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The Pharmacist Guide to Assigning a Beyond Use Date to a Compounded Sterile or Nonsterile Preparation

Introduction

A beyond use date (BUD) is the date or time after which a compounded sterile preparation (CSP) or compounded nonsterile preparation (CNSP) may not be stored or transported and is calculated from the date or time of compounding. A BUD decreases risks to patients, identifying the time by which the preparation must be used before it is at risk of chemical degradation, physical degradation, or microbial contamination.[1-3] Simply stated, a BUD is the time at which a compounded preparation should not be used.[3-6]

A BUD is assigned when a product is manipulated via the compounding process. The person or organization involved in the compounding process is the party responsible for assigning the BUD,[7] which in most cases is the pharmacy staff involved in the compounding. Assigning a BUD often requires the professional judgment of the pharmacist who assesses the available scientific evidence and applies the evidence within existing regulatory requirements.[6] The purpose of this article is to guide pharmacists in choosing the most appropriate BUD for a compounded product.

In terms of understanding a BUD, it is helpful to define what a BUD is *not*:

- A BUD differs from **in use time**, which starts when a product is opened (eg, a vial is punctured) and lasts until the product is discarded.[7]

- Additionally, a BUD is different than the **infusion time** ("hang time"), which is the administration time of the drug to a patient.[7,8] The infusion time is outside the scope of the United States Pharmacopeial Convention (USP), but the Centers for Disease Control and Prevention (CDC) and Infusion Nurses Society have some guidance on infusion time.[9-11]

- Finally, a BUD is different than an **expiration date**. When preparing a compounded product or manipulating a commercial product outside of instructions in the package insert (PI), a BUD will need to be assigned. In contrast, an expiration date is established by the manufacturer and derived from the sterility, stability, and analytical chemical studies the manufacturer performs on their products within controlled conditions (eg, regulated temperatures).[1,3,5,7,12,13]

As delineated by the FDA, the expiration date may be synonymous with either non-reconstituted or reconstituted products, which often aligns with the date on the external packaging or the PI, respectively[14]:

1. The expiration date listed directly on the manufacturer-produced external packaging of the product is typically listed as a specific date (eg, March 31, 2024). This date represents the time after which the product should not be used (regardless of whether the product was opened or unopened), because the strength, quality, and purity of the shelf-life can no longer be guaranteed.[12]

2. The expiration date listed within the PI usually specifies how long after preparation the product can be used (eg, discard if not used within 24 hours after reconstitution), but is only applicable pending the instructions and conditions for preparation as outlined in the PI are precisely adhered to.

As information listed in approved PIs must conform to stringent US FDA requirements for stability and sterility testing, manufacturer information for expiration dating listed in the PI may be used assuming the directions for dosing and administration in the PI are strictly adhered to, conditions used for preparation also match requirements for sterility (as applicable), and the medication final product is not repackaged or altered from that as outlined in the PI instructions.[1,12,14,15] A key difference between an expiration date and a BUD is the consideration of the sterility component.[5] A theme throughout this resource which also applies to expiration dating: in general, the most conservative dating option should be applied. Ultimately, the pharmacist will have to exercise judgment to arrive at the most appropriate BUD assignment for a CSP or CNSP.

Regulatory Oversight

There are several regulatory organizations involved in the guidance or oversight of BUDs (**Table 1**). The most influential in regard to BUDs is the United States Pharmacopeial Convention (USP), which is a non-profit, independent, non-governmental organization that sets quality, purity, strength, and identity standards for medicines, food ingredients, and dietary supplements.[16] At the time of writing, the USP standards for non-sterile (USP Chapter <795>) and sterile (USP Chapter <797>) BUDs are undergoing revision and may change significantly with the new updated chapters. In the interim, BUD assignments should reference the currently approved chapters, which were formalized in 2008 and last updated in February 2021.[1,2] Recommendations set forth in the USP Compounding Compendia are used by other organizations as a reference for BUD assignment.

