

Certificate of Analysis

Product name: **Calcii orotas dihydricus**

Batch number / Weight: **21I30-B02-216199 / 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	$\leq 0,2$	$< 0,01$	%	
Any other impurity	$\leq 0,10$	$< 0,01$	%	
Sum of impurities	$\leq 0,3$	$< 0,01$	%	
Sulphates	≤ 200	< 200	ppm	
Heavy metals	≤ 20	Conform	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

11-02-2022

Expiration: 30-09-2024

Conclusion: APPROVED

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