

Certificate of Analysis

Product name: **Zinci orotas dihydricus**

Batch number / Weight: **23C13-B05-228359 / 25 G**

Analysed according to: **Monograph**

Number of analysis / Inspection Code **23C13-B05 / INS-23-3210**

Reference Code / No.: **V01507 / ORZ01020**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------------|--|---------|------|-----------------|
| Appearance | (Almost) White, crystalline powder | Conform | | |
| Identification A | Conform | Conform | | |
| pH | 3,0 - 5,0 | 4,03 | | |
| Specific absorbance | 269 - 285 | 269 | | |
| Amino acids | Absence | Conform | | |
| Related substances | Conform | Conform | | |
| Impurity A | <=0,2 | <0,2 | % | |
| Any other impurity | <=0,10 | <0,01 | % | |
| Total impurities | <=0,3 | <0,3 | % | |
| 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 | 98,8 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

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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:

Agnieszka Pszczółka

Qualified Person

24-05-2023

Expiration: 30-11-2025

Conclusion: APPROVED

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