 B

Establishing Beyond Use Dates for Category 1 and 2 Compounded Sterile Preparations

Category 1 compounded sterile preparations (CSPs) may be compounded in an International Organization of Standards (ISO) Class 5 primary engineering control (PEC) in either a segregated compounding area or a buffer room.

Category 2 CSPs must be compounded in an ISO Class 5 PEC located in an ISO Class 7 buffer room.

Determining a beyond-use date (BUD) for a CSP:

- 1) Verify manufacturer information on stability and expiration.
- 2) Assign the shorter time based on the stability data, the expiration data, and the BUDs listed in Table 1.

Table 1: BUD Limits for Category 1 and 2 CSPs

	Storage Conditions		
	Controlled Room Temperature (20° - 25° C)	Refrigerator (2° - 8° C)	Freezer (-25° to -10° C)
Category 1	≤ 12 hours	≤ 24 hours	N/A
Category 2*	4 days	10 days	45 days

**Only Category 2 CSPs prepared from sterile components and not terminally sterilized are listed above. Consult USP 797 for BUDs when starting from nonsterile components or when terminally sterilizing*