

## **Certificate of Analysis**

Cholinii dihydrogenocitras Product name:

22K28-B12-232305 / 100 G Batch number / Weight:

Analysed according to: Monograph

Number of analysis / Inspection Code 22K28-B12 / INS-22-10359

V01485 / 3025945 Reference Code / No.:

| Tests                           | Requirement                                  | Result  | Unit | Standard remark |
|---------------------------------|--|---------|------|-----------------|
| Appearance                      | White, crystalline powder                    | Conform |      |                 |
| Identification A                | 101 - 105                                    | 104,82  | °C   |                 |
| Identification B                | Conform                                      | Conform |      |                 |
| Identification C                | Conform                                      | Conform |      |                 |
| Identification D                | Conform                                      | Conform |      |                 |
| Appearance of solution          | Clear / colourless                           | Conform |      |                 |
| Acidity                         | Conform                                      | 20,0 ml |      |                 |
| pH                              | 3,5 - 4,5                                    | 3,85    |      | 25%             |
| Trimethylamine                  | Conform                                      | Conform |      |                 |
| Chlorides                       | <=250  | <250    | ppm  |                 |
| Ammonium salts                  | Conform                                      | Conform |      |                 |
| Heavy metals                    | <=20   | <20     | ppm  |                 |
| Loss on drying                  | <=1,0  | 0,15    | %    |                 |
| Sulphated ash                   | <=0,1  | 0,08    | %    |                 |
| Assay Choline dihydrogencitrate | 98,0 - 101,0                                 | 99,68   | %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 EL Spol

Release: Dominika Sołtysik Qualified Person

23-10-2023

Expiration: 21-10-2025

Conclusion: APPROVED

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