



Certificate of Analysis

Productname: Adeps lanae

Inspection No: J10399/1222/536

Batchnumber: 100879

Expiration date: 30.09.2024

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

Customer: FAGRON a.s.

Sample Unit: 4 x 25 g

Batch Size: 500 x 25 g

Batch no. of vendor: L05308/2

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Yellow, unctuous substance. When melted, it is a clear or almost clear, yellow liquid. A solution in light petroleum is opalescent.	Conform		
Solubility	Conform	Conform		
IDENTIFICATION				
Identification A	Conform	Conform		green
Identification B	Conform	Conform		Red / strong green fluorescence
TESTS				
Water-soluble acid or alk. substances	Conform	Conform		
Water-absorption capacity	>= 20	35	ml	
Acid value	<=1,0	0,73		
Peroxide value	<=20	6,1		
Saponification value	90 - 105	103		
Water-soluble oxidisable substances	Conform	Conform		
Paraffins	<= 1,0	0,05	%	
Pesticide residues	Conform	Conform		
Chlorides	<=150	<150	ppm	
Loss on drying	<=0,5	0,02	%	105 °C
Sulfated ash	<=0,15	0,039	%	
Microbiology	Conform	Conform		
TAMC	<=2 x 10 ³	<10	CFU/g	
TYMC	<=2 x 10 ²	<10	CFU/g	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Metallic residues	ICH Q3D	Conform		
Drop point	38 - 44	44	°C	
Butylhydroxytoluene	calculated value	157,810	ppm	

Quality: Excipient

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Performed by: Pavla Šlézarová
Responsible: Mgr. Zdeňka Šinclová, QC
Mgr. Barbora Agatha Halouzková, QP
Date: 08.12.2022

Conclusion: **APPROVED**

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