



Certificate of Analysis

Productname: Ricini oleum virginale

Inspection No: J02441/0422/536

Batchnumber: 22B18-T02-093770

Expiration date: 31.12.2023

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

Original Manuf. Date: 31.10.2021

Sample Unit: 1 x 10 ml

Batch Size: 21 x 100 ml

Identification of producer: V00225

Batch no. of vendor: 159174

	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	0,963			Fagron CZ
Refractive index	about 1,479	1,479			Fagron CZ
IDENTIFICATION					
Identification B	<=0,7	0,4		Specific absorbance, 270 nm	Fagron CZ
Identification C	Conform	Conform		Composition of fatty acids, GC	Contract Lab
TESTS					
Optical rotation	+3,5 - +6,0	+4,0	°		Fagron CZ
Specific absorbance	<=0,7	0,4		270 nm	Fagron CZ
Acid value	<=1,5	0,98			Fagron CZ
Hydroxyl value	>=160	164			Fagron CZ
Peroxide value	<=10,0	1,40			Fagron CZ
Unsaponifiable matter	<=0,8	0,3	%		Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
palmitic acid	<=2,0	1,2	%		Contract Lab
stearic acid	<=2,5	1,5	%		Contract Lab
Oleic acid and isomer	2,5 - 6,0	4,1	%		Contract Lab
linoleic acid	2,5 - 7,0	5,8	%		Contract Lab
linolenic acid	<=1,0	1,0	%		Contract Lab
eicosenoic acid	<=1,0	0,4	%		Contract Lab
ricinoleic acid	85,0 - 92,0	90,9	%		Contract Lab
any other fatty acid	<=1,0	<0,1	%		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

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Performed by: Ludmila Stochlebová

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA

Date: 22.04.2022

Conclusion: **APPROVED**

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