

Certificate of Analysis

Productname: Lini oleum virginale

Inspection No: J09665/0123/536
Batchnumber: 22129-T08-099387
Expiration date: 31.03.2024
Analysed according to: ČL 2017, Ph.Eur.10.0

Customer: FAGRON a.s.
Sample Unit: 1 x 200 ml
Batch Size: 10 x 200 g

Batch no. of vendor: 161583

	Requirement	Result	Unit	Standard remark
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		
Solubility	Conform	Conform		
Relative density	About 0,931	0,921		
Refractive index	About 1,480	1,479		
IDENTIFICATION				
Identification B	160 - 200	167		Iodine value
Identification C	Conform	Conform		Composition of fatty acids, GC
TESTS				
Acid value	<=4,5	2,4		
Iodine value	160 - 200	167		
Peroxide value	<=15,0	1,2		
Saponification value	188 - 195	191		
Unsaponifiable matter	<=1,5	0,7	%	
Composition of fatty acids	Conform	Conform		GC
Fatty ac. with a chain length <C16	<=1,0	<0,05	%	
Palmitic acid	3,0 - 8,0	5,5	%	
Palmitoleic acid	<=1,0	0,1	%	
Stearic acid	2,0 - 8,0	5,1	%	
Oleic acid	11,0 - 35,0	20,8	%	
Linoleic acid	11,0 - 24,0	15,6	%	
Linolenic acid	35,0 - 65,0	52,9	%	
Arachidic acid	<=1,0	<0,05	%	
Cadmium	<=0,5	0,01	ppm	
Water	<=0,1	0,050	%	
Microbiology	Conform	Conform		
TAMC	<=2 x 103	<10	CFU/g	
TYMC	<=2 x 102	<10	CFU/g	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Metallic residues	ICH Q3D	Conform		

Quality: Excipient

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

Performed by: Ekocentrum
Responsible: Ing. Pavel Mišák, QC
RNDr. Jana Bernátová, QA
Date: 08.12.2022

Conclusion: **APPROVED**

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