

## Certificate of Analysis

**Product name:** **Levomentholum (syntheticum)**

**Batch number / Weight:** **22A26-B10-222459 / 50 G**

**Analysed according to:** **Ph.Eur.10**

**Number of analysis / Inspection Code** **22A26-B10 / INS-22-3628**

**Reference Code / No.:** **V01545 / 10300378**

| Tests                     | Requirement                                       | Result     | Unit | Standard remark |
|---------------------------|---|------------|------|-----------------|
| Appearance                | Prismatic or acicular, colourless, shiny crystals | Conform    |      |                 |
| Identification A          | -48 - -51   | Conform    |      |                 |
| Identification C          | Conform   | Conform    |      |                 |
| Melting point             | about 43  | 44,24      | °C   |                 |
| Appearance of solution    | Clear and colourless                              | Conform    |      |                 |
| Acidity or alkalinity     | Conform   | 0,1ml NaOH |      |                 |
| Specific optical rotation | -48 - -51   | -49,2      |      |                 |
| Related substances        | <=1   | 0,00       | %    |                 |
| Residue on evaporation    | <= 0,05   | 0,005      | %    |                 |
| Metallic residues         | CHMP/ICH/353369/2013                              | Conform    |      | Data producer   |
| Residual solvents         | CPMP/ICH/82 260/06                                | Conform    |      | Data producer   |
| TSE/BSE-statement:        | No contamination with TSE/BSE-risk materials      | Conform    |      | Data producer   |
| Residual solvents         |   |            |      |                 |
| Methanol                  | <=3000  | <3000      | ppm  |                 |
| Acetone                   | <5000 ppm   | <5000      | ppm  |                 |

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release:  
Dominika Soltysik  
Qualified Person

30-08-2022

Expiration: 30-11-2023

Conclusion: APPROVED

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