

Certificate of Analysis

Productname: Ricini oleum virginale

Inspection No: J09463/0123/536

Batchnumber: 100016

Expiration date: 30.09.2024

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

Customer: FAGRON a.s.

Sample Unit: 2 x 50 ml

Batch Size: 600 x 50 ml

Batch no. of vendor: 161090

| | Requirement | Result | Unit | Standard remark |
|----------------------------|--------------------------------------------------------------|---------|-------|--------------------------------|
| CHARACTERS | | | | |
| Appearance | Clear at 40°C, slightly yellow, viscous, hygroscopic liquid. | Conform | | |
| Solubility | Conform | Conform | | |
| Relative density | about 0,958 | 0,962 | | |
| Refractive index | about 1,479 | 1,479 | | |
| IDENTIFICATION | | | | |
| Identification B | <=0,7 | 0,3 | | Specific absorbance, 270 nm |
| Identification C | Conform | Conform | | Composition of fatty acids, GC |
| TESTS | | | | |
| Optical rotation | +3,5 - +6,0 | 4,3 | ° | |
| Specific absorbance | <=0,7 | 0,3 | | 270 nm |
| Acid value | <=1,5 | 0,5 | | |
| Hydroxyl value | >=160 | 161 | | |
| Peroxide value | <=10,0 | 2,7 | | |
| Unsaponifiable matter | <=0,8 | 0,5 | % | |
| Composition of fatty acids | Conform | Conform | | GC |
| palmitic acid | <=2,0 | 1,0 | % | |
| stearic acid | <=2,5 | 1,3 | % | |
| Oleic acid and isomer | 2,5 - 6,0 | 3,5 | % | |
| linoleic acid | 2,5 - 7,0 | 4,5 | % | |
| linolenic acid | <=1,0 | 0,4 | % | |
| eicosenoic acid | <=1,0 | 0,3 | % | |
| ricinoleic acid | 85,0 - 92,0 | 90,8 | % | |
| any other fatty acid | <=1,0 | <0,05 | % | |
| Watter micro-determination | <=0,3 | 0,162 | % | |
| Microbiology | Conform | Conform | | |
| TAMC | <=2 x 103 | <10 | CFU/g | |
| TYMC | <=2 x 102 | <10 | CFU/g | |
| TSE/BSE | No contamination with TSE/BSE-risk materials. | Conform | | |
| Residual solvents | ICH Q3C | Conform | | |
| Metallic residues | ICH Q3D | Conform | | |

Quality: Excipient

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

Performed by: Ekocentrum
Responsible: Ing. Pavel Mišák, QC
Mgr. Barbora Agatha Halouzková, QP
Date: 08.12.2022

Conclusion: **APPROVED**

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

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|-------------|------------------------------------------------|------------------|---------------------------|------------------|------------------|
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