



# Certificate of Analysis

1.01042.9029 Aluminium potassium sulfate dodecahydrate EMPROVE® ESSENTIAL  
Ph Eur, BP, USP  
Batch AM1270242

	Spec. Values		Batch Values	
Assay (complexometric)	99.0 - 100.5	%	99.1	%
Assay (complexometric; calculated on dried substance)	99.0 - 100.5	%	99.5	%
Identity	passes test		passes test	
Appearance of solution	passes test		passes test	
pH-value (10 %; water)	3.0 - 3.5		3.1	
Heavy metals (as Pb)	≤ 0.002	%	≤ 0.002	%
Cr (Chromium)	≤ 0.0003	%	≤ 0.0003	%
Fe (Iron)	≤ 0.01	%	≤ 0.01	%
NH <sub>4</sub> (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	%	45.8	%

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 examination (DD.MM.YYYY) 06.02.2018  
Minimum shelf life (DD.MM.YYYY) 28.02.2023

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