Federal regulatory bodies, including the FDA, refer to the latest USP recommendations with regard to BUD assignment. However, state board of pharmacies vary as to enforcement of BUD requirements and may be more stringent than USP standards.[4,17] Refer to your specific state board of pharmacy website via the National Association of Boards of Pharmacy for individual state requirements.[18,19]

Centers for Medicare and Medicaid Services (CMS) states, "BUD is to be based on information provided by the manufacturer, whenever such information is available."[20] Healthcare institutions should maintain policies and procedures to assign BUDs when information is not available from the manufacturer. General BUD information assignments reference that of USP Chapters <795> and <797>.

There are multiple non-governmental organizations that serve as healthcare accreditation bodies, with a few of the most common being the Joint Commission TJC), Det Norse Veritas (DNV), and Healthcare Facilities Accreditation Program (HFAP). The goal of these accrediting organizations is to set standards that ensure consistent high-quality care and patient safety. All of the aforementioned serve as CMS-deeming authorities, meaning that organizations will meet or exceed CMS standards and regulations when certified by any of these organizations, and would therefore qualify for federal reimbursement from CMS.[21]

Similar to CMS, The Joint Commission (TJC) requires storage practices and conditions to be in accordance with the original product manufacturer's instructions. If not addressed in the PI, a

pharmacist should be consulted to determine any applicable change in the product dating. Although published literature may provide alternative stability data other than that outlined by the manufacturer, tests used in such publications do not necessarily meet U.S. FDA standards and thus may not be acceptable.[13] Furthermore, JC references USP standards and state boards of pharmacy for determining BUD assignments.[22] Similarly, DNV follows USP Chapter <797> recommendations for assignment of sterile preparation of BUDs. All of the accrediting bodies discussed (i.e., JC, DNV, HFAP) are aligned with CMS regarding BUD expectations.

Overall, regulatory organizations recognize that professional judgment for BUDs may be required in specific circumstances and tend to encourage the most conservative dating possible for the sake of patient safety. See an overview of various organizations' stance on BUD below (**Table 1**).

Table 1. Regulatory or Pharmacy Organizations' Stance on Beyond Use Dates

Organization	Relevance of Organization to BUD	Stance on BUD
American Society of Health-System Pharmacists (ASHP)	• The largest pharmacy organization in the world. • A section advisory group exists to address compounding practice.	• ASHP Guidelines on Compounding Sterile Preparations references USP standards.[3]
Centers for Medicare and Medicaid Services (CMS)	• US federal agency that sets minimum standards of care (for both patients and is intended to set the bar for high quality and value. • Acts as a third-party reimbursement service for healthcare facilities that provide care to patients who qualify for Medicare or Medicaid services. • Non-compliance with CMS minimum standards would make health systems ineligible for reimbursement and therefore CMS works with other organizations to ensure compliance with minimum standards.	• "BUD is to be based on information provided by the manufacturer, whenever such information is available."[20] • General reference to USP standards.
Det Norse Veritas (DNV), healthcare sector	• Non-profit, independent, non-governmental organization that aligns with CMS standards, but may also exceed federal standards to achieve the highest safety, quality, and value standards. • Recognized as a CMS deeming authority.[a]	• Aligned with CMS.
Healthcare Facilities Accreditation Program (HFAP)	• Non-profit, independent, non-governmental organization that aligns with CMS standards, but may also exceed federal standards to achieve the highest safety, quality, and value standards. • Recognized as a CMS deeming authority.[a]	• Aligned with CMS.
National Association of Boards of Pharmacy (NABP)	• Provides a platform for contact information and web links for individual state boards of pharmacy.[18]	• State board of pharmacies vary as to enforcement of BUD requirements and may be more stringent than USP standards.[4,17,19]
Joint Commission (JC)	• Non-profit, independent, non-governmental organization that aligns with CMS standards, but may also exceed federal standards to achieve the highest safety, quality, and value standards. • Recognized as a CMS deeming authority.[a]	• Aligned with CMS. • General reference to USP standards.[17]
United States Food and Drug Administration (FDA)	• A federal regulatory body that includes medications (both prescription and over-the-counter) in its oversight.	• Provides compounding-related guidance (much of it targeted at outsourcing facilities).[17,23] • Sets expiration date expectations that drug manufacturers must comply with.[12] • Defers to USP guidance for BUD assignment.

