

Certificate of Analysis

Product name: **Amiloridi hydrochloridum dihyd**

Batch number / Weight: **21J26-B19-216092 / 5 G**

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

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|--|---------|------|-----------------|
| Appearance | pale yellow or greenish-yellow powder | Conform | | |
| Identification A | Conform | Conform | | |
| Identification C | Conform | Conform | | |
| Identification D | 11,0 - 13,0 % | Conform | | |
| Free acid | Conform | Conform | | |
| Related substances | acc. to Ph. Eur. | Conform | | |
| Impurity C | $\leq 0,2$ | 0,07 | % | |
| Unspecified impurities | $\leq 0,10$ | 0,10 | % | |
| Total impurities | $\leq 0,4$ | 0,23 | % | |
| Water (Karl Fischer) | 11,0 - 13,0 | 12,09 | % | |
| Sulphated ash | $\leq 0,1$ | 0,05 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | |
| Assay | 98,0 - 101,0 | 100,08 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | |

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

19-05-2022

Expiration: 28-02-2026

Conclusion: APPROVED

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