

## Certificate of Analysis

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

**Batch number / Weight:** **23L07-B03-233640 / 50 G**

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

**Number of analysis / Inspection Code** **23L07-B03 / INS-24-0598**

**Reference Code / No.:** **V01507 / ORC00123**

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	298,3		
Amino acids	Conform	Conform		
Related substances	Conform	Conform		
Impurity A	$\leq 0,2$	0,005	%	
Any other impurity	$\leq 0,10$	$< 0,01$	%	
Sum of any other impurities	$\leq 0,3$	0,00	%	
Sulphates	$\leq 200$	$< 200$	ppm	
Heavy metals	$\leq 20$	$< 20$	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	98,61	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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Fagron Services Northern Europe Sp. z o.o.  
ul. Armii Krajowej 3  
32-540 Trzebinia, Poland  
e-mail: fsne@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 Fagron PL, EI Spol

Release:  
Ewelina Gadzinowska  
Qualified Person

23-02-2024

Expiration: 31-01-2026

Conclusion: APPROVED

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

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