

Certificate of Analysis

Productname: Carboxymethylamylum natricum A
Number of analysis/Inspection Code: 1 / KEUR-186292B
Batchnumber: 20H19-F05-374007
Reference code / No.: 4350 / 105KZDJ
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder	Conform		Very hygroscopic !
Identification A	5,5 - 7,5	Conform		pH
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		Sodium
Appearance of solution	Clear and colourless	Conform		3.33%; supernatant liquid
pH	5,5 - 7,5	6,9		3.33%; supernatant vloeistof
Sodium glycollate	<= 2,0	<2,0	%	
Sodium chloride	<= 7,0	4,6	%	
Iron	<= 20	Conform	ppm	
Loss on drying	<=10,0	5,0	%	4 h 105 °C
Assay Sodium	2,8 - 4,2	3,8	%m/m	Washed and dried
E. coli	Negative	Conform	/ g	
Salmonella	Negative	Conform	/ 10 g	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
Paul Hofman
Pharmacist - Qualified Person

10/13/20

Expiration: 01-2025

Conclusion: APPROVED

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