

## Certificate of Analysis

**Product name:** **Calcii orotas dihydricus**

**Batch number / Weight:** **22J13-B03-229314 / 50 G**

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

**Number of analysis / Inspection Code** **22J13-B03 / INS-22-9280**

**Reference Code / No.:** **V01507 / ORC00121**

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

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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 Fagron PL, ElSpol

Release:

Agnieszka Pszczółka

Qualified Person

28-04-2023

Expiration: 30-09-2024

Conclusion: APPROVED

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