

Certificate of Analysis

Productname: Ricini oleum virginale

Inspection No: J09461/0123/536

Batchnumber: 100019

Expiration date: 30.09.2024

Analysed according to: ČL 2017-Dopl.2021,Ph.Eur.10.5

Customer: FAGRON a.s.

Sample Unit: 1 x 1 l

Batch Size: 10 x 1 l

Batch no. of vendor: 161090

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Clear at 40°C, slightly yellow, viscous, hygroscopic liquid.	Conform		
Solubility	Conform	Conform		
Relative density	about 0,958	0,962		
Refractive index	about 1,479	1,479		
IDENTIFICATION				
Identification B	<=0,7	0,3		Specific absorbance, 270 nm
Identification C	Conform	Conform		Composition of fatty acids, GC
TESTS				
Optical rotation	+3,5 - +6,0	4,3	°	
Specific absorbance	<=0,7	0,3		270 nm
Acid value	<=1,5	0,5		
Hydroxyl value	>=160	161		
Peroxide value	<=10,0	2,7		
Unsaponifiable matter	<=0,8	0,5	%	
Composition of fatty acids	Conform	Conform		GC
palmitic acid	<=2,0	1,0	%	
stearic acid	<=2,5	1,3	%	
Oleic acid and isomer	2,5 - 6,0	3,5	%	
linoleic acid	2,5 - 7,0	4,5	%	
linolenic acid	<=1,0	0,4	%	
eicosenoic acid	<=1,0	0,3	%	
ricinoleic acid	85,0 - 92,0	90,8	%	
any other fatty acid	<=1,0	<0,05	%	
Watter micro-determination	<=0,3	0,162	%	
Microbiology	Conform	Conform		
TAMC	<=2 x 10 ³	<10	CFU/g	
TYMC	<=2 x 10 ²	<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

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		Post Code	779 00	Fax No.	+420 585 226 521

Performed by: Ekocentrum
Responsible: Ing. Pavel Mišák, QC
Mgr. Barbora Agatha Halouzková, QP
Date: 08.12.2022

Conclusion: **APPROVED**

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