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PHARMACY PRODUCTS
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The beyond-use-date or BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their BUDs are assigned on the basis of criteria different from those applied to assigning expiration dates to manufactured drug products.

In the absence of stability information that is applicable to a specific drug and preparation, the following table presents maximum BUDs recommended for non-sterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature, unless otherwise indicated Drugs or chemicals known to be labile to decomposition will require shorter BUDs.

BUD by Type of Formulation
For Non-aqueous Formulations—The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.
For Water-Containing Oral Formulations—The BUD is not later than 14 days when stored at controlled cold temperatures.
For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations—The BUD is not later than 30 days.

These maximum BUDs are recommended for non-sterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. The BUD shall not be later than the expiration date on the container of any component.

Susceptible preparations should contain suitable antimicrobial agents to protect against bacteria, yeast, and mold contamination inadvertently introduced during or after the compounding process. When antimicrobial preservatives are contraindicated in such compounded preparations, storage of the preparation at controlled cold temperature is necessary; to ensure proper storage and handling of such compounded preparations by the patient or caregiver, appropriate patient instruction and consultation is essential. Antimicrobial preservatives should not be used as a substitute for good compounding practices.

Extension of BUDs

Extension of BUD beyond USP <795> 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. Consult state pharmacy statutes and regulations on extension of BUDs.

Documentation should be recorded on the master formulation record, with specific references sited and in accordance with internal SOPs.

Compounding pharmacists and technicians are advised to read, understand and document the yearly review of USP Chapter <795>, paying particular attention to the assignment of BUDs for each type of formulation.

Source: USP Chapter <795> Current with USP-38-NF 33

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