



Certificate of Analysis

Productname: Lini oleum virginale

Inspection No: J11990/0323/536
Batchnumber: 22I29-T08-101015
Expiration date: 31.03.2024
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 30.9.2022

Sample Unit: 1 x 10 ml
Batch Size: 34 x 1 l

Identification of producer: V00225
Batch no. of vendor: 161583

	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	0,921			Contract Lab
Refractive index	About 1,480	1,479			Contract Lab
IDENTIFICATION					
Identification B	160 - 200	167		Iodine value	Contract Lab
Identification C	Conform	Conform		Composition of fatty acids, GC	Contract Lab
TESTS					
Acid value	<=4,5	2,4			Contract Lab
Iodine value	160 - 200	167			Contract Lab
Peroxide value	<=15,0	1,2			Contract Lab
Saponification value	188 - 195	191			Contract Lab
Unsaponifiable matter	<=1,5	0,7	%		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	5,5	%		Contract Lab
Palmitoleic acid	<=1,0	0,1	%		Contract Lab
Stearic acid	2,0 - 8,0	5,1	%		Contract Lab
Oleic acid	11,0 - 35,0	20,8	%		Contract Lab
Linoleic acid	11,0 - 24,0	15,6	%		Contract Lab
Linolenic acid	35,0 - 65,0	52,9	%		Contract Lab
Arachidic acid	<=1,0	<0,05	%		Contract Lab
Cadmium	<=0,5	0,01	ppm		Contract Lab
Water	<=0,1	0,050	%		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: Ekocentrum

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QP

Date: 30.01.2023

Conclusion: **APPROVED**

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