

Certificate of Analysis

Product name: **Kalii chloridum**
Batch number / Weight: **22C11-B04-224360 / 1 KG**
Analysed according to: **Ph. Eur. 10.8**
Number of analysis / Inspection Code **22C11-B04 / INS-22-4642**
Reference Code / No.: **V00582 / 2022073224**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Acidity or alkalinity	Conform	0,15 ml NaO		
Bromides	$\leq 0,1$	Conform	%	
Iodides	Conform	Conform		
Sulphates	≤ 300	<300	ppm	
Aluminium	$\leq 1,0$	<0,5	ppm	
Iron	≤ 20	Conform	ppm	
Magnesium and alkaline-earth m	≤ 200	Conform	ppm	
Sodium	$\leq 0,1$	0,02	%	
Loss on drying	$\leq 1,0$	0,08	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay	99,0 - 101,0 (dried substance)	99,90	%m/m	
Endotoxins	$\leq 0,1$	<0,1	IU / mg	
Total aerobic microbial count (TA	Conform	<1	CFU / g	
Total yeasts and moulds (TYMC)	Conform	<1	CFU/g	
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 Fagron PL, EI Spol, CBMiA

Release:

Ewelina Gadzinowska

Qualified Person

04-11-2022

Expiration: 07-11-2024

Conclusion: APPROVED

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