

1602 - 1038


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: CRS250116
 Retest date: 25.01.2019
 Production date: 25.01.2016 - 27.01.2016

		Specification	Unit	Result	Unit
Identification	Na+	positive		conforms	-
Identification	Cl-	positive		conforms	-
Assay	NaCl	99,5 - 100,5	%	99,95	%
Bromides	Br-	<= 100	ppm	<= 100	ppm
Iodides	I-	<= 10	ppm	<= 10	ppm
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
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	%
Apearance 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: 28.01.2016

Birgit Spreitz
 28.01.2016

Salinen Austria AG

Qualitätskontrolle
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