



Certificate of Analysis

Productname: Ricini oleum virginale

Inspection No: K02306/0623/536

Batchnumber: 23C01-T06-103308

Expiration date: 31.10.2024

Analysed according to: ČL 2017-Dopl.2021, Ph.Eur. 11.0

Original Manuf. Date: 31.7.2022

Sample Unit: 1 x 10 ml

Batch Size: 22 x 100 ml

Identification of producer: V00225

Batch no. of vendor: 161906

	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	1,478			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	+4,3	°		Fagron CZ
Specific absorbance	<=0,7	0,3		270 nm	Fagron CZ
Acid value	<=1,5	0,78			Fagron CZ
Hydroxyl value	>=160	164			Fagron CZ
Peroxide value	<=10,0	2,37			Fagron CZ
Unsaponifiable matter	<=0,8	0,4	%		Fagron CZ
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	3,6	%		Contract Lab
linoleic acid	2,5 - 7,0	4,7	%		Contract Lab
linolenic acid	<=1,0	0,4	%		Contract Lab
eicosenoic acid	<=1,0	0,4	%		Contract Lab
ricinoleic acid	85,0 - 92,0	88,4	%		Contract Lab
any other fatty acid	<=1,0	<0,05	%		Contract Lab
Watter micro-determination	<=0,3	0,11	%		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

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	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521

Performed by: Bc. Andrea Šmídová

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 09.06.2023

Conclusion: **APPROVED**

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