

Certificate of Analysis

Product name: **Kalii chloridum**

Batch number / Weight: **23F23-B02-233658 / 1 KG**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **23F23-B02 / INS-23-5485**

Reference Code / No.: **V00582 / 2023217094**

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	Conform		
	<= 0,5 ml NaOH (0,01M) or HCl (0,01M)	(NaOH)0,05	ml	
Bromides	<= 0,1	<0,1	%	
Iodides	Conform	Conform		
Sulphates	<= 300	<300	ppm	
Aluminium	<= 1,0	<0,1	ppm	
Iron	<= 20	<20	ppm	
Magnesium and alkaline metals	<= 200	<200	ppm	
Sodium	<= 0,1	<0,01	%	
Loss on drying	<=1,0	0,03	%	
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)	99,36	%m/m	
Endotoxins	<= 0,1	<0,1	IU / mg	
Total aerobic microbial count (TA)	<=10	<1	CFU / g	
Total yeasts and moulds (TYMC)	<=1	<1	CFU/g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:fsne@fagron.pl

fagron.pl

Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl

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:

Agnieszka Pszczółka

Qualified Person

11-01-2024

Expiration: 01-02-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:fsne@fagron.pl