

## Certificate of Analysis

**Product name:** **Natrii chloridum**

**Batch number / Weight:** **22D05-B06-222946 / 100 G**

**Analysed according to:** **Ph. Eur. 10**

**Number of analysis / Inspection Code** **22D05-B06 / INS-22-3944**

**Reference Code / No.:** **V00789 / CRS190122**

Tests	Requirement	Result	Unit	Standard remark
Appearance	white or almost white, crystalline powder or colourless crystals	Conform		
Appearance	or (almost) white pearls			
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Acidity or alkalinity	Conform	Conform		
Bromides	$\leq 100$	Conform	ppm	
Ferrous cyanides	Conform	Conform		
Iodides	Conform	Conform		
Nitrites	Conform	Conform		
Phosphates	$\leq 25$	Conform	ppm	
Sulphates	$\leq 200$	$< 200$	ppm	
Aluminium	$\leq 0,2$	$< 0,1$	ppm	
Arsenic	$\leq 1$	Conform	ppm	
Barium	Conform	Conform		
Iron	$\leq 2$	Conform	ppm	
Magnesium and alkaline-earth metals	$\leq 100$	Conform	ppm	
Potassium	$\leq 500$	108	ppm	
Loss on drying	$\leq 0,5$	$< 0,01$	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 100,5	99,7	%m/m	
Endotoxins	$< 5$	$< 5$	IU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		

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Total aerobic microbial count (TA  $\leq 10^3$   
Total yeasts and moulds (TYMC)  $\leq 10^2$

<1 CFU/g  
<1 CFU/g

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, ElSpol

Release:  
Dominika Soltysik  
Qualified Person

21-09-2022

Expiration: 19-01-2025

Conclusion: APPROVED

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