Organization	Relevance of Organization to BUD	Stance on BUD
United States Pharmacopeial Convention (USP)	• Non-profit, independent, non-governmental organization that sets quality, purity, strength, and identity standards for medicines.[16] • The guidance within USP is recognized as the universal standard on how the sterility component contributes toward BUD assignment. • USP guidance is routinely cited by other authoritative organizations.	• Provides recommendations for BUD assignment (primarily based on the sterility component) which is intended to be used in the absence of other scientific data (eg, direct stability and sterility testing).[1,2]

BUD = beyond use date; **CMS** = Centers for Medicare and Medicaid Services; **US** = United States of America.

[a] Organizations who meet the standards of this accreditation body automatically qualify for the standards set forth by CMS for reimbursement.

Establishing an Appropriate BUD

When preparing a product in accordance with PI instructions, the storage and stability information in the PI would dictate the assigned dating as this falls outside the scope of USP.[1] According to expert opinion and many regulatory agencies (such as some state boards of pharmacy), following PI instructions does not constitute compounding.[7]

However, when a product is compounded, knowing the stability of a drug is critical to assigning an appropriate BUD.[3,4,6,7,19] Stability constitutes the "drug, diluent, container, and closure system"[7] whereas sterility, which is perhaps the most difficult-to-control variable,[4] constitutes the absence of microbial contamination.[19] Stability can be impacted by a wide variety of factors, including temperature, light, and the material of the storage container.[4] Notably, USP Chapter <797> does not address chemical stability, and therefore that must be a separate consideration for the pharmacist when assigning a BUD and is typically determined by assessing the PI and peer-reviewed literature.[1,6,19,24] The BUD is ultimately a risk assessment based on best compounding practices and available information.[5,7] Considerations of assigning a BUD are as follows:

- Batch size[19]
- Compatibility[4]
- Concentration[4]
- Environment in which the compounded product is being manipulated[7,19]
- Legal requirements[6,19]
- Microbiologic risk level[19]
- Patient safety[6]
- Stability (including chemical stability)[3,4,6,7,19]
- Starting ingredients[6,7]
- Storage temperature[6,7,19]
- Sterility[3,4,19]
- Type of manipulation (eg, aseptic addition to bag, autoclave)[7]
- USP guidance (which primarily focuses on sterility)[3,6,7,19]

The pharmacist ultimately assigns a BUD that must neither exceed those standards set forth by USP nor exceed the manufacturer expiration of any single ingredient in the compound. Pharmacists may choose to be more conservative than the PI expiration or USP BUD recommendations. Sometimes the PI indicates a more conservative expiration date compared with USP BUD recommendations, in which case it is safest to assign the most conservative dating between the PI versus USP Chapter <797>.[7] Alternatively, the PI may recommend longer dating than USP BUD recommendations. Though this latter situation is rarer, the safest action is again to default to the most conservative dating. Likewise, if conflicting information exists regarding BUD assignment among different regulatory agencies with oversight for a particular compounding pharmacy, the actual BUD assigned should be the most conservative of the collective regulatory group. It is important to maintain written policies and procedures to ensure standard, consistent BUD assignment for each product.[3,7]

Notably, the USP recommendations provide short-term dating generalizations in the absence of supporting scientific data whereas existing studies of the drug provide more specific data.[6] Current USP Chapter <797> BUD guidelines are based exclusively on considering the sterility of a product, not the chemical, physical, therapeutic, or toxicological stability of a product.[1,6,19,24] Specifically, USP Chapter

