



Certificate of Analysis

Productname: Olivae oleum virginale

Inspection No: J08465/1022/536

Batchnumber: 22H29-T10-098684

Expiration date: 31.01.2024

Analysed according to: ČL 2017,Dopl.2018,Ph.Eur.10.0

Original Manuf. Date: 31.1.2022

Sample Unit: 1 x 100 ml

Batch Size: 304 x 1 l

Identification of producer: V00225

Batch no. of vendor: 160932

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|------------------------------|--|---------|-------|----------------------------|--------------|
| CHARACTERS | | | | | |
| Appearance | Clear,transparent, yellow or greenish-yellow liquid. | Conform | | | Fagron CZ |
| Solubility | Conform | Conform | | | Fagron CZ |
| Relative density | About 0,913 | 0,915 | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification B | Conform | Conform | | Composition of fatty acids | Contract Lab |
| TESTS | | | | | |
| Absorbance (270 nm) | <=0,20 | 0,025 | | | Fagron CZ |
| Absorbance (232 nm : 270 nm) | >8 | 29 | | | Fagron CZ |
| Acid value | <=2,0 | 0,62 | | | Fagron CZ |
| Peroxide value | <=20,0 | 10,2 | | | Fagron CZ |
| Unsaponifiable matter | <=1,5 | 0,78 | % | | Fagron CZ |
| Composition of fatty acids | Conform | Conform | | GC | Contract Lab |
| Saturated fatty acids < C16 | <=0,1 | <0,05 | % | | Contract Lab |
| Palmitic acid | 7,5 - 20,0 | 12,9 | % | | Contract Lab |
| Palmitoleic acid | <=3,5 | 1,2 | % | | Contract Lab |
| Stearic acid | 0,5 - 5,0 | 2,3 | % | | Contract Lab |
| Oleic acid and isomer | 56,0 - 85,0 | 74,7 | % | | Contract Lab |
| Linoleic acid | 3,5 - 20,0 | 8,3 | % | | Contract Lab |
| Linolenic acid | <=1,2 | 0,6 | % | | Contract Lab |
| Arachidic acid | <=0,7 | <0,05 | % | | Contract Lab |
| Eicosenoic acid | <=0,4 | <0,05 | % | | Contract Lab |
| Behenic acid | <=0,2 | <0,05 | % | | Contract Lab |
| Lignoceric acid | <=0,2 | <0,05 | % | | Contract Lab |
| Sterols | Conform | Conform | | | Contract Lab |
| cholesterol | <=0,5 | <0,5 | % | | Contract Lab |
| campesterol | <=4,0 | 3,2 | % | | Contract Lab |
| delta 7-stigmasterol | <=0,5 | <0,5 | % | | Contract Lab |
| sum of contents of sterols | >=93,0 | 95,9 | % | | Contract Lab |
| stigmasterol <= campesterol | Conform | Conform | | | Contract Lab |
| Sesame oil | Conform | Conform | | | Fagron CZ |
| Water | <=0,1 | 0,068 | % | | Contract Lab |
| Microbiology | Conform | Conform | | | Contract Lab |
| TAMC | <=2 x 103 | <10 | CFU/g | | Contract Lab |

Name Fagron a.s. (CZ)
Kontrolní laboratoř č. 536

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| | | | | |
|-------------------|---|---------|-------|---------------|
| TYMC | <=2 x 10 ² | <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 |

Quality: Excipient

Performed by: Ludmila Stochlebová

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QP

Date: 30.09.2022

Conclusion: **APPROVED**

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