

Certificate of Analysis

Product name: **Natr.dihydrogenophosph.dihydr.**

Batch number / Weight: **23D04-B05-224825 / 50 G**

Analysed according to: **Ph.Eur.11.1**

Number of analysis / Inspection Code **23D04-B05 / INS-23-3375**

Reference Code / No.: **V01208 / D27813A**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
pH	4,2 - 4,5	4,36		
Reducing substances	Conform	Conform		
Chlorides	<= 200	<200	ppm	
Sulphates	<= 300	<300	ppm	
Iron	<= 10	<10	ppm	
Loss on drying	21,5 - 24,0	23,16	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Sodium dihydrogen phosph	98,0 - 100,5	100,10	%m/m	
Total aerobic microbial count (TA	<=100	<1	CFU/g	
Total yeasts and moulds (TYMC)	<=10	<1	CFU/g	
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 lab,CBMiA

Release:

Ewelina Gadzinowska

Qualified Person

20-06-2023

Expiration: 14-09-2024

Conclusion: APPROVED

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