<797> varies based on low-, medium-, or high-risk compounding level and is derived from microbiological risk level associated with sterile compounding and potential physical contamination derived from environmental conditions.[1,19] If a pharmacist wishes to extend the BUD beyond the associated risk-level recommendations in USP Chapter <797>, a stability test (to affirm the container and closure system used) and a sterility test (to affirm microbial contamination is not occurring) must occur to justify a BUD that exceeds USP Chapter <797> recommendations.[7] The sterility testing should be in accordance with USP Chapter <71>.[1,6,19,24] However, even though stability and sterility testing can be outsourced, for many health systems, it is rarely, if ever performed on CSPs,[1,5,7] likely due to cost and time constraints. Hence, in the absence of stability and sterility testing, best practice would be for the pharmacist to default to the most conservative dating between the PI versus USP guidance.

In summary, some key concepts for the compounding pharmacist to consider when establishing dating assignment for medication products are as follows:

- Be familiar with pertinent state, federal, and accrediting organization standards to understand the constraints and opportunities.[4,6,7,17]
- Both the PI of the drug(s) and compounding literature should be utilized to assess known characteristics the drug(s), with stability being especially important to determining appropriate dating assignment.[3,4,6,7,19]
- USP addresses sterility, but not stability. Hence, stability information must be sought out in the PI and other compounding literature.[1,6,19,24]
- USP recommendations provide the longest BUD that can be assigned if a sterility test is not performed on *every* batch, assuming operational standards are met.[19]
- Using literature to extend a BUD is an extrapolation since exact conditions are difficult to replicate. Assumptions based on clinical judgment remain a liability.[6]
- Patient safety should always supersede convenience when assigning a BUD.[6] Assigning the most conservative dating generally minimizes risk to patients.[3,6,7,19]
- Maintain written policies and procedures to ensure standard, consistent dating assignment for each product.[3,7]

Frequently Encountered BUD Examples

Because of the broad range of possible variables when compounding, the pharmacist is faced with a multitude of often complex scenarios when assigning a BUD to a compounded product. Below are some more common examples the compounding pharmacist is likely to encounter. Pharmacists should be mindful of variables that could change outcomes based on their individual circumstances.

1. **What should the assigned BUD be for a single-dose vial?**

In general, items opened outside of a sterile environment should be used within 1 hour, with the intention of immediate use. This 1-hour BUD includes needle-punctured single-dose vials (SDV) and is commonly used for medications prepared in procedure areas or at bedside, clinic administered medications, or in emergency settings. However, if a needle-punctured SDV remains in an International Organization for Standardization (ISO) Class 5 or cleaner environment, then the BUD can be extended up to 6 hours.[1]

2. **What should the assigned BUD be for a multiple-dose vial?**

Unless the manufacturer information would lead to more conservative dating, multiple-dose vials (MDVs) can be opened and maintained for 28 days, regardless of whether the vial is opened and maintained in an ISO class 5 environment or less clean air. MDVs typically contain antimicrobial preservatives within the formulation to allow for longer dating compared with SDVs.[1,3,10]

3. **Can a closed-system transfer device be used to extend the BUD of a SDV or MDV?**

A closed-system transfer device (CSTD) is not approved by the FDA for use in extending medication dating, and thus does not accept CSTDs to extend dating as a standard of practice. Regulatory bodies generally will follow the FDA stance that CSTDs are not a sufficient means to allow for extended BUDs, despite some published literature suggesting otherwise.[13,25]

4. **What should the assigned BUD be for a compounded stock solution?**

A compounded stock solution (sometimes referred to as a "stock bag" or in USP terminology, a "pharmacy bulk package"[1]) is a sterile compound used as a base to prepare additional CSPs. The compounded stock solution must only be prepared and contained in ISO class 5 or cleaner environment. An initial BUD may be assigned to the compounded stock solution based on USP guidance and pharmacist judgment. However, once the compounded stock solution is entered or punctured to create multiple medium-risk CSPs, a 6-hour BUD then applies to the compounded stock solution, pending the manufacturer information does not dictate more conservative dating. Note that entry to the stock solution must occur prior to expiration of the initial BUD assignment to the stock solution. The CSPs created from the compounded stock solution can then be stored in accordance with USP Chapter <797> BUDs or further stability and sterility testing can be performed to extend the BUD.[1,3]

