

Navigating APF26 non-sterile bases requirements

Water activity (a_w) defines the amount of free, unbound, or available water in a formulation. Different from water content, water activity is the available water to support microbial growth or hydrolytic reactions. As per current APF26, non-aqueous (or anhydrous) preparations are defined as having $a_w < 0.6$.

Water activity of Medisca non-aqueous (anhydrous) bases ($a_w < 0.6$)

Category	Product name	Water activity	Preserved or unpreserved	APF26 expiry date*	Databank
Topical - gels	CopaSil®	0.559	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
	Lipmax™, lecithin and isopropyl palmitate	0.237	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
	VersaPro™ anhydrous base	0.208	N/A	180 days or less when store below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
Topical - ointments	AlpaWash®	0.155	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
	OleaBase™ Plasticized	0.173	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
	Ointment base, emulsifying	0.578	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
Oral bases	CapsuBlend®-H	0.282	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
	CapsuBlend®-P	0.302	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
	CapsuBlend®-S	0.293	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
	Medi-RDT™ base	0.323	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180

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Category	Product name	Water activity	Preserved or unpreserved	APF26 expiry date*	Databank
Oral bases (cont.)	Oral Mix Dry Alka, SF, cherry flavored (powder) When reconstituted with water, a_w would be above 0.6.	0.289	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
	Oral Mix Dry Alka, SF, unflavored (powder) When reconstituted with water, a_w would be above 0.6.	0.272	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
	Troche base	0.273	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
	Troche base, NS	0.351	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
Oral Transmucosal Films (OTF)	Compounded blank NovaFilm™ OTF, air dried	0.287	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
	Compounded blank NovaFilm™ OTF, oven dried	0.344	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
	Compounded sildenafil 22 mg NovaFilm™ OTF, oven dried	0.449	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
Suppositories	Polypeg suppository base	0.179	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
	SPG Supposi-Base™	0.499	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180
	SPG™ natural supposi-base	0.222	N/A	180 days or less when stored below 25°C per APF26 (in the absence of stability information)	No studies as a_w is less than 0.6 so BUD is automatically 180

Note: Water activity (a_w) results are based on testing of the blank base, unless otherwise specified. The addition of water-containing or other components during compounding may alter the water activity of the final compounded preparation.

* The non-sterile expiry dates outlined in this table may be assigned in the absence of stability information as per current APF26. The expiry date must not be later than the expiry of any ingredient used in the compounded preparation. Maximum default expiry in the absence of stability indicating study.

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Water activity of Medisca aqueous bases ($a_w \geq 0.6$)

Category	Product name	Water activity	Preserved or unpreserved	APF26 expiry date*	Link to databank
Topical - creams & lotions	HRT cream base	1.009	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	BUD library Stability studies Medisca
	VersaPro™ cream base	0.99	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	BUD library Stability studies Medisca
	VersaPro™ lotion base	1.002	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—
	Lipo cream Base	1.004	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—
	PenDerm™ cream base	0.962	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—
	PLO transdermal cream	0.989	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—
	Transdermal pain base	1	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—
Topical - gels	HRT gel base	0.998	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—
	Hydrogel	1.009	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—
	PLO Gel MediFlo™ 30 pre-mixed	1	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	BUD library Stability studies Medisca
	Pluronic gel, 30%, F127	0.997	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—
	NovaFilm™ gel base	1	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—
VersaPro™ gel base	1.012	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	BUD library Stability studies Medisca	
Topical - hair care	Foamil®	0.967	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	BUD library Stability studies Medisca
	VersaPro™ foam	0.978	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—
	VersaPro™ shampoo	0.951	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—

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Category	Product name	Water activity	Preserved or unpreserved	APF26 expiry date*	Link to databank
Oral vehicles	Methylcellulose gel, 1%	1.007	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—
	Oral Mix flavored suspending vehicle	0.994	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	BUD library Stability studies Medisca
	Oral Mix, SF, sugar-free flavored suspending vehicle	0.993	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	BUD library Stability studies Medisca
	Oral suspend	0.99	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—
	Oral syrup	0.914	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—
	Oral syrup, SF	0.979	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—
	Simple syrup, NF	0.874	Preserved	28 days or less when stored below 25°C per APF26 (in the absence of stability information)	—

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Recommended resources

Sansom, L N, Australian Pharmaceutical Formulary and Handbook, 26th Ed., Canberra: Pharmaceutical Society of Australia; 2024.

[BUD library | Stability studies | Medisca](#)

For more information
1300 786 392 [medisca.com.au](https://www.medisca.com.au)

