

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 CRS280911
Retest date 28.09.2014
Production date 28.09.11 - 30.09.11

MÁSOLAT
 Csak a piros szín hiteles!
 A példány tulajdonosa: *Dombóczy Várfőrtőgye*
 Dátum: 2011. 10. 27. Aláírás: *M. Müller*

	Specification	Unit	Result	Unit
Identification	Na+	positive	conforms	-
Identification	Cl-	positive	conforms	-
Assay	NaCl	99,5 - 100,5	99,96	%
Bromides	Br-	<= 100	<= 100	ppm
Iodides	I-	<= 10	<= 10	ppm
Sulphates	SO42-	<= 200	<= 200	ppm
Phosphates	PO43-	<= 25	<= 25	ppm
Nitrites	NO2-	<= 0,01	<= 0,01	A
Heavy metals	as Pb	<= 3	<= 3	ppm
Iron	Fe	<= 2	<= 2	ppm
Aluminium	Al	<= 0,2	<= 0,2	ppm
Arsenic	As	<= 1	<= 1	ppm
Potassium	K	<= 500	<= 500	ppm
Barium	Ba	<= 10	<= 10	ppm
Magnesium and alkaline-earth metals	calc. as Ca	<=100	<=100	ppm
Ferrocyanides	[Fe(CN)6]4-	<= 1	<= 1	ppm
Insoluble matters		<= 50	<= 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

365/11

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: 2011-10-10

Salinen Austria AG

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