

Certificate of Analysis

Product name: **Acidum citricum anh. cryst.**

Batch number / Weight: **23C01-B01-230270 / 250 G**

Analysed according to: **Ph.Eur.11.1**

Number of analysis / Inspection Code **23C01-B01 / INS-23-3125**

Reference Code / No.: **V01192 / UJ223**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White and colourless crystals	Conform		
Identification B	Conform	Conform		
Identification E	$\leq 1,0$	Conform		
Melting point	about 153	154,7	°C	
Appearance of solution	Clear / $\leq Y7$, BY7 or GY7	Conform		
Readily carbonisable substances	Conform	Conform		
Sulphates	≤ 150	< 150	ppm	
Oxalic acid		< 360	ppm	
Aluminium	$\leq 0,2$	$< 0,1$	ppm	
Water (Karl Fischer)	$\leq 1,0$	0,08	%	
Sulphated ash	$\leq 0,1$	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Citric acid	99,5 - 100,5	100,02	%m/m	
Endotoxins	$\leq 0,5$	$< 0,5$	IU / mg	
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

Release:

Ewelina Gadzinowska

Qualified Person

26-06-2023

Expiration: 06-06-2025

Conclusion: APPROVED

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