



Certificate of Analysis

1.06441.9025 Sodium fluoride suitable for use as an active pharmaceutical ingredient
EMPROVE® api Ph Eur,BP,USP
Batch FN1370141

	Spec. Values		Batch Values	
Assay (precipitative titration, calculated on dried substance)	98.5 - 100.5	%	100.5	%
Identity	passes test		passes test	
Appearance of solution	clear and colourless		clear and colourless	
Alkalinity (as NaOH)	≤ 0.1	%	< 0.1	%
Acidity (as HF)	≤ 0.2	%	< 0.1	%
Chloride (Cl)	≤ 0.01	%	≤ 0.01	%
Hexafluorosilicate (SiF ₆)	≤ 0.1	%	≤ 0.1	%
Sulfate (SO ₄)	≤ 0.02	%	≤ 0.02	%
Heavy metals (as Pb)	≤ 0.003	%	≤ 0.003	%
Fe (Iron)	≤ 0.005	%	< 0.005	%
Loss on drying (150 °C, 4 h)	≤ 0.5	%	0.1	%
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 examination (DD.MM.YYYY) 13.11.2017

Minimum shelf life (DD.MM.YYYY) 31.07.2022

Manuel Schaffroth

Responsible laboratory manager quality control

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