Fagron
personalizing medicine

Certificate of Analysis

Productname: **Ricini oleum virginale**

Inspection No: I08917/1121/536
Batchnumber: **21J15-T13-090068**
Expiration date: 31.10.2023
Analysed according to: Ph.Eur.10.5
Original Manuf. Date: 31.8.2021

Sample Unit: 0 x
Batch Size: 179 x 1 l

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
Watter micro-determination	<=0,3	0,03	%		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	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

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

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