



## CERTIFICATE OF ANALYSIS

Laboratory Salinen Austria AG

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

Lot number: CRS271115  
Retest date: 27.11.2018  
Production date: 27.11.2015 - 29.11.2015

		Specification	Unit	Result	Unit
Identification	Na+	positive		conforms	-
Identification	Cl-	positive		conforms	-
Assay	NaCl	99,5 - 100,5	%	99,98	%
Bromides	Br-	<= 100	ppm	<= 100	ppm
Iodides	I-	<= 10	ppm	<= 10	ppm
Sulfate	SO <sub>4</sub> 2-	<= 200	ppm	<= 200	ppm
Phosphate	PO <sub>4</sub> 3-	<= 25	ppm	<= 25	ppm
Nitrite	NO <sub>2</sub> -	<= 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
Magnesium & alkaline-earth metals	calc. as Ca	<= 100	ppm	<= 100	ppm
Ferrocyanides	[Fe(CN) <sub>6</sub> ] <sup>4-</sup>	conforms	ppm	conforms	ppm
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			

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: 30.11.2015

*Birgit Spreitz*  
1.12.2015

**Salinen Austria AG**

Qualitätskontrolle  
Steinkogelstraße 30  
A-4802 Ebensee  
Tel. 06132 / 200-0  
Fax 06132 / 200-4100