

Certificate of Analysis

Product name: **Carboxymethylamylum natricum A**

Batch number / Weight: **22C15-B05-226735 / 100 G**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **22C15-B05 / INS-22-9928**

Reference Code / No.: **V01922 / 108JC75**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder very hygroscopic !	Conform Conform		
Identification A	5,5 - 7,5	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
pH	5,5 - 7,5	6,83		
Sodium glycollate	<= 2,0	<2,0	%	
Sodium chloride	<= 7,0	4,3	%	
Iron	<= 20	<20	ppm	
Loss on drying	<=10,0	6,57	%	
Assay Sodium	2,8 - 4,2	3,1	%m/m	
E. coli	Negative	Conform	/ g	
Salmonella	Negative	Conform	/ 10 g	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
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 EI Spol, CBMiA

Release:
Dominika Soltysik
Qualified Person

10-01-2023

Expiration: 31-10-2026

Conclusion: APPROVED

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