

Certificate of Analysis

Productname: Ricini oleum virginale

Inspection No: I08916/1121/536
Batchnumber: 21J15-T13-090067
Expiration date: 31.10.2023
Analysed according to: Ph.Eur.10.5
Original Manuf. Date: 31.8.2021

Sample Unit: 0 x
Batch Size: 609 x 250 ml

Identification of producer: V00225
Batch no. of vendor: 158583

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear at 40°C, slightly yellow, viscous, hygroscopic liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Relative density	about 0,958	0,958			Fagron CZ
Refractive index	about 1,479	1,479			Fagron CZ
IDENTIFICATION					
Identification B	<=0,7	0,3		Specific absorbance, 270 nm	Fagron CZ
Identification C	Conform	Conform		Composition of fatty acids, GC	Contract Lab
TESTS					
Optical rotation	+3,5 - +6,0	+3,6	°		Fagron CZ
Specific absorbance	<=0,7	0,3		270 nm	Fagron CZ
Acid value	<=1,5	0,32			Fagron CZ
Hydroxyl value	>=160	177			Fagron CZ
Peroxide value	<=10,0	1,23			Fagron CZ
Unsaponifiable matter	<=0,8	0,1	%		Fagron CZ
Composition of fatty acids	Conform	Conform			Contract Lab
palmitic acid	<=2,0	1,1	%		Contract Lab
stearic acid	<=2,5	1,3	%		Contract Lab
oleic acid	2,5 - 6,0	3,7	%		Contract Lab
linoleic acid	2,5 - 7,0	5,0	%		Contract Lab
linolenic acid	<=1,0	0,4	%		Contract Lab
eicosenoic acid	<=1,0	0,5	%		Contract Lab
ricinoleic acid	85,0 - 92,0	88,7	%		Contract Lab
any other fatty acid	<=1,0	<0,1	%		Contract Lab
Water micro-determination	<=0,3	0,03	%		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	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

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

The product conforms to Ph.Eur.10.5.

Performed by: Lucie Kubáňová DiS.

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

Date: 08.12.2021



Conclusion: I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.

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

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