

Certificate of Analysis

Product name: Acidum citricum anh. cryst.
Batch number / Weight: 20A21-B10-201709 / 250 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	White and colourless crystals	Conform		
Identification B	Conform	Conform		
Identification E	<=1,0	Conform	%	
Appearance of solution	Clear / <=Y7, BY7 or GY7	Conform		
Readily carbonisable substances	Conform	Conform		
Oxalic acid	<=360	Conform	ppm	
Sulphates	<=150	Conform	ppm	
Aluminium	<=0,2	Conform	ppm	
Water (Karl Fischer)	<=1,0	0,05	%	
Sulphated ash	<=0,1	0,02	%	
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	99,93	%m/m	
Endotoxins	<=0,5	<0,5	IU / mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

08-07-2020

Expiration: 31-05-2022

Conclusion: APPROVED

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