

Certificate of Analysis

Histamini dihydrochloridum Product name:

21J01-B01-216268 / 5 G Batch number / Weight:

Ph. Eur. Analysed according to:

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------------|--|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder, hygroscopic! | Conform | | |
| Identification A | Conform | Conform | | |
| Identification D | White | Conform | | |
| Appearance of solution | Clear / <= Y7 | Conform | | |
| рН | 2,85 - 3,60 | 3,26 | | |
| Histidine | Conform | Conform | % | |
| Sulphates | <= 0,1 | <0,1 | % | |
| Loss on drying | <= 0,5 | 0,15 | % | |
| Sulphated ash | <= 0,1 | 0,05 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Histamine dihydrochloride | 98,5 - 101,0 | 100,25 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:

Agnieszka Pszczółka **Qualified Person**

11-03-2022

Expiration: 31-08-2024

Conclusion: APPROVED

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