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Review Article

Beyond-Use Dates of Nonsterile Pharmaceutical Preparations: A Narrative Review of Determination Methods and Knowledge

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ABSTRACT

Background: The beyond-use date (BUD) is the date after which a compounded preparation or a product removed from its primary packaging should no longer be used, however, their safe application depends on stability evidence and the knowledge of patients and health workers. This review synthesizes evidence on how the BUD of nonsterile pharmaceutical preparations is determined. **Methods**: A narrative review was conducted using Google Scholar, PubMed, and ScienceDirect for research articles published between January 2014 and December 2024. Data on analytical methods, storage conditions, observation periods, and knowledge outcomes were extracted and synthesized narratively using descriptive counts. **Results**: Twenty-four studies were included, 11 on BUD determination and 13 on knowledge. Stability was assessed using high-performance liquid chromatography in six studies (54.5%), UV–Vis spectrophotometry in four (36.4%), and an antimicrobial assay in one (9.1%). Supported stability periods ranged from 7 days (amoxicillin dry syrup, apixaban suspension, and paracetamol–tramadol capsules) to 90 days (thioguanine suspension and buprenorphine solution). In eight of the 11 studies, the reported stable period equalled the end of observation. The knowledge studies involved at least 989 participants. Among the pharmacists, 93.7% reported knowing the BUD concept, but only 13.1% correctly identified the BUD of crushed tablets. All 7 educational interventions reported improved knowledge. **Conclusion**: The BUDs of nonsterile preparations depend on the dosage form, storage temperature, and compounding, and many reported values reflect the length of observation rather than the true limit of stability. Knowledge gaps persist among both the public and health workers.

KEYWORDS

Beyond-use date, drug compounding, drug stability, nonsterile preparations, health knowledge, pharmacists

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INTRODUCTION

Nonsterile pharmaceutical preparations are drugs that do not require sterilization and can contain a certain number of microorganisms, although they must be free of pathogenic microbes. They include tablets, compounded capsules, powders (*pulveres*), ointments, suspensions, creams, pastes, and suppositories. A preparation is considered stable if, in its container and closure system, it remains within its physical, chemical, microbiological, therapeutic, and toxicological specifications from preparation until use, including storage at home or in hospital wards [1]. Stability is not determined by the active ingredient alone. A literature survey of 83 extemporaneously prepared liquid dosage forms revealed that the instability observed was caused mainly by interactions between the drug and the excipients rather than by oxidation, hydrolysis, or photolysis of the active ingredient [2].

The expiration date, printed on the label, applies to a manufactured product in its unopened primary packaging. Once the preparation is compounded or the primary packaging is opened, the limit of use is determined by the beyond-use date (BUD) [3]. The United States Pharmacopeia (USP) defines the BUD as the date, or the hour and date, after which a compounded nonsterile preparation should not be used, and the revised General Chapter <795> assigns default BUDs according to water activity and preservation: 14 days refrigerated for nonpreserved aqueous dosage forms, 35 days for preserved aqueous forms, 90 days for nonaqueous oral liquids, and 180 days for other nonaqueous forms [4]. These defaults may be extended only when supported by stability data obtained using a stability-indicating analytical method [4,5].

The application of BUDs faces two practical challenges in Indonesia. First, the compounding of *pulveres* and capsules from commercial tablets is common [6], yet BUDs are not always written on the label. An audit of 69 pediatric prescriptions revealed that all compounded preparations had a calculated BUD, but only 53.62% displayed it on the label [7]. Second, the people who must apply BUDs may not understand them. A national survey of 221 Indonesian pharmacists revealed that only 13.1% correctly identified the BUD of crushed tablets [8].

Previous Indonesian studies have examined either the stability of single preparations or the knowledge of a single population, and the two bodies of evidence have not been synthesized. Such a synthesis is needed because accurate BUDs are useful only when they are communicated and understood by the patient. This review synthesizes evidence on (1) the methods used to determine the BUD of nonsterile preparations, (2) the factors that shorten it, and (3) the level of BUD knowledge among patients, the public, and health workers.

