

Certificate of Analysis

Product name: **Sulfacetamidum natricum**

Batch number / Weight: **22B15-B04-232214 / 100 G**

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

Number of analysis / Inspection Code **22B15-B04 / INS-22-4052**

Reference Code / No.: **V01799 / 456430 (V6926)**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellowish) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Identification F	Conform	Conform		
Appearance of solution	Clear <=GY4	Conform		
pH	8,0 - 9,5	9,21		
Related substances	Conform	Conform		
Impurity A	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	<0,05		
Total impurities	<=0,5	0,00	%	
Sulphates	<= 200	Conform	ppm	
Water	6,0 - 8,0	7,30	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Sulfacetamide-Sodium	99,0 - 101,0	100,81	%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 lab

Release:
Dominika Soltysik
Qualified Person

07-11-2023

Expiration: 13-10-2026

Conclusion: APPROVED

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