

Certificate of Analysis

Product name: **Acidum citricum monohydricum**

Batch number / Weight: **22D13-B04-216060 / 250 G**

Analysed according to: **Ph. Eur. 10.8**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White and colourless, transparent crystals	Conform		
Identification B	Conform	Conform		
Identification E	7,5 - 9,0	Conform	%	
Appearance of solution	Clear <=Y7, BY7 or GY7	Conform		
Readily carbonisable substances	Conform	Conform		
Oxalic acid	<=360	Conform	ppm	
Sulphates	<=150	C	ppm	
Water (Karl Fischer)	7,5 - 9,0	8,64	%	
Sulphated ash	<=0,1	0,03	%	
Assay Citric acid	99,5 - 100,5 (anhydrous substance)	99,67	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Endotoxins	< 0,5	<0,5	IU / mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA)	<=10 ³	Conform	CFU/g	
Total yeasts and moulds (TYMC)	<=10 ²	Conform	CFU/g	

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

05-08-2022

Expiration: 31-01-2025

Conclusion: APPROVED

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