

Certificate of Analysis

Productname: **Sulfacetamidum natricum**
Number of analysis/Inspection Code: 1 / KEUR-176592B
Batchnumber: **18J10-B02-362108**
Reference code / No.: 4121 / 451616
Analysed according to: **PH.EUR 9.5**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellowish) white, crystalline powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Identification F	Conform	Conform		Sodium
Appearance of solution	Clear <=GY4	Conform		5%/V
pH	8,0 - 9,5	8,7		5%/V
Related substances	Conform	Conform		HPLC
Impurity A	<=0,2	0,2	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,2	%	
Sulphates	<= 200	Conform	ppm	
Water	6,0 - 8,0	7,5	%	Karl Fischer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Sulfacetamide-Sodium	99,0 - 101,0	100,7	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

09/27/19

Expiration: 04-2023

Conclusion: APPROVED

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