



Certificate of Analysis

1.01042.9029 Aluminium potassium sulfate dodecahydrate EMPROVE® ESSENTIAL
Ph Eur, BP, USP
Batch AM1747242

	Spec. Values		Batch Values	
Assay (complexometric)	99.0 - 100.5	%	99.7	%
Assay (complexometric; calculated on dried substance)	99.0 - 100.5	%	99.2	%
Identity	passes test		passes test	
Appearance of solution	passes test		passes test	
pH-value (10 %; water)	3.0 - 3.5		3.0	
Heavy metals (as Pb)	≤ 0.002	%	≤ 0.002	%
Cr (Chromium)	≤ 0.0003	%	≤ 0.0003	%
Fe (Iron)	≤ 0.01	%	≤ 0.01	%
NH ₄ (Ammonium)	≤ 0.2	%	≤ 0.2	%
Residual solvents (ICH Q3C)	excluded by manufacturing process		excluded by manufacturing process	
Loss on drying (400 °C)	43.0 - 46.0	%	45.3	%

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) 12.05.2021

Date of examination (DD.MM.YYYY) 02.07.2021

Minimum shelf life (DD.MM.YYYY) 31.05.2026

Claudia Wiegand

Responsible laboratory manager quality control

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