Fagron personalizing medicine

Certificate of Analysis

Productname: **Ricini oleum virginale**

Inspection No: J02440/0422/536
Batchnumber: **22B18-T02-093705**
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: 243 x 1 l

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**

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

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