MATERIALS AND METHODS

Research design

This was a narrative literature review study. The reporting was structured according to the Scale for the Assessment of Narrative Review Articles (SANRA), which covers the justification and aims of the review, literature search, reference, level of evidence, and presentation of endpoint data [9].

Search strategy

Articles were searched using the Publish or Perish application in Google Scholar, PubMed, and ScienceDirect. The search terms were combined as follows: “Beyond Use Date,” “Stabilization” AND “Beyond Use Date,” “Determination of Beyond Use Date,” “knowledge overview” AND “Beyond Use Date,” and “Pharmaceutical Personnel” AND “Beyond Use Date.” The publication period ranged from January 2014 to December 2024.

Eligibility criteria and study selection

Articles were included if they (1) were original research articles, including laboratory stability studies, surveys, community education reports, and prescription audits; (2) addressed nonsterile preparations; (3) reported the determination of a BUD, the consequences of exceeding it, or the level of BUD knowledge; and (4) were available in full text. Review articles, studies on sterile

preparations, and articles discussing BUDs in general without a specific focus on nonsterile preparations were excluded. Titles and abstracts were screened first, followed by full texts, and duplicate records were excluded. The included articles were published in English or Indonesian.

Data extraction and synthesis

For stability studies, the extracted data were prepared, and analytical methods, storage conditions, observation periods, and reported stable periods were used. For knowledge studies, the extracted data included the population, sample size, design, and main findings. Because the included studies differed in design, instruments, and outcome measures, meta-analysis was not appropriate. The findings were therefore synthesized narratively, grouped by dosage form and analytical method for stability studies and by population for knowledge studies, and summarized with descriptive counts, following the principles of synthesis without meta-analysis [10]. Formal critical appraisal of individual studies was not performed.

RESULTS

Characteristics of the included studies

Twenty-four studies met the inclusion criteria of this review. Eleven articles addressed BUD determination and the consequences of exceeding the BUD (**Table 1**), and 13 addressed BUD knowledge or practices (**Table 2**).

Table 1. Determination of the BUD of nonsterile preparations (n = 11)

Preparation	Method	Storage	Period	Main finding	Ref.
Thioguanine suspension (compounded)	HPLC	22 °C and 4 °C	90 days	The samples were stable at both temperatures for 90 days. Method validated	[14]
Ambroxol HCl syrup	HPLC	RT	36 days	Stable for 36 days	[3]
Cefixime *pulveres*	UV–Vis, pH, organoleptic	26 °C and 5 °C	28 days	The content was stable for 28 days. The pH changed but remained within 2.6–4.1. No change in color or odor	[16]
Amoxicillin 125 mg dry syrup	Agar well diffusion (*S. aureus*, *E. coli*)	Below 10 °C	Days 7 and 28	The inhibition zone decreased from 29 to 19 mm (*S. aureus*) and from 25 to 15.5 mm (*E. coli*). Stable only for 7 days below 10 °C	[11]
Apixaban suspension	HPLC	RT	7 days	Stable for 7 days at RT	[12]
Buprenorphine HCl solution	HPLC	≈19.8 °C and ≈2.4 °C	90 days	BUD up to 90 days	[15]
Paracetamol–tramadol capsules	HPLC	25–28 °C	14 days	BUD 7 days due to degradation. Storage at 25 °C with silica gel was most suitable	[13]

Preparation	Method	Storage	Period	Main finding	Ref.
Gabapentin cream (Lipoderm)	HPLC, spreadability	25 °C, 4 °C, and 40 °C	90 days	BUD 30 days at 25 °C	[18]
Nevirapine *pulveres*	UV–Vis, pH, organoleptic	25 °C and 4 °C	28 days	No significant change in color, odor, content, or pH	[17]
Paracetamol syrup	UV–Vis	20–25 °C and 30–40 °C	14 days	No significant decrease in content. Storage at 20–25 °C recommended	[19]
Ibuprofen *pulveres*	UV–Vis, dissolution	Not reported	4 weeks	Crushed and blended *pulveres* stable for 4 weeks ($p > 0.05$) with no change in dissolution profile or content	[6]

HPLC: high-performance liquid chromatography. UV–Vis: ultraviolet–visible spectrophotometry. RT, room temperature.

