

Certificate of Analysis

Product name: **Leucinum apyrogen**

Batch number / Weight: **21F14-B22-215005 / 100 G**

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

| Tests | Requirement | Result | Unit | Standard remark |
|----------------------------------|--|---------|--------|-----------------|
| Appearance | (Almost) white, crystalline powder or shining flakes | Conform | | |
| Identification A | +14,5 - +16,5 | Conform | | |
| Identification B | Conform | Conform | | |
| Appearance of solution | Clear / <=BY6 | Conform | | |
| Specific optical rotation | +14,5 - +16,5 | +15,85 | | |
| Ninhydrin-positive substances | Conform | Conform | | |
| Impurity A at 570 nm | <=0,8 | <0,05 | % | |
| Any ninhydrin-positive substance | <=0,2 | <0,05 | % | |
| Ammonium at 570 nm | <=0,02 | <0,02 | % | |
| Total | <=1,0 | <0,05 | % | |
| Chlorides | <=200 | Conform | ppm | |
| Sulphates | <=300 | Conform | ppm | |
| Iron | <=10 | Conform | ppm | |
| Loss on drying | <=0,5 | 0,00 | % | |
| Sulphated ash | <=0,1 | 0,03 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay L-Leucine | 98,5 - 101,0 | 99,83 | %m/m | |
| Endotoxins | <6 | <6 | IU / g | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:

Dominika Soltysik

Qualified Person

28-02-2022

Expiration: 11-10-2024

Conclusion: APPROVED

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