

Certificate of Analysis

Productname: Lanae alcoholum unguentum/Wollwachsalkoholsalbe DAB

Inspection No: H09258/1020/536
Batchnumber: 20C23-T26-081551
Expiration date: 28.02.2022
Analysed according to: DAB 2008, FAPL 027
Original Manuf. Date: 28.2.2020

Sample Unit: 0 x 50 g
Batch Size: 200 x 1 kg

Identification of producer: V00230
Batch no. of vendor: 1331322

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Transparent, white, yellowish to light yellow soft ointment.	Conform			Fagron CZ
Odour (2.3.4)	Slight odour	Conform			Fagron CZ
IDENTIFICATION					
Cholesterol	Conform	Conform			Fagron CZ
TESTS					
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 ³	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	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: 26.10.2020

Conclusion: APPROVED

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