



Specification

1.37093.0000 Sodium dihydrogen phosphate monohydrate EMPROVE® EXPERT BP,
ChP, USP

	Spec. Values	
Assay (alkalimetric, calculated on dried substance)	98.0 - 100.5	%
Assay (alkalimetric, calculated on anhydrous substance)	98.0 - 100.5	%
Assay (alkalimetric, calculated on dried substance; ChP)	98.0 - 100.5	%
Identity	passes test	
Appearance of solution	passes test	
Insoluble substances	≤ 0.2	%
pH-value (5 %; water)	4.2 - 4.5	
Acidity	4.1 - 4.7	
Chloride (Cl)	≤ 0.0100	%
Sulfate (SO ₄)	≤ 0.0300	%
Heavy metals (as Pb)	≤ 0.0010	%
Al (Aluminium)	≤ 0.0002	%
As (Arsenic)	≤ 0.0002	%
Fe (Iron)	≤ 0.0010	%
Aluminium, Calcium and related elements	passes test	
Calcium salt	≤ 0.01	%
Reducing substances	passes test	
Residual solvents (ICH Q3C)	excluded by manufacturing process	
Loss on drying (130 °C)	11.5 - 14.5	%
Water	10.0 - 15.0	%
Endotoxins	≤ 2.5	I.U./g
Total aerobic microbial count	≤ 100	CFU/g
Total yeast and mould count	≤ 100	CFU/g
DNases (Exo- and endonucleases)	passes test	
RNases (not detectable)	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 BP, ChP, USP

Kristin Starke

Responsible laboratory manager quality control

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