



Specification

1.28205.0000 Sodium acetate trihydrate EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP

	Spec. Values	
Assay (perchloric acid titration, calculated on dried substance)	99.5 - 101.0	%
Identity	passes test	
Appearance	colorless crystals	
Appearance of solution	passes test	
In water insoluble matter	≤ 0.03	%
Acidity or alkalinity	passes test	
pH-value (5 %; water)	7.5 - 9.0	
Chloride (Cl)	≤ 0.005	%
Sulfate (SO ₄)	≤ 0.003	%
Heavy metals (as Pb)	≤ 0.0006	%
Al (Aluminium)	≤ 0.00002	%
As (Arsenic)	≤ 0.0001	%
Ca (Calcium)	≤ 0.002	%
Fe (Iron)	≤ 0.0006	%
K (Potassium)	≤ 0.005	%
Mg (Magnesium)	≤ 0.002	%
Ca + Mg (calcium and magnesium)	passes test	
free acetic acid	≤ 0.4	%
Other residual solvents (ICH Q3C)	excluded by manufacturing process	
Substances reducing potassium permanganate (as HCOOH)	passes test	
Loss on drying (130 °C)	39.0 - 40.5	%
Endotoxins	≤ 2.5	IU/g
Total aerobic microbial count (TAMC)	≤ 100	CFU/g
Total combined yeasts and molds count (TYMC)	≤ 100	CFU/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

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