



Certificate of Analysis

1.00242.0000 Citric acid monohydrate cryst. EMPROVE® ESSENTIAL Ph Eur,BP,ChP,
JP,USP,E 330,FCC
Batch K56694042

	Spec. Values		Batch Values	
Assay (alkalimetric, calculated on anhydrous substance)	99.5 - 100.5	%	100.1	%
Identity (IR-spectrum)	passes test		passes test	
Identity (wet chemistry)	passes test		passes test	
Appearance	white to almost white or colorless crystals		passes test	
Appearance of solution (200 g/l; water)	clear (≤ 1.5 NTU) and not more intense in color than reference solution Y ₇ , BY ₇ or GY ₇		passes test	
Chloride (Cl)	≤ 5	ppm	≤ 5	ppm
Sulfate (SO ₄)	≤ 50	ppm	≤ 50	ppm
Heavy metals (as Pb)	≤ 5	ppm	≤ 5	ppm
Al (Aluminium)	≤ 0.2	ppm	≤ 0.2	ppm
As (Arsenic)	≤ 1	ppm	≤ 1	ppm
Ca (Calcium)	passes test		passes test	
Fe (Iron)	≤ 10	ppm	≤ 10	ppm
Hg (Mercury)	≤ 1	ppm	≤ 1	ppm
Pb (Lead)	≤ 0.5	ppm	≤ 0.5	ppm
Oxalates (as C ₂ H ₂ O ₄)	≤ 100	ppm	≤ 100	ppm
Oxalate (C ₂ H ₂ O ₄) (ChP)	passes test		passes test	
Residual solvents (ICH (Q3C))	excluded by manufacturing process		excluded by manufacturing process	
Readily carbonisable substance	passes test		passes test	
Sulfated ash (600 °C)	≤ 0.05	%	< 0.01	%
Water (according to Karl Fischer)	7.5 - 8.8	%	8.5	%
Bacterial endotoxins	< 0.5	I.U./mg	< 0.1	I.U./mg

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).

Corresponds to Ph. Eur., BP, ChP, JP, USP, E 330, FCC

Conforms to the purity criteria on food additives according to the current European Commission Regulation.

Date of manufacture (DD.MM.YYYY) 02.04.2025

Date of examination (DD.MM.YYYY) 14.05.2025

Minimum shelf life (DD.MM.YYYY) 30.04.2028

Dr. Sebastian Lips

Responsible laboratory manager quality control

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