

Certificate of Analysis

Product name: **Calcii hydrogenophosphas dihyd**

Batch number / Weight: **22H27-B01-226854 / 1 KG**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **22H27-B01 / INS-22-9798**

Reference Code / No.: **V01208 / D22612A**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	White	Conform		
Identification B	Yellow	Conform		
Identification C	Conform	Conform		
Acid-insoluble substances	$\leq 0,2$	Conform	%	
Carbonates	Conform	Conform		
Chlorides	$\leq 0,25$	$< 0,25$	%	
Fluorides	≤ 100	< 10	ppm	
Sulphates	$\leq 0,5$	$< 0,5$	%	
Arsenic	≤ 10	< 10	ppm	
Barium	Conform	Conform		
Iron	≤ 400	< 400	ppm	
Loss on ignition	24,5 - 26,5	26,15	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,0 - 105,0	99,63	%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:

Ewelina Gadzinowska

Qualified Person

20-01-2023

Expiration: 21-04-2025

Conclusion: APPROVED

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