



# Certificate of Analysis

1.06432.0000 tri-Sodium citrate dihydrate cryst., EMPROVE® ESSENTIAL Ph Eur,BP,JP,  
USP,E 331  
Batch K56423132

	Spec. Values		Batch Values	
Assay (Perchloric acid titration, calc. on anhydrous substance (Ph Eur))	99.0 - 101.0	%	99.8	%
Assay (Perchloric acid titration, previously dried substance) (JP/USP)	99.0 - 100.5	%	100.1	%
Identity (Na)	passes test		passes test	
Identity (Citrate)	passes test		passes test	
Identity (reaction upon ignition)	passes test		passes test	
Appearance	white to almost white crystals		passes test	
Appearance of solution (100 g/l, CO <sub>2</sub> -free water)	clear and colorless		passes test	
Acidity or alkalinity	passes test		passes test	
pH (50 g/l CO <sub>2</sub> -free water)	7.5 - 8.5		8.4	
Chloride (Cl)	≤ 50	ppm	≤ 50	ppm
Sulfate (SO <sub>4</sub> )	≤ 150	ppm	≤ 150	ppm
Al (Aluminium)	≤ 5	ppm	≤ 5	ppm
As (Arsenic)	≤ 1	ppm	≤ 1	ppm
Hg (Mercury)	≤ 1	ppm	≤ 1	ppm
Pb (Lead)	≤ 1	ppm	≤ 1	ppm
Oxalate (as C <sub>2</sub> H <sub>2</sub> O <sub>4</sub> )	≤ 100	ppm	≤ 100	ppm
Tartrate (C <sub>4</sub> H <sub>4</sub> O <sub>6</sub> )	passes test		passes test	
Residual solvents (ICH (Q3C))	excluded by manufacturing process		excluded by manufacturing process	
Readily carbonisable substance	passes test		passes test	
Water (according to Karl Fischer)	11.0 - 13.0	%	12.3	%
Loss on drying (180 °C, 18 h)	10.0 - 13.0	%	12.2	%

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, JP, USP, E 331

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

Date of manufacture (DD.MM.YYYY) 09.11.2024

Date of examination (DD.MM.YYYY) 16.01.2025

Minimum shelf life (DD.MM.YYYY) 30.11.2027

Dr. Sebastian Lips

Responsible laboratory manager quality control

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