



Certificate of Analysis

Productname: Citronellae etheroleum

Inspection No: K04935/0823/536

Batchnumber: 23E30-T02-104765

Expiration date: 22.05.2026

Analysed according to: ČL 2017, Ph.Eur.11.0

Original Manuf. Date: 23.5.2023

Sample Unit: 1 x 1 ml

Batch Size: 81 x 250 ml

Identification of producer: V00201

Batch no. of vendor: 1353378

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|-------------------------|---|---------|-------|-----------------------------|---------------|
| CHARACTERS | | | | | |
| Appearance | Light yellow or brownish yellow liquid. | Conform | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification B | Conform | Conform | | Chromatographic profile, GC | Contract Lab |
| TESTS | | | | | |
| Relative density | 0,881 - 0,895 | 0,891 | | | Fagron CZ |
| Refractive index | 1,463 - 1,475 | 1,469 | | | Fagron CZ |
| Optical rotation | -4 - +1,5 | -3,6 | ° | | Fagron CZ |
| Chromatographic profile | Conform | Conform | | GC | Contract Lab |
| limonene | 1,0 - 5,0 | 3,8 | % | | Contract Lab |
| citronellal | 30,0 - 45,0 | 33,9 | % | | Contract Lab |
| citronellyl-acetate | 2,0 - 4,0 | 2,5 | % | | Contract Lab |
| neral | <=2,0 | 0,2 | % | | Contract Lab |
| geranial | <=2,0 | 0,4 | % | Geranial | Contract Lab |
| geranyl-acetate | 3,0 - 8,0 | 3,4 | % | | Contract Lab |
| citronellol | 9,0 - 15,0 | 12,0 | % | | Contract Lab |
| geraniol | 20,0 - 25,0 | 21,8 | % | | Contract Lab |
| 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: Ludmila Burianová

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 22.08.2023

Conclusion: **APPROVED**

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