

Expiry Dates (Beyond Use Dates) – Australia

Expiry Dates (Beyond-Use Dates) Non-Sterile

The below are the default expiry dates that must be used unless the pharmacist can document evidence of a suitable expiry date based on reputable guidance such as a formulation from the Australian Pharmaceutical Formulary and Handbook or USP <795>.

BUD Extension:

- BUD may be extended if the compounder has:
 - A reliable stability-indicating study that uses a valid method
 - The study is for the same formulation and strengths or is bracketed
 - A stability-indicating study is published in a reputable reference should be used if available
 - Extended stability studies must also demonstrate minimal microbial growth and meet antimicrobial effectiveness test requirements for BP or USP-NF
 - The BUD may not be extended beyond 180 days

Type of Preparation	Storage Temperature	Max Expiry Date	Notes
Preservative-Free Aqueous Dosage Form (oral, topical etc.)	Below 25°C	7 days	Package in such a way to minimize microbial contamination, especially for multi-dose preparations
	Refrigerated (2-8°C)	14 days	
Preserved Aqueous Dosage Form (oral, topical etc.)	Refrigerated (2-8°C) or room temperature (below 25°C)	28 days	Guideline notes that suspensions and emulsions are difficult to preserve, preservative status should be based on reputable evidence such as AET*
Non-Aqueous Oral Liquids	Refrigerated (2-8°C) or room temperature (below 25°C)	90 days	
All Other Non-Aqueous Dosage Forms (capsules, troches, suppositories etc.)	Refrigerated (2-8°C) or room temperature (below 25°C)	180 days	Risk assessment should address physical and chemical stability

*AET: Antimicrobial Effectiveness Testing per BP or USP-NF

Expiry dates for sterile medications (including injectables) that have NOT passed sterility testing (does not apply to ophthalmic preparations)

Sterilization Method	Starting Materials	Storage Temp and BUD
Aseptic Processing or Sterile Filtration	One or more non-sterile starting ingredients (and sterile filtration)	<ul style="list-style-type: none"> • 1 day or less, stored below 25 °C • 4 days or less, stored at 2–8 °C • 45 days or less, stored frozen (below –18 °C)

	All sterile starting ingredients (filtration preferred but not required)	<ul style="list-style-type: none"> • 4 days or less, stored below 25 °C • 10 days or less, stored at 2–8 °C • 45 days or less, stored frozen (below –18 °C)*
Terminal Sterilization	Sterile or non-sterile starting ingredients	<ul style="list-style-type: none"> • 14 days or less, stored below 25 °C • 28 days or less, stored at 2–8 °C • 45 days or less, stored frozen (below –18 °C)*

- The expiry date of injectables that have not passed sterility testing should be 24 hours or less from the time of compounding if quality standards are not met
- Preservative-free injectables must be supplied in single-dose containers and used immediately after opening
- Preservative-free topical sterile products (ophthalmic preparations, bladder irrigations, preparations for inhalation etc.) may receive up to 24 hours at room temperature (25°C or less) or up to 72 hours at refrigerated (2-8°C) temperatures.
- Preserved injectable medications may receive up to 28 days after first opening (or up to expiry date, whichever is earlier) with adequate testing such as antimicrobial effectiveness testing per USP <51> or BP
- Guidelines do not specifically discuss endotoxin testing

Expiry dates for topical sterile preparations (ophthalmic preparations)

Aqueous or Non-Aqueous	Preservative-Status	Sterilization Technique	Storage and Expiry	Multiple-Dose?
Aqueous	Preservative Free (aqueous)	Aseptic Processing	<ul style="list-style-type: none"> • 4 days or less, stored below 25 °C • 10 days or less, stored at 2–8 °C • 45 days or less, stored frozen (below –18 °C)* 	Up to 24 hours below 25C Up to 72 hours refrigerated
		Terminal Sterilization	<ul style="list-style-type: none"> • 14 days or less, stored below 25 °C • 28 days or less, stored at 2–8 °C • 45 days or less, stored frozen (below –18 °C)* 	Up to 24 hours below 25C Up to 72 hours refrigerated
	Preserved (aqueous)	Aseptic Processing or Terminal Sterilization	<ul style="list-style-type: none"> • 28 days or less stored below 25 °C or at 2–8 °C, as determined by risk assessment 	28 days or less after opening

			<ul style="list-style-type: none"> 45 days or less, stored frozen (below $-18\text{ }^{\circ}\text{C}$)* 	
Non-Aqueous	Preserved or Preservative-Free	Aseptic Processing or Terminal Sterilization	<ul style="list-style-type: none"> 28 days or less stored below $25\text{ }^{\circ}\text{C}$ or at $2\text{--}8\text{ }^{\circ}\text{C}$, as determined by risk assessment 	28 days or less after opening