

Certificate of Analysis

Productname: Kalii citras
Number of analysis/Inspection Code: 1 / KEUR-180149B
Batchnumber: 19K28-F05-367470
Reference code / No.: 3671 / 3051122
Analysed according to: PH.EUR10.0

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white granular powder or	Conform		Hygroscopic
Appearance	colorless crystals	Conform		
Identification A	Conform	Conform		Citrate
Identification B	Conform	Conform		Potassium
Appearance of solution	Clear and colourless	Conform		10% <i>m/V</i>
Acidity or alkalinity	Conform	Conform		
Readily carbonisable substances	<=Y2 or GY2	Conform		
Chlorides	<=50	Conform	ppm	
Oxalates	<=300	Conform	ppm	
Sulphates	<=150	Conform	ppm	
Sodium	<=0,3	0,2	%	AES
Water (Karl Fischer)	4,0 - 7,0	5,5	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Tripotassium citrate	99,0-101,0	100,8	% <i>m/m</i>	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/05/20

Expiration: 06-2024

Conclusion: APPROVED

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