



Certificate of Analysis

1.37017.5000 Sodium chloride suitable for the biopharmaceutical production EMPROVE®
bio Ph Eur, BP, JP, USP
Batch K50810717

	Spec. Values		Batch Values	
Assay (argentometric; calculated on dried substance)	99.5 - 100.5	%	99.6	%
Identity	passes test		passes test	
Appearance of solution	passes test		passes test	
Acidity or alkalinity	passes test		passes test	
Bromide (Br)	≤ 0.005	%	≤ 0.005	%
Ferrocyanides	passes test		passes test	
Iodide (I)	passes test		passes test	
Nitrite (NO ₂) (UV-absorption 354nm; 1cm; 10%; water)	≤ 0.01		≤ 0.01	
Phosphate (PO ₄)	≤ 0.0025	%	≤ 0.0025	%
Sulfate (SO ₄)	≤ 0.0200	%	≤ 0.0200	%
Heavy metals (as Pb)	≤ 0.0003	%	≤ 0.0003	%
Al (Aluminium)	≤ 0.00002	%	≤ 0.00002	%
As (Arsenic)	≤ 0.0001	%	≤ 0.0001	%
Ba (Barium)	passes test		passes test	
Ca (Calcium)	≤ 0.002	%	≤ 0.002	%
Fe (Iron)	≤ 0.0002	%	≤ 0.0002	%
K (Potassium)	≤ 0.01	%	≤ 0.01	%
Magnesium and alkaline-earth metals (as Ca)	≤ 0.0100	%	≤ 0.0100	%
Residual solvents (ICH Q3C)	excluded by production process		excluded by production process	
Loss on drying (105 °C, 2 h)	≤ 0.5	%	≤ 0.5	%
Endotoxins (kinetic turbidimetric test)	≤ 2.5	I.U./g	≤ 2.5	I.U./g
Microbiological purity (Total aerobic microbial count (TAMC))	≤ 100.0	CFU/g	≤ 100.0	CFU/g
Microbiological purity (Total yeast and mould count (TYMC))	≤ 100.0	CFU/g	≤ 100.0	CFU/g
DNases (Exo- and endonucleases) (not detectable)	passes test		passes test	
RNases (not detectable)	passes test		passes test	
Proteases (not detectable)	passes test		passes test	
Nicking Activity (not detectable)	passes test		passes test	

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

Date of examination (DD.MM.YYYY) 14.11.2018

Minimum shelf life (DD.MM.YYYY) 30.11.2023

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