

Certificate of Analysis

Product name: **Chinini hydrochloridum**
Batch number / Weight: **21E06-B02-213369 / 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 / $\leq Y_6$ | Conform | | |
| pH | 6,0 - 6,8 | 6,61 | | |
| Specific optical rotation | (-258)-(-245) | -246 | | |
| Related substances | Conform | Conform | | |
| Impurity C | ≤ 10 | 3,79 | % | |
| Unspecified impurities | ≤ 5 | 1,10 | % | |
| Total impurities | $\leq 2,5$ | $< 0,2$ | % | |
| Sulphate | ≤ 500 | < 500 | ppm | |
| Barium | ≤ 500 | Conform | | |
| Loss on drying | 6,0-10,0 | 7,46 | % | |
| Sulphated ash | $\leq 0,1$ | 0,07 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay | 99,0 - 101,0 | 100,2 | %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

26-08-2021

Expiration: 06-10-2025

Conclusion: APPROVED

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