

Certificate of Analysis

Product name: **Saccharinum natricum**
Batch number / Weight: **22K28-B09-230914 / 25 G**
Analysed according to: **Ph.Eur.11.1**
Number of analysis / Inspection Code **22K28-B09 / INS-23-0414**
Reference Code / No.: **V01401 / SH232/22**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Appearance	or colourless crystals, efflorescent in dry air			
Identification B	Conform	Conform		
Identification E	Conform	Conform		
Appearance of solution	Clear, colourless	Conform		
Acidity or alkalinity	Conform	Conform		
o- and p- Toluenesulfonamide	Conform	Conform		
o- Toluenesulfonamide	≤ 10	< 10	$\mu\text{g/g}$	
p- Toluenesulfonamide	≤ 10	0,0	$\mu\text{g/g}$	
Readily carbonisable substances	Conform	Conform		
Water (Karl Fischer)	$\leq 15,0$	14,32	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	100,45	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
TAMC	$\leq 10^3$	< 1	CFU/g	
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:
Dominika Soltysik
Qualified Person

23-06-2023

Expiration: 15-11-2027

Conclusion: APPROVED

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