1211 – 1218

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	**CRS170912**
Retest date	**17.09.2015**
Production date	**17.09.12 - 18.09.12**

		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	J-	<= 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: 2012-09-26

Roland Müller

Salinen Austria AG
Steinkogelstraße 30
A-4802 Ebensee
Tel. 06132 / 200 0
Fax 06132 / 200 400