

Certificate of Analysis

Product name: **Kalii citras**
Batch number / Weight: **23E17-B06-230277 / 250 G**
Analysed according to: **Ph.Eur.11.2**
Number of analysis / Inspection Code **23E17-B06 / INS-23-5254**
Reference Code / No.: **V00894 / 3062076**

Tests	Requirement	Result	Unit	Standard remark
Appearance	white or almost white, granular powder or transparent crystals, hygroscopic	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
Acidity or alkalinity	Conform	Conform		
	$\leq 0,2$ ml NaOH (0,1M) or HCl (0,1M)	HCl 0,05	ml	
Readily carbonisable substances	$\leq Y2$ or GY2	Conform		
Chlorides	≤ 50	< 50	ppm	
Oxalates	≤ 300	< 300	ppm	
Sulphates	≤ 150	< 150	ppm	
Sodium	$\leq 0,3$	0,13	%	
Water (Karl Fischer)	4,0 - 7,0	5,60	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0-101,0 (dried substance)	99,48	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA)	$\leq 10^3$	< 1	CFU/g	
Total yeasts and moulds (TYMC)	$\leq 10^2$	< 1	CFU/g	

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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 FAPL, EISpol, CBMiA, Eurofins

Release:

Agnieszka Pszczółka

Qualified Person

12-09-2023

Expiration: 31-12-2027

Conclusion: APPROVED

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