Specification

1.37003.1000 Citric acid monohydrate cryst. EMPROVE® EXPERT Ph Eur,BP,ChP,JP, USP

	Specification	
Assay (alkalimetric, calculated on anhydrous substance)	99.5 - 100.5	%
Identity (IR-spectrum)	passes test	
Identity (wet chemistry)	passes test	
Appearance	white to almost white or colorless crystals	
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	
Chloride (Cl)	≤ 5	ppm
Sulfate (SO_4)	≤ 50	ppm
Heavy metals (as Pb)	≤ 5	ppm
Al (Aluminium)	≤ 0.2	ppm
As (Arsenic)	≤ 1	ppm
Ca (Calcium)	passes test	
Fe (Iron)	≤ 10	ppm
Oxalates (as $C_2H_2O_4$)	≤ 360	ppm
Oxalate ($C_2H_2O_4$) (ChP)	passes test	
Residual solvents (ICH (Q3C))	excluded by manufacturing process	
Readily carbonisable substance	passes test	
Sulfated ash (600 °C)	≤ 0.05	%
Water (according to Karl Fischer)	7.5 - 9.0	%
Total aerobic microbial count (TAMC)	≤ 100	CFU/g
Total combined yeasts/moulds count (TYMC)	≤ 10	CFU/g
Bile-tolerant gram-negative bacteria (absent in 1 g)	passes test	
Candida albicans (absent in 1 g)	passes test	
Escherichia coli (absent in 1 g)	passes test	
Pseudomonas aeruginosa (absent in 1 g)	passes test	
Salmonella (absent in 10 g)	passes test	
Staphylococcus aureus (absent in 1 g)	passes test	
DNases (Exo- and endonucleases)	not detectable	
RNases	not detectable	
Bacterial endotoxins	< 10	I.U./g

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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

Dr. Sebastian Lips
Responsible laboratory manager quality control

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