

NVBOP - Beyond Use Dating for Sterile Compounded Products

BUD definition – The date beyond which the drug must not be stored

Immediate Use Compounded Sterile Products

- Intended use is for emergency or immediate patient administration of a CSP.
- May be compounded in an unclassified ISO level area.
- Compounding process involves simple transfer of no more than three commercially packages of sterile products.
- Compounding procedure is a continuous process not to exceed 1 hour.
- Administration begins not later than 1 hour following the start of the preparation of the CSP.

Low Risk Level Compounded Sterile Products

- CSP's are compounded entirely within ISO Class 5 or better air quality using only sterile ingredients. ISO Class 5 PEC is located within an ISO Class 7 or better buffer room. ISO 8 ante room is located adjacent to ISO 7 buffer room.
- Not more than three commercially products are used.
- 48 hours BUD at room temperature.
- 14 days BUD refrigerated.
- 45 days BUD frozen.

Low Risk Level Compounded Sterile Products with 12 hour or less BUD

- ISO Class 5 or better BSC or LAFW located in segregated compounding area (Non ISO classified area)
- Personnel must follow all gowning and garbing requirements.
- Administration shall commence within 12 hours of preparation.

Medium Risk Level Compounded Sterile Products

- CSP's are compounded entirely within ISO Class 5 or better air quality using only sterile ingredients. ISO Class 5 PEC is located within an ISO Class 7 or better buffer room. ISO 8 ante room in located adjacent to ISO 7 buffer room.
- Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered to multiple patients or to one patient on multiple occasions.
- 30 hours BUD at room temperature.
- 9 days BUD refrigerated.
- 45 days BUD frozen.

High Risk Level Compounded Sterile Products

- Using non-sterile products to compound CSP's.
- 24 hours BUD at room temperature.
- 3 days BUD refrigerated.
- 45 days BUD frozen.

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.