

**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** CRS130114  
**Retest date** 13.01.2017  
**Production date** 13.01.14 - 14.01.14

		Specification	Unit	Result	Unit
Identification	Na <sup>+</sup>	positive		conforms	-
Identification	Cl <sup>-</sup>	positive		conforms	-
Assay	NaCl	99,5 - 100,5	%	99,97	%
Bromides	Br <sup>-</sup>	<= 100	ppm	<= 100	ppm
Iodides	I <sup>-</sup>	<= 10	ppm	<= 10	ppm
Sulphates	SO <sub>4</sub> <sup>2-</sup>	<= 200	ppm	<= 200	ppm
Phosphates	PO <sub>4</sub> <sup>3-</sup>	<= 25	ppm	<= 25	ppm
Nitrites	NO <sub>2</sub> <sup>-</sup>	<= 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) <sub>6</sub> ] <sup>4-</sup>	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	-
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  
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Date: 2014-01-27

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