5. **What should the assigned BUD be when a sterile injectable medication derived from a single-dose vial is used as an oral nonsterile compound?**

If it is deemed appropriate to default to guidance in USP Chapter <795>, the BUD would be 14 days refrigerated for non-preserved aqueous solutions and 35 days for those that contain a preservative.[1] However, the FDA has warned that syringes used in compounding are not approved devices for medication storage, and thus will not attest to stability in such situations.[26,27] Pharmacists are advised to search for compounding literature that can be used to assess the appropriateness of a BUD assignment.

6. **If a CSP was assigned a BUD of 12 hours per USP Chapter <797>, is it acceptable to *start* the infusion within 12 hours, or must the infusion of the drug to the patient be *completed* within 12 hours?**

In order to answer this question, an understanding of the following terminology should exist:

- **BUD**: Assigned by the compounder[7] and described as the time after which a CSP should not be used.[3-6]

- **In use time**: Starts when a product is opened (eg, a vial is punctured) and lasts until the product is discarded.[7]

- **Infusion ("hang") time**: The administration time of the drug to a patient.[7,8]

Unfortunately, there is no "one-size-fits all" answer to this question. Essentially, the answer would depend on the stability and sterility of the specific drug being used. In general, a pharmacist would need to consider whether the drug's stability would be expected to last beyond the 12-hour assigned BUD throughout the duration of the infusion. If the answer to that is yes (i.e., the drug is considered stable), then the infusion ("hang") time can usually extend beyond the BUD.[8] In rare cases, a medication would not be expected to be stable for the duration of the infusion, in which case special planning for that circumstance would need to occur (eg, communication with the nurse).[28]

It is understandable how people can get confused on this question since the definition of a BUD is the time at which a compounded preparation should not be used.[3-6] To some, this definition (understandably) implies that the administration to the patient should be completed before the BUD. For example, one might challenge by stating, "If you allow a drug to be infused past the assigned BUD, then you in essence risk violation of either the sterility or stability being compromised." In all truthfulness – that is a fair assumption and why each medication must be considered on a case-by-case basis to answer this question. Both the sterility and stability should be considered, as well as the duration of the infusion time.

The generalization that will fit most circumstances is: the infusion time of most medications is of a short enough duration that if the drug is anticipated to stay stable throughout the infusion time, then the sterility of the drug is less of a concern pending best practice standards were used to compound the drug in a sterile environment. However, it may also be helpful to think of the BUD as a storage time,[28] which ends when administration of the product begins. Thinking of BUD as a *storage time* helps better differentiate the BUD definition from the *infusion time* definition.

It may also be helpful to remember that the guidance in USP Chapter <797> provides default *in use times*[29] and focuses on the *sterility* component,[1,6,19,24] which is intended to help the pharmacist choose an appropriate BUD. However, the pharmacist needs to also independently assess the *stability* of the drug (typically via PI and peer-reviewed studies), as an additional consideration when assigning the BUD. Ultimately the assigned BUD should default to the more conservative dating after an assessment of sterility and stability. The point being: the BUD is an assignment that requires *judgment* on the part of the pharmacist. Likewise, the pharmacist can use their *judgment* as to whether the drug will still be safe and effective throughout the infusion time of the drug and plan accordingly.

