



## Certificate of Analysis

**Productname:** Ricini oleum virginale

**Inspection No:** J07567/0922/536

**Batchnumber:** 22G11-T03-097547

**Expiration date:** 30.06.2024

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

**Original Manuf. Date:** 31.5.2022

**Sample Unit:** 1 x 10 ml

**Batch Size:** 225 x 250 ml

**Identification of producer:** V00225

**Batch no. of vendor:** 161048

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear at 40°C, slightly yellow, viscous, hygroscopic liquid.	Conform			Contract Lab
Solubility	Conform	Conform			Contract Lab
Relative density	about 0,958	0,962			Contract Lab
Refractive index	about 1,479	1,479			Contract Lab
IDENTIFICATION					
Identification B	<=0,7	<0,7		Specific absorbance, 270 nm	Contract Lab
Identification C	Conform	Conform		Composition of fatty acids, GC	Contract Lab
TESTS					
Optical rotation	+3,5 - +6,0	+4,5	°		Contract Lab
Specific absorbance	<=0,7	0,7		270 nm	Contract Lab
Acid value	<=1,5	0,6			Contract Lab
Hydroxyl value	>=160	164			Contract Lab
Peroxide value	<=10,0	3,6			Contract Lab
Unsaponifiable matter	<=0,8	0,4	%		Contract Lab
Composition of fatty acids	Conform	Conform		GC	Contract Lab
palmitic acid	<=2,0	1,1	%		Contract Lab
stearic acid	<=2,5	1,3	%		Contract Lab
Oleic acid and isomer	2,5 - 6,0	3,7	%		Contract Lab
linoleic acid	2,5 - 7,0	4,9	%		Contract Lab
linolenic acid	<=1,0	0,4	%		Contract Lab
eicosenoic acid	<=1,0	0,4	%		Contract Lab
ricinoleic acid	85,0 - 92,0	89,9	%		Contract Lab
any other fatty acid	<=1,0	<0,05	%		Contract Lab
Watter micro-determination	<=0,3	0,1	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 103	<10	CFU/g		Contract Lab
TYMC	<=2 x 102	<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:** Ing. Pavel Mišák, QC  
PharmDr. Ivana Urbánková, QP

**Date:** 24.08.2022

**Conclusion:** **APPROVED**

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