



## Certificate of Analysis

**Productname:** Citri etheroleum

**Inspection No:** K06222/1023/536  
**Batchnumber:** 22E26-T09-106112  
**Expiration date:** 28.04.2025  
**Analysed according to:** Ph.Eur.10.7  
**Original Manuf. Date:** 29.4.2022

**Sample Unit:** 1 x 1 ml  
**Batch Size:** 4 x 25 ml

**Identification of producer:** V00201  
**Batch no. of vendor:** 1308243

|  | Requirement   | Result  | Unit  | Standard remark             | Insp. Site    |
|--|---|---------|-------|-----------------------------|---------------|
| CHARACTERS                               |   |         |       |                             |               |
| Appearance                               | Clear, mobile, pale yellow or greenish-yellow liquid.<br>It may become cloudy at low temperatures.<br>Characteristic odour. | Conform |       |                             | Fagron CZ     |
| IDENTIFICATION                           |   |         |       |                             |               |
| Identification B                         | Conform   | Conform |       | Chromatographic profile, GC | Contract Lab  |
| TESTS                                    |   |         |       |                             |               |
| Relative density                         | 0,850 - 0,858   | 0,853   |       |                             | Fagron CZ     |
| Refractive index                         | 1,473 - 1,476   | 1,474   |       |                             | Fagron CZ     |
| Optical rotation                         | +5,7 - +7,0   | +6,3    | °     |                             | Fagron CZ     |
| Absorbance                               | 0,20 - 0,96   | 0,39    |       |                             | Fagron CZ     |
| Fatty oils and resinified essential oils | Conform   | Conform |       |                             | Fagron CZ     |
| Chromatographic profile                  | Conform   | Conform |       | GC                          | Contract Lab  |
| beta-pinene                              | 7,0 - 17,0  | 14,5    | %     |                             | Contract Lab  |
| sabinene                                 | 1,0 - 3,0   | 1,9     | %     |                             | Contract Lab  |
| limonene                                 | 56,0 - 78,0   | 66,7    | %     |                             | Contract Lab  |
| gamma-terpinene                          | 6,0 - 12,0  | 8,6     | %     |                             | Contract Lab  |
| beta-caryophyllene                       | <=0,5   | 0,1     | %     |                             | Contract Lab  |
| neral                                    | 0,3 - 1,5   | 0,6     | %     |                             | Contract Lab  |
| alfa-terpineol                           | <=0,6   | 0,1     | %     |                             | Contract Lab  |
| neryl-acetate                            | 0,2 - 0,9   | 0,3     | %     |                             | Contract Lab  |
| geranial                                 | 0,5 - 2,3   | 1,2     | %     |                             | Contract Lab  |
| geranyl-acetate                          | 0,1 - 0,8   | 0,1     | %     |                             | Contract Lab  |
| Residue on evaporation                   | 1,8 - 3,6   | 2,1     | %     |                             | Fagron CZ     |
| Microbiology                             | Conform   | Conform |       |                             | Contract Lab  |
| TAMC                                     | <=2 x 10 <sup>3</sup>   | <10     | CFU/g |                             | Contract Lab  |
| TYMC                                     | <=2 x 10 <sup>2</sup>   | <10     | CFU/g |                             | Contract Lab  |
| TSE/BSE                                  | No contamination with TSE/BSE-risk materials.   | Conform |       |                             | Data Producer |
| Residual solvents                        | ICH Q3C   | Conform |       |                             | Data Producer |
| Metallic residues                        | ICH Q3D   | Conform |       |                             | Data Producer |

Quality: Excipient

|             |                            |                  |                           |                  |                  |
|-------------|----------------------------|------------------|---------------------------|------------------|------------------|
| <b>Name</b> | Fagron a.s. (CZ)           | <b>Address</b>   | Holická 1098/31m, Olomouc | <b>Phone No.</b> | +420585222590    |
|             | Kontrolní laboratoř č. 536 | <b>Post Code</b> | 779 00                    | <b>Fax No.</b>   | +420 585 226 521 |

**Performed by:** Mgr. Zdeňka Šinclová

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

**Date:** 05.10.2023

**Conclusion:** **APPROVED**

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