

Certificate of Analysis

Product name: **Calcii orotas dihydricus**
Batch number / Weight: **21B12-B08-204375 / 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	298		
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	Conform	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	98,5	%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

28-05-2021

Expiration: 31-05-2022

Conclusion: APPROVED

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