

Certificate of Analysis

Product name: **Cysteyni hydrochloridum monoh.**

Batch number / Weight: **22A13-B16-215613 / 25 G**

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

| Tests | Requirement | Result | Unit | Standard remark |
|----------------------------------|---|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder / crystals | Conform | | |
| Identification A | +5,5 - +7,0 | Conform | | |
| Identification B | Conform | Conform | | |
| Identification E | Conform | Conform | % | |
| Appearance of solution | Clear / colour <=BY6 | Conform | | |
| Specific optical rotation | +5,5 - +7,0 | +6,6 | | |
| Ninhydrin-positive substances | Conform | Conform | | |
| Impurity A at 570 nm | <=0,5 | 0,07 | % | |
| Any ninhydrin-positive substance | <=0,2 | <0,05 | % | |
| Total | <=1,0 | 0,07 | % | |
| Ammonium at 570 nm | <=0,02 | <0,02 | % | |
| Sulphates | <=300 | <300 | ppm | |
| Iron | <=20 | Conform | ppm | |
| Loss on drying | 8.0 - 12.0 | 10,10 | % | |
| Sulphated ash | <=0,1 | 0,04 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay L-Cysteine hydrochloride | 98,5 - 101,0 | 100,08 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| Remark | Not for use as API !! | | | |

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

27-05-2022

Expiration: 16-05-2023

Conclusion: APPROVED

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