



## Certificate of Analysis

**Productname:** Lini oleum virginale

**Inspection No:** K05482/0923/536

**Sample Unit:** 1 x 10 ml

**Batchnumber:** 23C15-T04-105624

**Batch Size:** 2 x 1 l

**Expiration date:** 30.09.2024

**Analysed according to:** ČL 2017, Ph.Eur.11.0

**Original Manuf. Date:** 6.3.2023

**Identification of producer:** V00225

**Batch no. of vendor:** 163048

	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			Contract Lab
Solubility	Conform	Conform			Contract Lab
Relative density	About 0,931	0,930			Contract Lab
Refractive index	About 1,480	1,481			Contract Lab
IDENTIFICATION					
Identification B	160 - 200	183		Iodine value	Contract Lab
Identification C	Conform	Conform		Composition of fatty acids, GC	Contract Lab
TESTS					
Acid value	<=4,5	1,1			Contract Lab
Iodine value	160 - 200	183			Contract Lab
Peroxide value	<=15,0	1,2			Contract Lab
Saponification value	188 - 195	190			Contract Lab
Unsaponifiable matter	<=1,5	0,8	%		Contract Lab
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	5,3	%		Contract Lab
Palmitoleic acid	<=1,0	0,1	%		Contract Lab
Stearic acid	2,0 - 8,0	4,3	%		Contract Lab
Oleic acid	11,0 - 35,0	19,0	%		Contract Lab
Linoleic acid	11,0 - 24,0	13,8	%		Contract Lab
Linolenic acid	35,0 - 65,0	56,5	%		Contract Lab
Arachidic acid	<=1,0	0,3	%		Contract Lab
Cadmium	<=0,5	<0,01	ppm		Contract Lab
Water	<=0,1	0,032	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<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

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

**Performed by:** Ekocentrum

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

**Date:** 20.09.2023

**Conclusion:** **APPROVED**

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