Table 2. Knowledge and practices of the community and health workers regarding BUDs (n = 13)

Population (n)	Design	Main findings	Ref.
Indonesian pharmacists (221)	Cross-sectional survey	93.7% claimed to know the BUD concept, but correct answers were 13.1% for crushed tablets, 82.8% for dry syrup, and 29.4% for ointment	[8]
Pharmacy students, Universitas Mataram, cohorts 2017–2020 (160)	Cross-sectional survey	Knowledge varied. Most knew the definitions of ED and BUD and the pharmacist's role, but knowledge of BUDs of compounded preparations was lacking	[21]
Patients filling compounded prescriptions, Kimia Farma 180 Pharmacy, Sidoarjo (171)	Descriptive survey	Most did not know the term BUD but could recognize preparations that were unfit for use. Better knowledge among women, bachelor's degree holders, and private-sector employees	[22]
Patients at Menteng subdistrict health center (110)	Descriptive survey	Most knew the definitions of BUD and ED, but not the BUDs of poultices, ointments, and dry syrups	[1]
Health workers, Udayana University Hospital: 35 doctors, 58 nurses, 2 pharmacists, 5 pharmacy technicians (100)	Descriptive survey	Knowledge mostly moderate (56–75%)	[20]
PKK mothers, Kecepit village, Banjarnegara (32)	Education, pre–post	Minimal knowledge before counseling, with significant improvement afterwards	[24]
PKK mothers, Demangan village (120 across three meetings)	Education, pre–post	Insufficient knowledge of BUDs and signs of damaged medicines. Knowledge increased by 62.8%	[25]
Elderly, mothers, and cadres, Musuk village, Boyolali (28)	Education, pre–post	Improved understanding of DAGUSIBU and BUD	[26]

Village alert cadres, Karangan, Trenggalek (22)	Education, pre–post	Most were unaware of the term BUD. Significant improvement after the session	[23]
Community around Teladan Stadium, Medan, aged 20–50 years (25)	Education, pre–post	Low understanding before education, with improvement afterwards	[27]
Patients and community, Kimia Farma 188 Pharmacy, Banjarmasin (not reported)	Education, pre–post	Significant increase, with a posttest mean of 97.7%	[28]
Outpatients, Callista Farma Clinic and Pharmacy (not reported)	Education, pre–post	Increased knowledge between pretest and posttest	[29]
Pediatric compounded prescriptions (69)	Prescription audit	BUD calculated for 100% of prescriptions, but labeled on 53.62%	[7]

BUD, beyond-use date. ED, expiration date. PKK, Family Welfare Movement (*Pemberdayaan Kesejahteraan Keluarga*). DAGUSIBU, obtain, use, store, and dispose of medicines (*Dapatkan, Gunakan, Simpan, Buang*).

Determination of the BUD of nonsterile preparations

The 11 stability studies covered six liquid preparations (two suspensions, two syrups, one dry syrup, and one solution), four solid preparations (three *pulveres* and one compounded capsule), and one cream. High-performance liquid chromatography (HPLC) was used in six studies (54.5%), UV–Vis spectrophotometry in four (36.4%), and an antimicrobial agar well diffusion assay in one (9.1%) (Table 1). The observation periods ranged from 7 to 90 days, and the storage temperatures ranged from approximately 2.4 °C to 40 °C. The supported stable periods ranged from 7 days for amoxicillin dry syrup [11], apixaban suspension [12], and paracetamol–tramadol capsules [13] to 90 days for thioguanine suspension [14] and buprenorphine solution [15]. Three *pulp* preparations (cefixime, nevirapine, and ibuprofen) remained stable for 28 days or 4 weeks [6,16,17], and gabapentin cream was assigned a BUD of 30 days at 25 °C [18]. In eight of the 11 studies, the reported stable period was the same as the end of the observation period. Only three studies reported degradation within the study period, namely, amoxicillin dry syrup [11], paracetamol–tramadol capsules [13], and gabapentin cream [18].

