



SALINEN AUSTRIA

**CERTIFICATE OF ANALYSIS**

Laboratory Salinen Austria AG

"PHARMASAL" – Chemically Pure Salt  
Sodium Chloride for pharmaceutical use, Natrii chloridum  
according to European Pharmacopoeia, BP, USP, JP

Lot number: CRS011220  
Retest date: 01.12.2023  
Production date: 01.12.2020 - 05.12.2020

	Specification	Unit	Result	Unit
Identification	Na+	positive	conforms	-
Identification	Cl-	positive	conforms	-
Assay	NaCl	99,5 - 100,5	99,97	%
Bromides	Br-	<= 100	<= 100	ppm
Iodides	I-	<= 10	<= 10	ppm
			conforms Ph. Eur	
Sulfate	SO4 2-	<= 200	<= 200	ppm
Phosphate	PO4 3-	<= 25	<= 25	ppm
Nitrite	NO2-	<= 0,01	<= 0,01	abs.
Heavy metals	as Pb	<= 3	<= 3	ppm
Iron	Fe	<= 2	<= 2	ppm
Aluminium	Al	<= 0,2	<= 0,2	ppm
Arsenic	As	<= 1	<= 1	ppm
Potassium	K	<= 500	<= 500	ppm
Barium	Ba	<= 10	<= 10	ppm
			conforms Ph. Eur	
Magnesium & alkaline-earth metals	calc. as Ca	<= 100	<= 100	ppm
Ferrocyanides	[Fe(CN)6]4-	conforms	conforms	-
Insoluble matters		<= 50	<= 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		< 5	< 5	I.U./g
TAMC		<= 10	<= 10	CFU/g
TYMC		<= 10	<= 10	CFU/g

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.

*Birgit Spreitz*  
21.12.2020

Qualified Person  
Dipl.-Ing. Birgit Spreitz  
Date: 17.12.2020

**Salinen Austria AG**  
Labor

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