Fagron personalizing medicine

Certificate of Analysis

Productname: **Lanae alcoholum unguentum/Wollwachsalkoholsalbe DAB**

Inspection No: I08697/1121/536
Batchnumber: **21I23-T01-090738**
Expiration date: 30.09.2023
Analysed according to: DAB 2008, FAPL 027
Original Manuf. Date: 21.9.2021

Sample Unit: 0 x 50 g
Batch Size: 137 x 1 kg

Identification of producer: V00230
Batch no. of vendor: 1421072

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Transparent, white, yellowish to light yellow soft ointment.	Conform			Data Producer
Odour (2.3.4)	Slight odour	Conforrm			Fagron CZ
IDENTIFICATION					
Cholesterol	Conform	Conform			Fagron CZ
TESTS					
Appearance after melting	Conform	Conform		FAPL 027	Fagron CZ
Freezing point	38,0 - 56,0	51	°C		Fagron CZ
Loss on drying (2.2.32)	<=0,5	0,04	%	DAB 2008	Fagron CZ
Loss on drying (2.2.32)	<=5,0	0,04	%	105 °C FAPL 027	Fagron CZ
Water-absorption ability	>=20	80	ml	DAB 2008	Fagron CZ
Water-absorbtion ability	>=30	80	g	FAPL 027	Fagron CZ
Microbiology	Conform	Conform			Fagron CZ
TAMC	<=2 x 103	<10	CFU/g		Contract Lab
TYMC	<=2 x 102	<10	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

The product conforms to DAB 2008, FAPL 027.

Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 10.11.2021

Conclusion: **I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.**

This document has been produced electronically from our quality system and is valid without signature.

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