



Specification

4.80648.0000 Sodium hydroxide solution 10 mol/L EMPROVE® EXPERT

	Specification	
Assay (acidimetric,NaOH)	9.9 - 10.1	mol/l
Assay (acidimetric)	29.9 - 30.3	%
Identity	passes test	
Carbonate (as Na ₂ CO ₃)	≤ 1.0	%
Chloride (Cl)	≤ 60	ppm
Sulfate (SO ₄)	≤ 30	ppm
Al (Aluminium)	≤ 10	ppm
Fe (Iron)	≤ 3	ppm
Ni (Nickel) *	≤ 2.00	ppm
Residual solvents (ICH Q3C)	...excluded by production process	

Parameter with periodic testing	Specification	
Endotoxins	≤ 2.0	I.U./ml

Filtered with 0.2 µm

This product has been manufactured from Sodium hydroxide pellets Ph Eur, BP, JP, NF and water for injection USP. Water for injection USP has been prepared for this product by using purified water according to Ph Eur.

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 (*).

The original manufacturer name and address will be disclosed subsequent to signing a confidentiality agreement.

Christian Herrmann
Responsible laboratory manager quality control

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