



Specification

1.16224.1000 Sodium chloride EMPROVE® EXPERT Ph Eur,BP,JP,USP

	Specification	
Assay (argentometric; calculated on dried substance)	99.5 - 100.5	%
Identity (wet chemistry)	passes test	
Appearance of solution	passes test	
Acidity or alkalinity	passes test	
Bromide (Br)	≤ 50	ppm
Ferrocyanides	passes test	
Iodide (I)	passes test	
Nitrite (NO ₂) (UV-absorption 354nm; 1cm; 10%; water)	≤ 0.01	
Phosphate (PO ₄)	≤ 25	ppm
Sulfate (SO ₄)	≤ 200	ppm
Heavy metals (as Pb)	≤ 3	ppm
Al (Aluminium)	≤ 0.2	ppm
As (Arsenic)	≤ 1	ppm
Ba (Barium)	passes test	
Ca (Calcium)	≤ 20	ppm
Fe (Iron)	≤ 2	ppm
K (Potassium)	≤ 100	ppm
Magnesium and alkaline-earth metals (as Ca)	≤ 100	ppm
Residual solvents (ICH Q3C)	excluded by production process	
Loss on drying (105 °C, 2 h)	≤ 0.5	%
Endotoxins (kinetic turbidimetric test)	≤ 2.5	I.U./g
Microbiological purity (Total aerobic microbial count (TAMC))	≤ 1•10 ²	CFU/g
Microbiological purity (Total yeast and mould count (TYMC))	≤ 1•10 ¹	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 Ph Eur, BP, JP, USP

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Responsible laboratory manager quality control

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