



Certificate of Analysis

Productname: Adeps lanae

Inspection No: I07945/1121/536

Batchnumber: 21103-T09-090739

Expiration date: 31.07.2023

Analysed according to: ČL 2017-Dopl.2020, Ph.Eur. 10.0

Original Manuf. Date: 31.7.2021

Sample Unit: 0 x 50 g

Batch Size: 10 x 1 kg

Identification of producer: V00328

Batch no. of vendor: L05006/2

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Yellow, unctuous substance. When melted, it is a clear or almost clear, yellow liquid. A solution in light petroleum is opalescent.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	Green	Conform			Fagron CZ
Identification B	Red / strong green fluorescence	Conform			Fagron CZ
TESTS					
Water-soluble acid or alk. substances	Conform	Conform			Fagron CZ
Water-absorption capacity	>= 20	35	ml		Fagron CZ
Acid value	<=1,0	0,64			Fagron CZ
Peroxide value	<=20	3,3			Fagron CZ
Saponification value	90 - 105	98			Fagron CZ
Water-soluble oxidisable substances	Conform	Conform			Fagron CZ
Paraffins	<=1,0	0,35	%		Fagron CZ
Pesticide residues	Conform	Conform			Contract Lab
Chlorides	<=150	<150	µg/g		Fagron CZ
Loss on drying	<=0,5	0,1	%	105 °C	Fagron CZ
Sulfated ash	<=0,15	0,0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<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
Drop point	38 - 44	43	°C		Fagron CZ

BHT 146,370 µg/g

Name	Fagron a.s. (CZ)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521

The product conforms to ČL 2017-Dopl.2020,Ph.Eur.10.0.

Performed by: Lucie Kubáňová DiS.

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

Date: 24.11.2021

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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