

**CERTIFICATE OF ANALYSIS**

Laboratory Salinen Austria AG

PHARMASAL HDChemically pure salt, Sodium chloride
according to Ph. Eur, BP, USP, JP

Lot number: CRS180123
Retest date: 18.01.2026
Production date: 18.01.2023 - 21.01.2023

		Specification	Unit	Result	Unit
Identification	Na+	positive		conforms	-
Identification	Cl-	positive		conforms	-
Assay	NaCl	99,5 - 100,5	%	99,96	%
Bromides	Br-	≤ 100	ppm	≤ 100	ppm
Iodides	I-	≤ 10	ppm	≤ 10	ppm
Sulfate	SO ₄ 2-	≤ 200	ppm	≤ 200	ppm
Phosphate	PO ₄ 3-	≤ 25	ppm	≤ 25	ppm
Nitrite	NO ₂ -	$\leq 0,01$	abs.	$\leq 0,01$	abs.
Heavy metals	as Pb	≤ 3	ppm	≤ 3	ppm
Iron	Fe	≤ 2	ppm	≤ 2	ppm
Aluminium	Al	$\leq 0,2$	ppm	$\leq 0,2$	ppm
Arsenic	As	≤ 1	ppm	≤ 1	ppm
Potassium	K	≤ 500	ppm	≤ 500	ppm
Barium	Ba	≤ 10	ppm	≤ 10	ppm
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		$\leq 0,5$	%	$\leq 0,5$	%
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.
Store in a clean and dry place, nmt. 70% rel. humidity.

It is suitable for various industrial applications and depending on country specific law in the
manufacture of peritoneal, hemodialysis and hemofiltration solutions.

Qualified Person: Birgit Spreitz

Date: 01.02.2023


06.02.2023**Salinen Austria AG**

Labor

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