

## Certificate of Analysis

**Productname:** Lanæ alcoholum unguentum/Wollwachsalkoholsalbe DAB  
**Inspection No:** H08990/1020/536 **Sample Unit:** 0 x 50 g  
**Batchnumber:** 20C23-T26-081552 **Batch Size:** 5 x 5 kg  
**Expiration date:** 28.02.2022  
**Analysed according to:** DAB 2008, FAPL 027  
**Original Manuf. Date:** 28.2.2020  
**Identification of producer:** V00230  
**Batch no. of vendor:** 1331322

	Requirement	Result	Unit	Standard remark	Insp. Site
<b>CHARACTERS</b>					
Appearance	Transparent, white, yellowish to light yellow soft ointment.	Conform			Fagron CZ
Odour (2.3.4)	Slight odour	Conform			Fagron CZ
<b>IDENTIFICATION</b>					
Cholesterol	Conform	Conform			Fagron CZ
<b>TESTS</b>					
Appearance after melting	Conform	Conform		FAPL 027	Fagron CZ
Freezing point	38,0 - 56,0	52,0	°C		Fagron CZ
Loss on drying (2.2.32)	<=0,5	0,1	%	DAB 2008	Fagron CZ
Loss on drying (2.2.32)	<=5,0	0,1	%	105 °C FAPL 027	Fagron CZ
Water-absorption ability	>=20	100	ml	DAB 2008	Fagron CZ
Water-absorbition ability	>=30	100	g	FAPL 027	Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	Conform	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

**Performed by:** Lucie Kubáňová DiS.

**Responsible:** Ing. Mgr. Kateřina Jokešová, QC  
PharmDr. Ivana Urbánková, QA

**Date:** 14.10.2020

**Conclusion:** APPROVED

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