



Certificate of Analysis

Productname: Lini oleum virginale

Inspection No: L02148/0324/536

Batchnumber: 24A31-T02-109659

Expiration date: 30.04.2025

Analysed according to: ČL 2023, Ph. Eur. 11.0

Original Manuf. Date: 31.10.2023

Sample Unit: 1 x 10 ml

Batch Size: 23 x 1 l

Identification of producer: V00225

Batch no. of vendor: 164903

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear,(brownish) yellow liquid, on exposure to air turning dark and gradually thickening.When cooled, it becomes a soft mass at about -20°C.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Relative density	About 0,931	0,930			Fagron CZ
Refractive index	About 1,480	1,481			Fagron CZ
IDENTIFICATION					
Identification B	160 - 200	179		Iodine value	Fagron CZ
Identification C	Conform	Conform		Composition of fatty acids, GC	Contract Lab
TESTS					
Acid value	<=4,5	1,2			Fagron CZ
Iodine value	160 - 200	179			Fagron CZ
Peroxide value	<=15,0	2,90			Fagron CZ
Saponification value	188 - 195	190			Fagron CZ
Unsaponifiable matter	<=1,5	0,86	%		Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Fatty ac. with a chain length <C16	<=1,0	<0,05	%		Contract Lab
Palmitic acid	3,0 - 8,0	5,5	%		Contract Lab
Palmitoleic acid	<=1,0	0,1	%		Contract Lab
Stearic acid	2,0 - 8,0	4,1	%		Contract Lab
Oleic acid	11,0 - 35,0	18,2	%		Contract Lab
Linoleic acid	11,0 - 24,0	15,4	%		Contract Lab
Linolenic acid	35,0 - 65,0	56,3	%		Contract Lab
Arachidic acid	<=1,0	0,1	%		Contract Lab
Cadmium	<=0,5	<0,02	ppm		Contract Lab
Water	<=0,1	0,08	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<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

Quality: Excipient

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

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

Responsible: Mgr. Barbora Vránová, QC
MVDr. Zdenka Borská, QA/ QP

Date: 15.04.2024

Conclusion: **APPROVED**

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