



Specification

Concerning Product:	
Article number	5785444LPUL
Trade name / designation / denomination	Tri-Calciumcitrat-4-hydrat Pharma quality
CAS number	5785-44-4
Other names / synonyms	•Calcium citrate tetrahydrate; •Calcium citrate tetrahydrate micronised; •tricalcium 2-hydroxypropane-1,2,3-tricarboxylate tetrahydrate;
Molecular weight [g / mol]	570.49452
Formula	C ₁₂ H ₁₈ Ca ₃ O ₁₈

Parameter	Specification	Unit
Organoleptic test		
Appearance of solution	complies	
Appearance	white powder	
Physical parameter		
Loss on drying	(150 °C / 4h) 10.0 – 13.3	%
Loss on drying	(180 °C / 4h) 11.5 – 13.5	%
pH value	5.0 – 6.0	
Solubility	Hydrochloric acid-insoluble ≤ 0,2	%
Identity		
Assay	Ca ₃ (C ₆ H ₅ O ₇) ₂ * 4H ₂ O ≥ 98,0	%
Assay	calculated on dried substance 98,0 – 100,5	%
Identification	Behavior against sulfuric acid: complies	
Identification	complies	
Impurities		
Oxalate (as anhydros Oxalic Acid)	≤ 0,03	ppm
Oxalate (as anhydros Oxalic Acid)	(C ₂ H ₂ O ₄) ≤ 0,01	ppm
Sulphates (SO ₄)	≤ 0,01	%
Impurity	Carbonat: complies	%
Residual Solvents		
Residual solvents	We confirm that the product is in the production, bottling and Storage with the in the Ph.Eur. (I 283/95) and USP <467> organic solvents ("residual solvents") are not in contact comes.	

Elemental Impurities		
Aluminium (Al)	≤ 200	mg/kg
Arsenic (As)	≤ 1	mg/kg
Cadmium (Cd)	≤ 1	ppm
Chlorides (Cl)	≤ 0,01	%
Fluorine (F)	≤ 30	mg/kg
Iron (Fe)	≤ 0,1	%
Mercury (Hg)	≤ 1	mg/kg
Lead (Pb)	≤ 0,001	%
Lead (Pb)	(Pb, ICH-Q3D): ≤ 1	ppm
Microbiological data		
Total Plate Count	≤ 2000	CFU/g
Yeast and Mould	≤ 200	CFU/g

Regulatory information:

Elemental Impurities: Other elements are not knowingly added. The specification includes monograph-specific element contaminants. These will continue to be considered in the specification according to the monograph specification.

The manufacturer confirms that the product has been evaluated according to the ICH Guideline Q3D and that no elements have been identified as potential contaminants.

Unless otherwise specified or specified, the presence of Class 1-3 elements (classification according to ICH Q3D) above the Q3D Option 1 limit is unlikely according to a review.

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 05. Nov. 2019

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