

1509-1187

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 CRS180915
Retest date 18.09.18
Production date 18.09.15 - 20.09.15

		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
Sulphates	SO ₄ ²⁻	<= 200	ppm	<=200	ppm
Phosphates	PO ₄ ³⁻	<= 25	ppm	<=25	ppm
Nitrites	NO ₂ ⁻	<= 0,01	A	<=0,01	A
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 and 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).

It is suitable for the use in the manufacture of injectable dosage forms, peritoneal dialysis solutions, hemodialysis solutions and hemofiltration solutions.

Store in a clean and dry place, nmt. 70% rel. Humidity.

Salinen Austria AG

Qualitätskontrolle
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Qualified Person
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 Date: 2015-09-22

Birgit Spreitz
 22.09.2015