



Specification

1.06398.0000 Sodium carbonate anhydrous EMPROVE® ESSENTIAL Ph Eur,BP,ChP,JP, NF

Spec. Values		
Assay (acidimetric; calculated on dried substance)	99.5 - 100.5	%
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Identity	passes test	
Appearance of solution	passes test	
Chloride (Cl)	≤ 0.0125	%
Sulfate (SO ₄)	≤ 0.0250	%
As (Arsenic)	≤ 0.00020	%
Fe (Iron)	≤ 0.0050	%
Alkali hydroxides and Alkali hydrogen carbonates	passes test	
Heavy metals (as Pb)	≤ 0.0010	%
Residual solvents (ICH Q3C)	excluded by manufacturing process	
Loss on drying (300 °C)	≤ 0.5	%

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, NF

The original manufacturer name and address will be disclosed subsequent to signing a confidentiality agreement.

Kristin Starke
Responsible laboratory manager quality control

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