

Certificate of Analysis

Product name: **Natrii hydrogenocarbonas**

Batch number / Weight: **23E24-B19-235438 / 5 KG**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23E24-B19 / INS-23-4608**

Reference Code / No.: **V00611 / 41230515/3**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) White, crystalline powder	Conform		
Identification A	Pink / red	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Solubility	acc. to Ph. Eur.	Conform		
Appearance of solution	Clear / colourless	Conform		
Carbonates	$\leq 8,6$	8,09		
Chlorides	≤ 150	<150	ppm	
Sulphates	≤ 150	<150	ppm	
Ammonium	≤ 20	<20	ppm	
Calcium	≤ 100	<100	ppm	
Iron	≤ 20	<20	ppm	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Sodium hydrogen carbonate	99,0 - 101,0	100,11	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA)	$\leq 10^3$	$0,1 \times 10^1$	CFU/g	
Total yeasts and moulds (TYMC)	$\leq 10^2$	<1	CFU/g	

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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:

Agnieszka Pszczółka

Qualified Person

18-12-2023

Expiration: 15-05-2025

Conclusion: APPROVED

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