

23/09/2022



Certificate of Analysis

1.06441.9025 Sodium fluoride EMPROVE® API Ph Eur,BP,USP
Batch FN1486241

	Spec. Values		Batch Values		Method
Assay (precipitative titration, calculated on dried substance)	98.5 - 100.5	%	99.3	%	In-house
Identity	passes test		passes test		In-house
Appearance of solution	clear and colourless		clear and colourless		Ph.Eur.
Alkalinity (as NaOH)	≤ 0.1	%	< 0.1	%	In-house
Acidity (as HF)	≤ 0.2	%	< 0.1	%	USP
Chloride (Cl)	≤ 0.01	%	≤ 0.01	%	In-house
Hexafluorosilicate (SiF ₆)	≤ 0.1	%	≤ 0.1	%	In-house
Sulfate (SO ₄)	≤ 0.02	%	≤ 0.02	%	Ph.Eur.
Heavy metals (as Pb)	≤ 0.003	%	≤ 0.003	%	In-house
Fe (Iron)	≤ 0.005	%	< 0.005	%	In-house
Loss on drying (150 °C, 4 h)	≤ 0.5	%	0.1	%	USP
Residual solvents (Ph Eur/USP/ICH)	Excluded by manufacturing process		Excluded by 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 Ph.Eur., BP, USP

Date of manufacture (DD.MM.YYYY) 31.08.2020

Date of examination (DD.MM.YYYY) 31.05.2021

Minimum shelf life (DD.MM.YYYY) 31.08.2025

Andreas Lang

Responsible laboratory manager quality control

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