

Certificate of Analysis

Productname: Eucalypti etheroleum

Inspection No: I04257/0621/536

Batchnumber: 20E18-F01-087114

Expiration date: 06.05.2023

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

Original Manuf. Date: 7.5.2020

Sample Unit: 1 x 1 ml

Batch Size: 75 x 250 ml

Identification of producer: V00201

Batch no. of vendor: 1204970

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|-------------------------|---|---------|-------|---------------------------------|---------------|
| CHARACTERS | | | | | |
| Appearance | Bezbarvá nebo světle žlutá kapalina. | Conform | | | Fagron |
| Odour | Reminiscent of 1,8-cineole. | Conform | | | Fagron |
| IDENTIFICATION | | | | | |
| Identification B | Conform | Conform | | GC | Contract Lab |
| TESTS | | | | | |
| Relative density | 0,906 - 0,927 | 0,911 | | | Fagron |
| Refractive index | 1,458 - 1,470 | 1,461 | | | Fagron |
| Optical rotation | 0 - +10 | +2,3 | ° | | Fagron |
| Solubility in alcohol | Conform | Conform | | 1,0 ml/2,0 ml ethanol (70% V/V) | Fagron |
| Aldehydes | Conform | Conform | | | Fagron |
| Chromatographic profile | Conform | Conform | | GC | Contract Lab |
| alfa-pinene | 0,05 - 10,0 | 2,5 | % | | Contract Lab |
| beta-pinene | 0,05 - 1,5 | 0,3 | % | | Contract Lab |
| sabinene | <=0,3 | <0,1 | % | | Contract Lab |
| alfa-phellandrene | 0,05 - 1,5 | 1,4 | % | | Contract Lab |
| limonene | 0,05 - 15,0 | 7,4 | % | | Contract Lab |
| 1,8-cineole | >=70,0 | 81,3 | % | | Contract Lab |
| Camphor | <=0,1 | <0,1 | % | | Contract Lab |
| Microbiology | Conform | Conform | | | Contract Lab |
| TAMC | <=2 x 103 | Conform | CFU/g | | Contract Lab |
| TYMC | <=2 x 102 | Conform | 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 |

| | | | | | |
|-------------|--|------------------|---------------------------|------------------|------------------|
| 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: Lucie Kubáňová DiS.
Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA
Date: 17.06.2021
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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