



Certificate of Analysis

Productname: Olivae oleum virginale

Inspection No: J02360/0422/536

Batchnumber: 22B18-T05-093711

Expiration date: 31.08.2023

Analysed according to: ČL 2017,Dopl.2018,Ph.Eur.10.0

Original Manuf. Date: 31.1.2022

Sample Unit: 1 x 100 ml

Batch Size: 408 x 1 l

Identification of producer: V00079

Batch no. of vendor: 159464

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear,transparent, yellow or greenish-yellow liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Relative density	About 0,913	0,914			Fagron CZ
IDENTIFICATION					
Identification B	Conform	Conform		Composition of fatty acids	Contract Lab
TESTS					
Absorbance (270 nm)	<=0,20	0,16			Fagron CZ
Absorbance (232 nm : 270 nm)	>8	10			Fagron CZ
Acid value	<=2,0	0,33			Fagron CZ
Peroxide value	<=20,0	6,17			Fagron CZ
Unsaponifiable matter	<=1,5	0,68	%		Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Saturated fatty acids < C16	<=0,1	<0,1	%		Contract Lab
Palmitic acid	7,5 - 20,0	11,3	%		Contract Lab
Palmitoleic acid	<=3,5	0,8	%		Contract Lab
Stearic acid	0,5 - 5,0	3,5	%		Contract Lab
Oleic acid and isomer	56,0 - 85,0	77,1	%		Contract Lab
Linoleic acid	3,5 - 20,0	5,9	%		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	<0,2	%		Contract Lab
Sterols	Conform	Conform			Contract Lab
cholesterol	<=0,5	<0,1	%		Contract Lab
campesterol	<=4,0	2,6	%		Contract Lab
delta 7-stigmasterol	<=0,5	0,4	%		Contract Lab
sum of contents of sterols	>=93,0	96,5	%		Contract Lab
stigmasterol <= campesterol	Conform	Conform			Contract Lab
Sesame oil	Conform	Conform			Fagron CZ
Water	<=0,1	0,06	%		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: Ludmila Stochlebová

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA

Date: 22.04.2022

Conclusion: **APPROVED**

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