Storage and Beyond-Use Dating, Sterile Compounds

Beyond-use dating for sterile compounds, including aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants be sterile when administered to patients and must have beyond-use dates assigned within the regulations of USP General Chapter <797> based on the chemical stability and the microbial sterility of the components.

Stability is defined as the capability of a particular formulation, in a specific container to remain within its chemical stability and microbial sterility. Assurance that a CSP will be stable for the life of its BUD must be derived from valid data on the drug and its packaging, as defined by USP <797>.

Beyond-Use Dating per USP <797>

Risk Level	Controlled Room Temperature	Cold Temperature	Solid Frozen State at −25° to −10° C or Colder
Low	≤ 48 Hours	≤ 14 Days	≤ 45 Days
Medium	≤ 30 Hours	≤ 9 Days	≤ 45 Days
High	≤ 24 Hours	≤ 3 Days	≤ 45 Days

To ensure consistent practices in determining and assigning BUDs, the compounding facility should have written policies and procedures governing the determination of the BUDs for all compounded products.

Compounding personnel who assign BUDs to CSPs when lacking direct chemical assay results must critically interpret and evaluate the most appropriate available information sources to determine a conservative and safe BUD. The SOP manual of the compounding facility and each specific CSP formula record shall describe the general basis used to assign the BUD and storage conditions.

Extension of BUDs

Extension of BUD beyond USP <797> guidelines requires sufficient documentation, such as a proper stability study or stability data from peer reviewed references performed on formulations with identical APIs and excipients present in the same concentrations, pH measurement, method suitability, sterility testing (USP <71>) and endotoxin testing (USP <85>) when applicable. Consult state pharmacy statutes and regulations on extension of BUDs.

Documentation of all of the above should be recorded in the master formulation record, with specific references sited, and lots tested in accordance with internal SOPs.

Compounding pharmacists and technicians are advised to read, understand and document the yearly review of USP Chapter <797>.

Source: USP Chapter <797> Current with USP-38-NF 33