

Certificate of Analysis

Product name: **Triamcinolonum micronisatum**

Batch number / Weight: **21I03-B01-218499 / 1 G**

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

| Tests | Requirement | Result | Unit | Standard remark |
|--------------------------------|---|---------|------|-----------------|
| Appearance | (Almost) white crystalline powder | Conform | | |
| Particle size | $\geq 99\%$ $< 25 \mu\text{m}$ / $\geq 90\%$ $< 10 \mu\text{m}$ | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Specific optical rotation | +65 - +72 | +69,5 | ° | |
| Related substances | Conform | Conform | | |
| Any impurity | ≤ 1 | 0,8 | % | |
| Max. 2 impurities $\geq 0,5\%$ | ≤ 2 | Conform | | |
| Total impurities | ≤ 2 | 1,8 | % | |
| Water (Karl Fischer) | $\leq 1,0$ | 0,43 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Triamcinolone | 97,0 - 103,0 | 99,93 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

20-01-2022

Expiration: 17-07-2026

Conclusion: APPROVED

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