



Certificate of Analysis

Productname: Decylis oleas

Inspection No: K10130/0124/536
Batchnumber: 23E31-T17-108265
Expiration date: 06.03.2025
Analysed according to: ČL 2017, Ph.Eur.11.0
Original Manuf. Date: 7.3.2023

Sample Unit: 1 x 50 ml
Batch Size: 29 x 250 ml

Identification of producer: V01648
Batch no. of vendor: 0027035661

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|-----------------------|---|---------|-------|----------------------|---------------|
| CHARACTERS | | | | | |
| Appearance | Clear, pale yellow or colourless liquid. | Conform | | | Fagron CZ |
| Solubility | Conform | Conform | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification A | 0,860 - 0,870 | 0,865 | | Relative density | Fagron CZ |
| Identification B | 130 - 140 | 133 | | Saponification value | Fagron CZ |
| Identification C | >=60,0 | 80,1 | % | Oleic acid | Contract Lab |
| TESTS | | | | | |
| Relative density | 0,860 - 0,870 | 0,865 | | | Fagron CZ |
| Acid value | <=1,0 | 0,32 | | | Fagron CZ |
| Iodine value | 55 - 70 | 61 | | | Fagron CZ |
| Peroxide value | <=10,0 | 0,371 | | | Fagron CZ |
| Saponification value | 130 - 140 | 133 | | | Fagron CZ |
| Content of oleic acid | >=60,0 | 80,1 | % | GC | Contract Lab |
| Water (Karl Fischer) | <=1,0 | 0,012 | % | | Fagron CZ |
| Total ash | <=0,1 | 0,0 | % | | Fagron CZ |
| Microbiology | Conform | Conform | | | Contract Lab |
| TAMC | <=2 x 10 ³ | <10 | CFU/g | | Contract Lab |
| 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

| | | | | | |
|-------------|----------------------------|------------------|---------------------------|------------------|------------------|
| Name | Fagron a.s. (CZ) | Address | Holická 1098/31m, Olomouc | Phone No. | +420585222590 |
| | 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: 10.01.2024

Conclusion: **APPROVED**

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