

Certificate of Analysis

Product name: **Zinci orotas dihydricus**

Batch number / Weight: **22F15-B02-227562 / 25 G**

Analysed according to: **Intern**

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

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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:

Ewelina Gadzinowska

Qualified Person

30-01-2023

Expiration: 30-04-2026

Conclusion: APPROVED

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