

## Certificate of Analysis

**Product name:** **Zinci orotas dihydricus**

**Batch number / Weight:** **22F15-B02-222956 / 25 G**

**Analysed according to:** **Monograph**

**Number of analysis / Inspection Code** **22F15-B02 / INS-22-6145**

**Reference Code / No.:** **V01507 / ORZ00121**

| Tests                        | Requirement                                  | Result  | Unit | Standard remark |
|------------------------------|--|---------|------|-----------------|
| Appearance                   | (Almost) White, crystalline powder           | Conform |      |                 |
| Identification A             | Conform                                      | Conform |      |                 |
| pH                           | 3,0 - 5,0                                    | 4,1     |      |                 |
| Specific absorbance          | 269 - 285                                    | 279     |      |                 |
| Amino acids                  | Conform                                      | Conform |      |                 |
| Related substances           | Conform                                      | Conform |      |                 |
| Impurity A                   | <=0,2  | <0,05   | %    |                 |
| Any other impurity           | <=0,10                                       | <0,05   | %    |                 |
| Total impurities             | <=0,3  | <0,05   | %    |                 |
| Chlorides                    | <=100  | <100    | ppm  |                 |
| Metallic residues            | CHMP/ICH/353369/2013                         | Conform |      | Data producer   |
| Residual solvents            | CPMP/ICH/82 260/06                           | Conform |      | Data producer   |
| Assay Zinc orotate dihydrate | 98,0 - 101,0                                 | 98,9    | %m/m |                 |
| TSE/BSE-statement:           | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |

fagron.pl

Fagron Sp. z o.o.  
ul. Armii Krajowej 3  
32-540 Trzebinia, Poland  
e-mail: biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.  
ul. Pasternik 26, 31-354 Kraków, Poland  
tel.: +48 12 3343 512  
e-mail: biuro@fagron.pl

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:  
Ewelina Gadzinowska  
Qualified Person

19-10-2022

Expiration: 30-04-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl

Fagron Sp. z o.o.  
ul. Armii Krajowej 3  
32-540 Trzebinia, Poland  
e-mail:biuro@fagron.pl