



Certificate of Analysis

Productname: Terebinthinae etheroleum

Inspection No: J01804/0322/536

Batchnumber: 22A20-T15-095083

Expiration date: 03.01.2025

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

Original Manuf. Date: 4.1.2022

Sample Unit: 1 x 10 ml

Batch Size: 6 x 1 l

Identification of producer: V00201

Batch no. of vendor: 1289974

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|--|---|---------|-------|-----------------------------|---------------|
| CHARACTERS | | | | | |
| Appearance | Clear, colourless or pale yellow liquid of characteristic odour of alfa-pinen and beta-pinen. | Conform | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification B | Conform | Conform | | Chromatographic profile, GC | Contract Lab |
| TESTS | | | | | |
| Relative density | 0,856 - 0,872 | 0,867 | | | Fagron CZ |
| Refractive index | 1,465 - 1,475 | 1,470 | | | Fagron CZ |
| Optical rotation | -40 - -28 | -30 | ° | | Fagron CZ |
| Acid value | <=1,0 | 0,96 | | | Fagron CZ |
| Peroxide value | <=20 | 11 | | | Fagron CZ |
| Fatty oils and resinified essential oils | Conform | Conform | | | Fagron CZ |
| Chromatographic profile | Conform | Conform | | GC | Contract Lab |
| Alfa-pinene | 70,0 - 85,0 | 76,4 | % | | Contract Lab |
| Camphene | 0,5 - 2,0 | 1,0 | % | | Contract Lab |
| beta-Pinene | 5,0 - 20,0 | 13,8 | % | | Contract Lab |
| Car-3-ene | <=1,0 | <1,0 | % | | Contract Lab |
| β-Myrcene | 0,4 - 1,5 | 0,6 | % | | Contract Lab |
| Liimonene | 1,0 - 7,0 | 2,0 | % | | Contract Lab |
| Longifolene | 0,2 - 4,0 | 1,4 | % | | Contract Lab |
| β-Caryophyllene | 0,1 - 3,0 | 2,4 | % | | Contract Lab |
| Caryophyllene oxide | <=1,0 | 0,1 | % | | Contract Lab |
| Residue on evaporation | <=2,5 | 1,1 | % | | 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 | Conform ICH Q3C | 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: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 17.03.2022

Conclusion: **APPROVED**

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