

Certificate of Analysis

Product name: **Calcii orotas dihydricus**

Batch number / Weight: **22F02-B13-220556 / 1 KG**

Analysed according to: **Monograph**

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------------|--|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder | Conform | | |
| Identification A | Conform | Conform | | |
| Identification D | Conform | Conform | | |
| Acidity or alkalinity | Conform | Conform | | |
| Specific absorbance 285 nm | 286 - 304 | 300 | | |
| Amino acids | Conform | Conform | | |
| Related substances | Conform | Conform | | |
| Impurity A | <=0,2 | <0,01 | % | |
| Any other impurity | <=0,10 | <0,01 | % | |
| Sum of impurities | <=0,3 | <0,01 | % | |
| Sulphates | <=200 | <200 | ppm | |
| Heavy metals | <=20 | <20 | ppm | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Calcium orotate dihydrate | 98,0 - 102,0 | 99,9 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

19-07-2022

Expiration: 30-09-2024

Conclusion: APPROVED

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