

**CERTIFICATE OF ANALYSIS**

Laboratory Salinen Austria AG

PHARMASAL APISodium Chloride for pharmaceutical use
according to Ph. Eur, BP, USP, JP

Lot number: CRS070125
Retest date: 07.01.2028
Production date: 07.01.2025 - 11.01.2025

		Specification	Unit	Result	Unit
Identification	Na+	positive		conforms	-
Identification	Cl-	positive		conforms	-
Assay	NaCl	99,5 - 100,5	%	99,97	%
Bromides	Br-	<= 100	ppm	<= 100	ppm
Iodides	I-	<= 10	ppm	<= 10	ppm
				conforms Ph. Eur	
Sulfate	SO ₄ 2-	<= 200	ppm	<= 200	ppm
Phosphate	PO ₄ 3-	<= 25	ppm	<= 25	ppm
Nitrite	NO ₂ -	<= 0,01	abs.	<= 0,01	abs.
Heavy metals	as Pb	<= 3	ppm	<= 3	ppm
Iron	Fe	<= 2	ppm	<= 2	ppm
Aluminium	Al	<= 0,2	ppm	<= 0,2	ppm
Arsenic	As	<= 1	ppm	<= 1	ppm
Potassium	K	<= 500	ppm	<= 500	ppm
Barium	Ba	<= 10	ppm	<= 10	ppm
				conforms Ph. Eur	
Magnesium & alkaline-earth metals	calc. as Ca	<= 100	ppm	<= 100	ppm
Ferrocyanides	[Fe(CN) ₆] ⁴⁻	conforms	-	conforms	-
Insoluble matters		<= 50	ppm	<= 50	ppm
Loss on drying		<= 0,5	%	<= 0,5	%
Appearance of solution		clear, colourless		conforms	-
Acidity or Alkalinity		conforms		conforms	-
according to the regulations					
Residual Solvents		Impossible due to production process		conforms	-
according ICH-guideline					
Bacterial Endotoxins (Pyrogen free)		< 5	I.U./g	< 5	I.U./g
TAMC		<= 10	CFU/g	<= 10	CFU/g
TYMC		<= 10	CFU/g	<= 10	CFU/g

Appearance: white or almost white, crystalline powder or colorless crystals or white or almost white pearls
Solubility: freely soluble in water, practically insoluble in anhydrous ethanol

This lot conforms with the current Ph. Eur, USP, BP and JP monographs. In compliance with the guidelines on good manufacturing practice for active pharmaceutical ingredients (ICH Q7).
Store in a clean and dry place, nmt. 70% rel. Humidity.

It is suitable for the use in the manufacture of injectable dosage forms, peritoneal dialysis solutions, hemodialysis solutions and hemofiltration solutions.

Qualified Person: Birgit Spreitz

Date: 21.01.2025

21.01.2025**Salinen Austria AG**
LaborSteinkogelstraße 30
4802 Ebensee
Tel. +43 6132 / 200-0