



Certificate of Analysis

1.37046.1000 Sodium acetate anhydrous EMPROVE® EXPERT USP
Batch AM1668346

	Spec. Values		Batch Values	
Assay (perchloric acid titration, calculated on dried substance)	99.0 - 101.0	%	99.5	%
Identity	passes test		passes test	
In water insoluble matter	≤ 0.05	%	≤ 0.05	%
pH-value (3 %, water)	7.5 - 9.2		8.7	
Chloride (Cl)	≤ 0.01	%	≤ 0.01	%
Sulfate (SO ₄)	≤ 0.0050	%	≤ 0.0050	%
Heavy metals (as Pb)	≤ 0.001	%	≤ 0.001	%
Al (Aluminium)	≤ 0.00002	%	≤ 0.00002	%
K (Potassium)	≤ 0.003	%	≤ 0.003	%
Calcium and Magnesium	passes test		passes test	
Assay (Acetic acid)	≤ 0.4	%	≤ 0.4	%
Loss on drying (120 °C)	≤ 1.0	%	0.2	%
Other residual solvents (ICH Q3C)	excluded by manufacturing process		excluded by manufacturing process	
Endotoxins	≤ 2.5	I.U./g	≤ 2.5	I.U./g
Total aerobic microbial count	≤ 100	CFU/g	≤ 100	CFU/g
Total yeast and mould count	≤ 100	CFU/g	≤ 100	CFU/g

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 USP

Date of manufacture (DD.MM.YYYY) 29.10.2020

Date of examination (DD.MM.YYYY) 29.12.2020

Minimum shelf life (DD.MM.YYYY) 31.10.2022

Claudia Wiegand

Responsible laboratory manager quality control

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