

1211-1219

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 CRS011012
Retest date 01.10.2015
Production date 01.10.12 - 02.10.12

		Specification	Unit	Result	Unit
Identification	Na+	positive		conforms	-
Identification	Cl-	positive		conforms	-
Assay	NaCl	99,5 - 100,5	%	99,94	%
Bromides	Br-	<= 100	ppm	<= 100	ppm
Iodides	I-	<= 10	ppm	<= 10	ppm
Sulphates	SO42-	<= 200	ppm	<= 200	ppm
Phosphates	PO43-	<= 25	ppm	<= 25	ppm
Nitrites	NO2-	<= 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-	<= 1	ppm	<= 1	ppm
Insoluble matters		<= 50	ppm	<= 50	ppm
Loss on drying		<= 0,5	%	<= 0,5	%
pH solution 10 %		4,5 - 7,0		conforms	-
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	-
Bacterial Endotoxins		< 5,0	I.U./g	conforms	I.U./g
TAMC		<= 10	CFU/g	conforms	CFU/g
TYMC		<= 10	CFU/g	conforms	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.

Qualified Person
 Dr. Müller Roland
 Date: 2012-10-25

Roland Müller

Salinen Austria AG
 Steinkogelstraße 3D
 A-4807 Ebensee
 Tel. 06132 / 200 0
 Fax 06132 / 200-4100