Another consideration to this question is that nursing personnel (and even many pharmacy staff) are often unaware of the nuances of the terminology commonly used and therefore may erroneously think that a BUD is synonymous with infusion time or expiration date, so it is recommended that pharmacists thoughtfully educate and design labels for clarity to both nursing and pharmacy colleagues. For example, some have proposed using language such as, "Do Not Hang After" on the drug label for clarity, though local state requirements may need to be considered.[28] Finally, just as it is important to maintain written policies and procedures for BUDs,[3,7] it is also important to maintain written policies and procedures for infusion times.[28] As stated earlier, the infusion time is outside the scope of USP, but the CDC and Infusion Nurses Society have some guidance on infusion time.[9-11]

7. **A pharmacist is planning to batch a frequently used antibiotic to support efficient delivery of medications throughout their hospital. The PI instructions for compounding this antibiotic will**

be followed. The hope is that the batched CSPs can be stored in the refrigerator and be used during low-staffing times. The pharmacist determines that this compound qualifies as a medium-risk CSP according to USP Chapter <797>, and therefore would like to assign a 9-day refrigerated BUD. However, the PI instructions state the antibiotic is only stable for 96 hours. The pharmacist identifies peer-reviewed literature suggesting this antibiotic is stable for longer periods of time and therefore wonders if the USP 9-day refrigerated BUD can still be justified. What is the most appropriate BUD to assign?

In many circumstances, if the PI is being followed, then the expiration date should be applied (rather than assigning a BUD). However, in this case, compounding is occurring per USP Chapter <797> standards because the pharmacist is batching, and therefore this product would be considered a medium-risk CSP.[1] The safest option is to assign the most conservative dating to minimize risk to patients.[3,6,7,19] In this case, the most conservative dating would be to align with the expiration date of 96 hours per PI, which is lesser compared with USP Chapter <797>.

The PI rarely, if ever, defines the environment for which the CSP is prepared. Therefore, the pharmacist should always be consulting both the PI and USP guidance in tandem when determining a BUD. Although not common, it is possible that pharmacists encounter a PI that is longer than USP Chapter <797> guidance. As stated previously, USP guidance is based on highly conservative predictions of microbiologic risk.[1,19]

If the pharmacist felt justified in assigning a longer BUD by extrapolating the information identified in the compounding literature, then best practice would be to pursue stability and sterility testing to objectively confirm a longer BUD assignment is appropriate. Without pursuing direct stability or sterility testing on the CSP, the pharmacist should recognize they are making assumptions which pose liability risk. Patient safety should always supersede convenience when assigning a BUD.[6]

It is also worth noting that regulations from CMS and other regulatory organizations that follow suit to CMS guidance (**Table 1**) often drive pharmacy practice in assigning beyond use dates. This presents challenges, as the Institute for Safe Medication Practices (ISMP) pointed out when they published results of a survey in 2012.[32] Such challenges include the inability to apply the latest known evidence (eg, stability assurance) toward justification for an appropriate BUD of the drug without fear of regulatory citations.

In summary, pharmacists must be judicious when assigning a BUD, which is a responsibility within the purview of the pharmacist to decide based on the available information. USP states that “appropriate literature” sources may be used,[1] but it is up to the pharmacist to determine which literature is actually appropriate.[31] Therefore, pharmacists should recognize the liability they are taking on individually and on behalf of their organization when extrapolating data.[6] Ultimately, expectations from regulatory organizations, such as boards of pharmacy and accrediting bodies (eg, TJC) also play a major role in what the pharmacist feels empowered to do.[31] Overall, pharmacists should always make patient safety the priority.

Acronyms

- BUD = beyond use date
- CMS = Centers for Medicare and Medicaid Services
- CNSP = compounded nonsterile preparation

- CSP = compounded sterile preparation
- CSTD = closed-system transfer devices
- DNV = Det Norse Veritas Healthcare, Inc.
- FDA = United States Food and Drug Administration
- HFAP = Healthcare Facilities Accreditation Program
- ISO = International Organization for Standardization
- MDV = multiple-dose vial
- PI = package insert
- SDV = single-dose vial
- TJC = The Joint Commission
- USP = United States Pharmacopeial Convention

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