

Certificate of Analysis

Productname: Olivae oleum virginale

Inspection No: L02309/0524/536
Batchnumber: 23I29-T07-110771
Expiration date: 31.03.2025
Analysed according to: ČL 2017-Dopl.2018,Ph.Eur.11.0

Customer: FAGRON a.s.
Sample Unit: 1 x 200 ml
Batch Size: 30 x 1 l

Batch no. of vendor: 164284

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Clear,transparent, yellow or greenish-yellow liquid.	Conform		
Solubility	Conform	Conform		
Relative density	About 0,913	0,914		
IDENTIFICATION				
Identification B	Conform	Conform		Composition of fatty acids
TESTS				
Absorbance (270 nm)	<=0,20	0,19		
Absorbance (232 nm : 270 nm)	>8	13		
Acid value	<=2,0	1,2		
Peroxide value	<=20,0	14,2		
Unsaponifiable matter	<=1,5	0,95	%	
Composition of fatty acids	Conform	Conform		GC
Saturated fatty acids < C16	<=0,1	<0,05	%	
Palmitic acid	7,5 - 20,0	13,0	%	
Palmitoleic acid	<=3,5	1,0	%	
Stearic acid	0,5 - 5,0	3,2	%	
Oleic acid and isomer	56,0 - 85,0	70,8	%	
Linoleic acid	3,5 - 20,0	8,9	%	
Linolenic acid	<=1,2	0,7	%	
Arachidic acid	<=0,7	0,4	%	
Eicosenoic acid	<=0,4	0,2	%	
Behenic acid	<=0,2	0,1	%	
Lignoceric acid	<=0,2	0,1	%	
Sterols				
cholesterol	<=0,5	0,1	%	
campesterol	<=4,0	1,8	%	
delta 7-stigmasterol	<=0,5	<0,05	%	
sum of contents of sterols	>=93,0	96,7	%	
stigmasterol <= campesterol	Conform	Conform		
Sesame oil	Conform	Conform		
Water	<=0,1	0,05	%	
Microbiology				
TAMC	<=2 x 10 ³	<10	CFU/g	
TYMC	<=2 x 10 ²	<10	CFU/g	

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

TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform
Residual solvents	CPMP/ICH/82 260/2006	Conform
Metallic residues	ICH Q3D on elemental impurities	Conform

Quality: Excipient

Performed by: QC Fagron a.s. (CZ)

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QA/ QP

Date: 18.04.2024

Conclusion: **APPROVED**

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

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