

Certificate of Analysis

Product name: **Cholinii dihydrogenocitras**

Batch number / Weight: **21K09-B16-222287 / 100 G**

Analysed according to: **Monograph**

Number of analysis / Inspection Code **21K09-B16 / INS-22-1287**

Reference Code / No.: **/ 3020378**

| Tests | Requirement | Result | Unit | Standard remark |
|----------------------------------|--|---------|------|-----------------|
| Appearance | White, crystalline powder | Conform | | |
| Identification A | 101 - 105 | 104,8 | °C | Melting point |
| Identification B | Conform | Conform | | |
| Identification C | Conform | Conform | | |
| Identification D | Conform | Conform | | |
| Appearance of solution | Clear / colourless | Conform | | |
| Acidity | Conform | Conform | | |
| pH | 3,5 - 4,5 | 3,7 | % | 25% |
| Trimethylamine | Conform | Conform | | |
| Chlorides | <=250 | <250 | ppm | |
| Ammonium salts | Conform | Conform | | |
| Loss on drying | <=1,0 | 0,5 | % | |
| Sulphated ash | <=0,1 | 0,1 | % | |
| Assay Choline dihydrogenocitrate | 98,0 - 101,0 | 99,8 | %m/m | Dried |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Eurofins

Release:
Dominika Soltysik
Qualified Person

26-08-2022

Expiration: 22-07-2023

Conclusion: APPROVED

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