



Certificate of Analysis

Productname: Olivae oleum virginale

Inspection No: K02364/0523/536

Batchnumber: 23C15-T03-102629

Expiration date: 30.09.2024

Analysed according to: ČL 2017-Dopl.2018, Ph.Eur. 11.0

Original Manuf. Date: 28.2.2023

Sample Unit: 1 x 100 ml

Batch Size: 243 x 1 l

Identification of producer: V00225

Batch no. of vendor: 162894

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, transparent, yellow or greenish-yellow liquid.	Conform			Contract Lab
Solubility	Conform	Conform			Contract Lab
Relative density	About 0,913	0,914			Contract Lab
IDENTIFICATION					
Identification B	Conform	Conform		Composition of fatty acids	Contract Lab
TESTS					
Absorbance (270 nm)	<=0,20	0,10			Contract Lab
Absorbance (232 nm : 270 nm)	>8	20			Contract Lab
Acid value	<=2,0	0,6			Contract Lab
Peroxide value	<=20,0	4,9			Contract Lab
Unsaponifiable matter	<=1,5	0,9	%		Contract Lab
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Saturated fatty acids < C16	<=0,1	<0,05	%		Contract Lab
Palmitic acid	7,5 - 20,0	12,1	%		Contract Lab
Palmitoleic acid	<=3,5	0,9	%		Contract Lab
Stearic acid	0,5 - 5,0	3,2	%		Contract Lab
Oleic acid and isomer	56,0 - 85,0	74,1	%		Contract Lab
Linoleic acid	3,5 - 20,0	8,0	%		Contract Lab
Linolenic acid	<=1,2	0,7	%		Contract Lab
Arachidic acid	<=0,7	0,4	%		Contract Lab
Eicosenoic acid	<=0,4	0,2	%		Contract Lab
Behenic acid	<=0,2	0,1	%		Contract Lab
Lignoceric acid	<=0,2	0,1	%		Contract Lab
Sterols	Conform	Conform			Contract Lab
cholesterol	<=0,5	0,3	%		Contract Lab
campesterol	<=4,0	2,2	%		Contract Lab
delta 7-stigmasterol	<=0,5	0,3	%		Contract Lab
sum of contents of sterols	>=93,0	93,8	%		Contract Lab
stigmasterol <= campesterol	Conform	Conform			Contract Lab
Sesame oil	Conform	Conform			Contract Lab
Water	<=0,1	0,048	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 103	<10	CFU/g		Contract Lab

Name Fagron a.s. (CZ)

Kontrolní laboratoř č. 536

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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

Quality: Excipient

Performed by: Ekocentrum

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

Date: 24.05.2023

Conclusion: **APPROVED**

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