



Certificate of Analysis

1.06357.9029 Sodium disulfite (sodium metabisulfite) EMPROVE® ESSENTIAL Ph Eur,
BP,JP,NF,E 223
Batch K55479857

	Spec. Values		Batch Values	
Assay (iodometric)	97.0 - 100.0	%	98.2	%
Assay (iodometric, SO ₂)	65.4 - 67.4	%	66.2	%
Identity	passes test		passes test	
Appearance of solution	passes test		4.2	
pH-value (5 %; water)	3.5 - 5.0		≤ 0.01	%
Chloride (Cl)	≤ 0.01	% ✕	≤ 0.001	%
Heavy metals (as Pb)	≤ 0.001	% ✕	≤ 0.05	%
Thiosulfate (S ₂ O ₃)	≤ 0.05	% ✓	≤ 0.0002	%
As (Arsenic)	≤ 0.0002	% ✕	≤ 0.0005	%
Fe (Iron)	≤ 0.0005	% ✕	≤ 0.0001	%
Hg (Mercury)	≤ 0.0001	%	≤ 0.0002	%
Pb (Lead)	≤ 0.0002	%	≤ 0.0003	%
Se (Selenium)	≤ 0.0003	%	excluded by the manufacturing process	
Residual solvents (Ph Eur/USP/ICH)	excluded by the manufacturing process			

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 the purity criteria on food additives according to the current European Commission Regulation.
Conforms to Ph Eur, BP, JP, NF, E223

Date of manufacture (DD.MM.YYYY) 08.08.2023
Date of examination (DD.MM.YYYY) 21.08.2023
Minimum shelf life (DD.MM.YYYY) 31.08.2025

Dr. Dimitrij Ryvlin
Responsible laboratory manager quality control

This document has been produced electronically and is valid without a signature.

STANDARISASI CERTIFICATE OF ANALYSIS BAHAN BAKU

No	Nama Bahan	Manufaktur	Referensi pada CoA Manufacturer saat ini	Referensi pada CoA yang digunakan	Penyesuaian Parameter			Nomor SPBB	Keterangan
					Parameter yang Dihilangkan	Parameter yang Ditambah	Parameter yang direvisi		
1	Sodium Metabisulfite	Merck	USP/EP/BP/JP	USP 47/FI VI	Identifikasi C (Nanoram)		Pemerian di sesuaikan dengan USP 47 (Crystalin Powder)	RD-02-SBP/057.00	Update SPBB
							Tiosulfat : ≤ 0.05%		Update SPBB dan Penyesuaian CoA dari Manufacturer
							Klorida : ≤ 0.05%		

Diperiksa Oleh

Disetujui Oleh,

Koordinator QC

Koordinator TS

Koordinator QA

Manajer QA