



Certificate of Analysis

1.06360.0000 Sodium bromide EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP
Batch K56128860

	Spec. Values		Batch Values	
Assay according to Ph Eur/BP (argentometric; calculated on dried substance)	99.0 - 100.5	%	99.8	%
Assay according to USP (argentometric; calculated on dried substance)	99.0 - 100.5	%	99.7	%
Assay according to JP (argentometric; calculated on dried substance)	99.0 - 100.5	%	100.1	%
Identity	passes test		passes test	
Appearance of solution	passes test		passes test	
Alkalinity	passes test		passes test	
Acidic or alkaline impurities	passes test		passes test	
Bromate(BrO ₃)	passes test		passes test	
Chloride (Cl)	≤ 0.2	%	≤ 0.2	%
Iodide (I)	passes test		passes test	
Sulfate (SO ₄)	≤ 0.005	%	≤ 0.005	%
Heavy metals (as Pb)	≤ 0.001	%	≤ 0.001	%
As (Arsenic)	≤ 0.00015	%	≤ 0.00015	%
Ba (Barium)	passes test		passes test	
Ca (Calcium)	≤ 0.005	%	≤ 0.005	%
Fe (Iron)	≤ 0.001	%	≤ 0.001	%
Mg (Magnesium)	≤ 0.002	%	≤ 0.002	%
Magnesium and alkaline-earth metals (as Ca)	≤ 0.02	%	≤ 0.02	%
Residual solvents (Ph Eur/ICH)	excluded by manufacturing process		excluded by manufacturing process	
Loss on drying (110 °C)	≤ 3.0	%	0.1	%

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 (*).

Conforms to Ph Eur, BP, USP, JP

Date of manufacture (DD.MM.YYYY) 15.01.2024

Date of examination (DD.MM.YYYY) 02.08.2024

Minimum shelf life (DD.MM.YYYY) 31.01.2029

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Responsible laboratory manager quality control

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