

## Certificate of Analysis

**Product name:** **Chinini hydrochloridum**  
**Batch number / Weight:** **22D21-B05-220923 / 25 G**  
**Analysed according to:** **Ph. Eur.**

| Tests                     | Requirement                                  | Result  | Unit | Standard remark |
|---------------------------|--|---------|------|-----------------|
| Appearance                | white or almost white, or colourless,        | Conform |      |                 |
| Appearance                | fine, silky needles, often in clusters       |         |      |                 |
| Identification A          | Conform                                      | Conform |      |                 |
| Identification B          | Conform                                      | Conform |      |                 |
| Identification C          | Conform                                      | Conform |      |                 |
| Identification D          | Conform                                      | Conform |      |                 |
| Identification E          | Conform                                      | Conform |      |                 |
| Appearance of solution    | Clear / $\leq Y6$                            | Conform |      |                 |
| pH                        | 6,0 - 6,8                                    | 6,35    |      |                 |
| Specific optical rotation | (-258)-(-245)                                | -250,5  |      |                 |
| Related substances        | Conform                                      | Conform |      |                 |
| Impurity C                | $\leq 10$                                    | 4,24    | %    |                 |
| Unspecified impurities    | $\leq 5$                                     | 0,94    |      |                 |
| Total impurities          | $\leq 2,5$                                   | $< 0,2$ | %    |                 |
| Sulphate                  | $\leq 500$                                   | $< 500$ | ppm  |                 |
| Barium                    | $\leq 500$                                   | Conform |      |                 |
| Loss on drying            | 6,0-10,0                                     | 6,82    | %    |                 |
| Sulphated ash             | $\leq 0,1$                                   | 0,02    | %    |                 |
| Metallic residues         | CHMP/ICH/353369/2013                         | Conform |      | Data producer   |
| Residual solvents         | CPMP/ICH/82 260/06                           | Conform |      | Data producer   |
| Assay                     | 99,0 - 101,0                                 | 100,52  | %m/m |                 |
| TSE/BSE-statement:        | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |
| Residual solvents         |  |         |      |                 |
| Toluene                   |  | $< 890$ | ppm  |                 |

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

25-07-2022

Expiration: 24-01-2027

Conclusion: APPROVED

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