

Certificate of Analysis

Product name: **Borax**
Batch number / Weight: **23B14-B16-229759 / 250 G**
Analysed according to: **Ph.Eur.11.1**
Number of analysis / Inspection Code **23B14-B16 / INS-23-2848**
Reference Code / No.: **V00583 / C01X**

Tests	Requirement	Result	Unit	Standard remark
Appearance	white or almost white, crystalline powder colourless crystals or crystalline masses efflorescent	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Appearance of solution	acc. to Ph. Eur.	Conform		
pH	9,0 - 9,6	9,40		
Sulfates	<=50	< 50	ppm	
Ammonium	<=10	< 10	ppm	
Calcium	<=100	<100	ppm	
Assay	99,0 - 103,0 %	100,94	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Particle size		>90% <250	µm	
Particle size		>80% <200	µm	

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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

Release:
Ewelina Gadzinowska
Qualified Person

05-05-2023

Expiration: 21-01-2025

Conclusion: APPROVED

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