



# Specification

1.37039.0000 Potassium dihydrogen phosphate cryst. EMPROVE® EXPERT Ph Eur, BP, JPC, NF

	Spec. Values	
Assay (alkalimetric, calculated on dried substance)	98.0 - 100.5	%
Assay (alkalimetric; dried substance)	≥ 99.0	%
Identity	passes test	
Appearance of solution	passes test	
Insoluble substances	≤ 0.2	%
pH-value (2 %; water)	4.2 - 4.6	
pH-value (5 %; water)	4.2 - 4.5	
Carbonate	passes test	
Condensed phosphate	passes test	
Chloride (Cl)	≤ 0.009	%
Fluoride (F)	≤ 0.0010	%
Sulfate (SO <sub>4</sub> )	≤ 0.017	%
Heavy metals (as Pb)	≤ 0.0010	%
Al (Aluminium)	≤ 0.0005	%
As (Arsenic)	≤ 0.0001	%
Fe (Iron)	≤ 0.0010	%
Na (Sodium)	≤ 0.1	%
Na (Sodium)	passes test	
Pb (Lead)	≤ 0.0004	%
Sb (Antimony) (*)	≤ 0.0009	%
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) (not detectable)	passes test	
RNases (not detectable)	passes test	
Proteases (not detectable)	passes test	
Residual solvents (ICH Q3C)	excluded by manufacturing process	
Reducing substances	passes test	
Loss on drying (105 °C)	≤ 0.5	%
Loss on drying (130 °C)	≤ 1.0	%

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, JPC NF

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Kristin Starke

Responsible laboratory manager quality control

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