

**CERTIFICATE OF ANALYSIS**

Laboratory Salinen Austria AG

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

Lot number: CRS240625
Retest date: 24.06.2028
Production date: 24.06.2025 - 28.06.2025

			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	SO4 2-	<= 200		ppm	<= 200	ppm
Phosphate	PO4 3-	<= 25		ppm	<= 25	ppm
Nitrite	NO2-	<= 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			conforms	-
according ICH-guideline		production process				
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: 08.07.2025

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