



**Preliminary certificate
without microbiological
analysis**

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: CRS130219
Retest date: 13.02.2022
Production date: 13.02.2019 - 17.02.2019

		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 according to the regulations		conforms		conforms	-
Residual Solvents according ICH-guideline		Impossible due to production process		conforms	-

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
Dipl.-Ing. Birgit Spreitz
Date: 18.02.2019

Birgit Spreitz
18.02.2019

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