



Specification

1.37018.0000 Sodium dihydrogen phosphate dihydrate EMPROVE® EXPERT Ph Eur,BP, ChP,USP,JPE

	Spec. Values	
Assay (alkalimetric, calculated on dried substance)	98.0 - 100.5	%
Assay (alkalimetric; dried substance)	98.0 - 101.0	%
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	
In water insoluble matter (calculated on dried substance)	≤ 0.15	%
pH-value (1 %, water)	4.1 - 4.7	
pH-value (5 %; water)	4.2 - 4.5	
pH-value (5.7 %; water)	4.1 - 4.5	
Acidity	4.1 - 4.7	
Chloride (Cl)	≤ 0.005	%
Sulfate (SO ₄)	≤ 0.01	%
Heavy metals (as Pb)	≤ 0.0005	%
Al, Ca and other elements detectable with ammonia	passes test	
Al (Aluminium)	≤ 0.01	%
As (Arsenic)	≤ 0.0001	%
Calcium salt	≤ 0.01	%
Fe (Iron)	≤ 0.0010	%
Residual solvents (ICH Q3C)	excluded by production process	
Substances reducing potassium permanganate (as O)	passes test	
Loss on drying (130 °C)	22.0 - 24.0	%
Water (according to Karl Fischer)	22.0 - 24.0	%
Endotoxins	≤ 2.5	I.U./g
Total aerobic microbial count	≤ 100	CFU/g
Total yeast and mould count	≤ 100	CFU/g
E.coli (absent in 1g)	passes test	
Pseudomonas aeruginosa (absent in 1g)	passes test	
Staphylococcus aureus (absent in 1g)	passes test	
Salmonella species (absent in 10g)	passes test	
Bile tolerante gram negative bacteria (absent in 1g)	passes test	
Candida albicans (absent in 1g)	passes test	
DNases (Exo- and endonucleases) (not detectable)	passes test	

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RNases (not detectable)	passes test
Proteases (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 Ph Eur, BP, ChP, USP, JPE

Kristin Starke

Responsible laboratory manager quality control

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