Knowledge of BUD among health workers, students, patients, and the public

The 13 knowledge studies included five descriptive surveys, seven community education reports with pre- and posttest evaluations, and one prescription audit (Table 2). The 10 studies that reported the number of human participants included at least 989 participants. Among 221 pharmacists, 93.7% reported knowing the BUD concept, but correct answers were given by only 13.1% for crushed tablets, 29.4% for ointments, and 82.8% for dry syrups [8]. Knowledge among hospital health workers was mostly moderate [20], and pharmacy students lacked knowledge of BUDs for compounded preparations [21]. Among patients and the public, most were unfamiliar with the term BUD or did not know the BUDs of specific dosage forms [1,22,23]. All seven education reports revealed improved knowledge after the intervention [23–29].

DISCUSSIONS

Analytical methods for BUD determination

HPLC is the most frequently used method because it separates the active ingredient from degradation products, which is the defining requirement of a stability-indicating assay [5,30]. UV–Vis spectrophotometry is simpler and less expensive, but it measures the total absorbance at a selected wavelength. If the degradation products absorb at the same wavelength, the assay may overestimate the remaining drug and, therefore, overestimate the BUD [5]. This limitation was reflected in the included studies. The HPLC method for ambroxol syrup met all the validation parameters [3], as did the HPLC assay used for paracetamol–tramadol capsules [13]. The UV–Vis method for paracetamol syrup met the validation requirements [19], whereas the UV–Vis method

for nevirapine *powder* met only some of the parameters [17]. Therefore, BUDs determined by UV–Vis spectrophotometry should be interpreted with caution unless their stability-indicating capability has been demonstrated. The antimicrobial assay provides different information. The inhibition zone of reconstituted amoxicillin against *Staphylococcus aureus* decreased from 29 mm on day 7 to 19 mm on day 28 and against *Escherichia coli* from 25 mm to 15.5 mm [11]. This approach results in a loss of biological activity but cannot quantify the drug content; therefore, it complements rather than replaces a chemical assay. Sample preparation for HPLC and UV–Vis analysis generally involved dissolving the sample in a suitable solvent followed by sonication, such as with an apixaban suspension in methanol–water (50:50 v/v) [12] and thioguanine in dimethyl sulfoxide for 10 minutes [14].

Factors that determine and shorten the BUD

Three factors explain most of the variations in BUD across studies. The first is the dosage form and water content. Liquid preparations showed the widest range, from 7 days for amoxicillin dry syrup and apixaban suspension [11,12] to 90 days for buprenorphine solution and thioguanine suspension [14,15]. This pattern is consistent with USP <795>, which assigns shorter default shelf lives to aqueous preparations because water supports hydrolysis and microbial growth [4]. The 90-day stability of thioguanine suspension exceeds the 35-day default for preserved aqueous forms; however, this is permitted by USP <795> when supported by a stability-indicating study [4,14]. The second factor is the storage temperature. Amoxicillin dry syrup remained stable only below 10 °C [11], and paracetamol syrup was recommended for storage at 20–25 °C rather than at 30–40 °C [19]. The third factor is compounding itself. Crushing tablets into *pulveres* changes the particle size and dissolution behavior [6], and combining paracetamol and tramadol in one capsule led to degradation that limited the BUD to 7 days [13].

The stability parameters also differed according to the dosage form. Physical changes include organoleptic changes in color, clarity, sediment, and odor, and chemical changes include crystal formation and changes in pH [3,12,14,19]. For powders, stability is characterized by the absence of clumping, color or odor change, and loss of drug content [6], and for creams, stability is characterized by spreadability [18]. The spreadability of gabapentin cream decreased after 28 days at 25 °C, which is consistent with the BUD of not more than 30 days for water-containing topical and semisolid preparations in the previous version of USP <795>. [18,31]. In contrast to the liquid forms, the *powders* remained stable for 28 days [16,17], well within the 180-day default for nonaqueous solid forms [4].

