

Certificate of Analysis

Product name: Natrii chloridum

Batch number / Weight: 21A21-B07-204496 / 5 KG

Analysed according to: Ph.Eur.

Tests	Requirement	Result	Unit	Standard remark
	white or almost white, crystalline powder or colourless crystals or white	Conform		
	or almost white pearls			
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	Conform	Conform		
Acidity or alkalinity	Conform	Conform		
Bromides	<=100	Conform	ppm	
Ferrous cyanides	Conform	Conform		
lodides	Conform	Conform		
Nitrates	Conform	Conform		
Phosphates	<=25	Conform	ppm	
Sulphates	<=200	Conform	ppm	
Aluminium		Conform	ppm	
Arsenic	<=1	Conform	ppm	
Barium	Conform	Conform		
Iron	<=2	Conform	ppm	
Magnesium and alcaline-earth metal	<=100	Conform	ppm	
Potassium		139	ppm	
Loss on drying	<=0,5	0,07	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 100,5 (dried substance)	99,29	%m/m	
Endotoxins		<5	IU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		
Total aerobic microbial count (TAMC)	<=10^3	Conform	CFU/g	
Total yeasts and moulds (TYMC)	<=10^2	Conform	CFU/g	

Analysis performed by the authorized lab.

Release:

Dominika Sołtysik Qualified Person



25-03-2021

Expiration: 17-11-2023

Conclusion: APPROVED

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