



Certificate of Analysis

1.37042.9029 TRI-SODIUM CITRATE DIHYDRAT. CRYST. EMPROVE® EXPERT
Ph Eur,BP,JP,USP,ACS
Batch K51603842

	Spec. Values		Batch Values	
Assay (Perchloric acid titration, calc. on anhydrous substance (Ph Eur))	99.0 - 101.0	%	99.4	%
Assay (Perchloric acid titration, previously dried substance) (JP/USP)	99.0 - 100.5	%	99.6	%
Identity (Na)	passes test		passes test	
Identity (Citrate)	passes test		passes test	
Identity (reaction upon ignition)	passes test		passes test	
Appearance	white crystals		passes test	
Appearance of solution (100 g/l, CO ₂ -free water)	clear and colorless		passes test	
Acidity or alkalinity	passes test		passes test	
pH (50 g/l CO ₂ -free water)	7.5 - 8.5		8.5	
In water insoluble matter #	≤ 50	ppm	≤ 50	ppm
Chloride (Cl)	≤ 30	ppm	≤ 30	ppm
Sulfate (SO ₄)	≤ 50	ppm	≤ 50	ppm
Heavy metals (as Pb)	≤ 5	ppm	≤ 5	ppm
Al (Aluminium)	≤ 5	ppm	≤ 5	ppm
As (Arsenic)	≤ 2	ppm	≤ 2	ppm
NH ₄ (Ammonium) #	≤ 30	ppm	≤ 30	ppm
Ca (Calcium) #	≤ 50	ppm	< 5	ppm
Fe (Iron) #	≤ 5	ppm	< 5	ppm
Oxalate (as C ₂ H ₂ O ₄)	≤ 300	ppm	≤ 300	ppm
Tartrate (C ₄ H ₄ O ₆)	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	%	12.4	%
Loss on drying (180 °C, 18 h)	10.0 - 13.0	%	12.2	%
Total aerobic microbial count (TAMC)	≤ 100	CFU/g	< 1	CFU/g
Total combined yeasts/moulds count (TYMC)	≤ 10	CFU/g	< 1	CFU/g
Bile-tolerant gram-negative bacteria (absent in 1 g)	passes test		passes test	
Candida albicans (absent in 1 g)	passes test		passes test	
Escherichia coli (absent in 1 g)	passes test		passes test	
Pseudomonas aeruginosa (absent in 1 g)	passes test		passes test	
Salmonella (absent in 10 g)	passes test		passes test	
Staphylococcus aureus (absent in 1 g)	passes test		passes test	
Bacterial endotoxins	≤ 2.5	I.U./g	< 1.6	I.U./g

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Additional requirements by ACS

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, ACS

Date of manufacture (DD.MM.YYYY) 29.07.2019

Date of examination (DD.MM.YYYY) 04.11.2019

Minimum shelf life (DD.MM.YYYY) 31.07.2022

Dr. Sebastian Lips

Responsible laboratory manager quality control

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