An important finding of this review is that eight of the 11 studies reported a stable period equal to the end of observation. In these studies, the true limit of stability was not reached, and the reported value was a lower bound than the actual BUD. This explains part of the apparent variation between studies because short observation periods produce short BUDs. This finding also indicates that some preparations may remain stable for longer than previously reported. The consequences of exceeding the BUD include changes in pH and organoleptic properties [6,13,16], physical and chemical instability of suspensions and syrups [3,12,14], and loss of drug content that may reduce therapeutic effects [3,15,19]. Microbial contamination is a further risk, particularly for aqueous preparations [4,32].

Knowledge of BUD and its determinants

Knowledge studies show a gap at every level of the medication-use chain. The difference between the proportion of pharmacists who reported knowing the concept (93.7%) and the proportion who answered correctly for crushed tablets (13.1%) suggests that self-assessment overestimates actual knowledge [8]. Because pharmacists are the main source of BUD information for patients, this gap is likely to be transmitted to the public. The prescription audit supports this interpretation because BUDs were calculated for all compounded preparations but labeled on only approximately half [7].

Evidence on the determinants of knowledge is limited. In one patient survey, respondents with a bachelor's degree and those employed in the private sector had better knowledge of BUDs, and the number of respondents with a good understanding was greater among women than among

men [22]. These associations come from a single descriptive study and were not adjusted for confounding; therefore, they should not be generalized. Education studies targeted adult groups, such as PKK mothers and *posyandu* cadres [23–26], and their consistent improvements indicate that BUD information is easily learned rather than age-determining knowledge. Educational studies should be interpreted with caution. All the studies used single-group pre- and posttest designs, with mostly small samples and immediate posttests; thus, the improvements may reflect short-term recall rather than sustained changes in storage practices [23,24,27–29]. No one measured whether participants subsequently discarded or stored medicines correctly.

Implications for practice and policy

Three implications follow. First, pharmacists should write the BUD on the label of every compounded or repackaged preparation because a BUD that is calculated but not labeled cannot guide patients. Second, continuing education for pharmacists and pharmacy technicians should address BUDs of specific dosage forms, especially crushed tablets and ointments, where knowledge is lowest. Third, pharmacist-led community education through pharmacies, *posyandu*, and the GERMAS program can improve public understanding, but its effect on storage behavior should be evaluated.

Limitations

This review has several limitations. The literature search was not systematic, the search date and screening procedure were not fully documented, and no formal critical appraisal was performed; therefore, selection bias cannot be excluded. Most of the included studies were Indonesian and published in national journals or proceedings, which limits international generalizability. The stability studies used heterogeneous methods and short observation periods, and several did not report full method validation. The knowledge studies used different instruments and categories, which prevented quantitative pooling.

CONCLUSIONS

BUDs of nonsterile preparations were most often determined with HPLC, and the supported stable periods ranged from 7 to 90 days, depending on the dosage form, storage temperature, and compounding. Because most studies ended before the preparations degraded, many reported BUDs are conservative lower bounds. Knowledge of BUDs, including pharmacists, remains limited among public and health workers, and BUDs are not consistently labeled. Future research should use validated stability-indicating methods with observation periods long enough to reach the limit of stability and evaluate whether education changes medical storage practices. In practice, routine BUD labeling and pharmacist-led education are recommended.

CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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AUTHOR CONTRIBUTIONS

Conceptualization: All; Introduction: FH; Methodology: NKAP, NPP; Article search: MMP, LPAM, NPMA, NMSGS; Review analysis: IKGK, IMGAK, NKAM; Discussion: IGRWB, RPBN; Abstract and conclusion: DPCN; Editing: KTS, NKASP, IMGAK; Visualization: IMGAK; Supervision: NKW.

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DECLARATION OF ARTIFICIAL INTELLIGENCE USE

In this study, artificial intelligence (AI) tools were used for the following tasks. Manuscript writing support: An AI-based language model (Claude, Anthropic) was employed for language refinement and technical writing assistance during the revision. We confirm that all AI-assisted processes were critically reviewed by the authors to ensure the integrity and reliability of our results. The final decisions and interpretations presented in this article were made solely by the authors.

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