Fagron personalizing medicine

Certificate of Analysis

Productname: **Adeps lanae**

Inspection No: J11031/0123/536
Batchnumber: **22J10-T02-101536**
Expiration date: 30.09.2024
Analysed according to: ČL 2017-Dopl.2020,Ph.Eur.10.0
Original Manuf. Date: 30.9.2022

Sample Unit: 1 x 5 g
Batch Size: 122 x 1 kg

Identification of producer: V00328
Batch no. of vendor: L05308/2

	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	Conform	Conform		green	Fagron CZ
Identification B	Conform	Conform		Red / strong green fluorescence	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	0,73			Fagron CZ
Peroxide value	<=20	6,1			Fagron CZ
Saponification value	90 - 105	103			Fagron CZ
Water-soluble oxidisable substances	Conform	Conform			Fagron CZ
Paraffins	<= 1,0	0,05	%		Fagron CZ
Pesticide residues	Conform	Conform			Contract Lab
Chlorides	<=150	<150	ppm		Fagron CZ
Loss on drying	<=0,5	0,02	%	105 °C	Fagron CZ
Sulfated ash	<=0,15	0,039	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
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	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer
Drop point	38 - 44	44	°C		Fagron CZ
Butylhydroxytoluene	calculated value	157,810	ppm		Data Producer

Quality: Excipient

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

Performed by:	Pavla Šlézarová
Responsible:	Mgr. Zdeňka Šinclová, QC MVDr. Zdenka Borská, QP
Date:	13.01.2023
Conclusion:	**APPROVED**

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

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