Certificate of Analysis

1.37010.0000 di-Potassium hydrogen phosphate anhydrous EMPROVE® EXPERT Ph Eur,BP,USP
Batch AM2087810

	Spec. Values		Batch Values	
Assay (alkalimetric, calculated on dried substance)	98.0 - 100.5	%	100.1	%
Identity	passes test		passes test	
Appearance of solution	passes test		passes test	
Insoluble substances	≤ 0.2	%	≤ 0.2	%
pH-value (5 %; water)	8.5 - 9.6		9.2	
Carbonate	passes test		passes test	
Chloride (Cl)	≤ 0.02	%	≤ 0.02	%
Fluoride (F)	≤ 0.001	%	≤ 0.001	%
Sulfate (SO_4)	≤ 0.1	%	≤ 0.1	%
Al (Aluminium)	≤ 0.0005	%	≤ 0.0005	%
As (Arsenic)	≤ 0.0002	%	≤ 0.0002	%
Fe (Iron)	≤ 0.0010	%	≤ 0.0010	%
Na (Sodium)	≤ 1.5	%	≤ 1.5	%
Na (sodium)	passes test		passes test	
Potassium dihydrogen phosphate	≤ 2.5	%	< 0.3	%
Potassium dihydrogen phosphate and tri-Potassium phosphate	passes test		passes test	
Residual solvents (ICH Q3C)	excluded by manufacturing process		excluded by manufacturing process	
Reducing substances	passes test		passes test	
Loss on drying (130 °C)	≤ 1.0	%	0.3	%
Endotoxins	≤ 2.5	I.U./g	≤ 2.5	I.U./g
Total aerobic microbial count	≤ 100	CFU/g	≤ 100	CFU/g
Total yeast and mould count	≤ 100	CFU/g	≤ 100	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	

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,USP

Date of manufacture (DD.MM.YYYY) 29.10.2024
Date of examination (DD.MM.YYYY) 06.12.2024
Minimum shelf life (DD.MM.YYYY) 31.10.2026

Kristin Starke
Responsible laboratory manager quality control

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