

## Certificate of Analysis

**Product name:** **Dinatrii edetas**

**Batch number / Weight:** **22G15-B01-221875 / 25 G**

**Analysed according to:** **Ph. Eur. 10.8**

**Number of analysis / Inspection Code** **22G15-B01 / INS-22-6148**

**Reference Code / No.:** **V01536 / 601EI298**

| Tests                  | Requirement                                  | Result  | Unit | Standard remark |
|------------------------|--|---------|------|-----------------|
| Appearance             | White, crystalline powder                    | Conform |      |                 |
| Identification A       | Conform                                      | Conform |      |                 |
| Identification B       | Conform                                      | Conform |      |                 |
| Identification D       | Conform                                      | Conform |      |                 |
| Appearance of solution | Clear and colourless                         | Conform |      |                 |
| pH                     | 4,0 - 5,5                                    | 4,47    |      |                 |
| Related substances     | <= 0,1                                       | 0,01    | %    |                 |
| Iron                   | <= 80  | <80     | ppm  |                 |
| Metallic residues      | CHMP/ICH/353369/2013                         | Conform |      | Data producer   |
| Residual solvents      | CPMP/ICH/82 260/06                           | Conform |      | Data producer   |
| Assay                  | 98,5 - 101,0                                 | 100,54  | %m/m |                 |
| TSE/BSE-statement:     | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |

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 FAGRON PL lab

Release:  
Ewelina Gadzinowska  
Qualified Person

31-08-2022

Expiration: 31-10-2024

Conclusion: APPROVED

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