

1411-1254

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 CRS271014
Retest date 27.10.2017
Production date 27.10.14 - 28.10.14

		Specification	Unit	Result	Unit
Identification	Na ⁺	positive		conforms	-
Identification	Cl ⁻	positive		conforms	-
Assay	NaCl	99,5 - 100,5	%	99,97	%
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	-
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.

Salinen Austria AG
 Qualitätskontrolle
 Steinkogelstraße 30
 A-4802 Ebensee
 Tel. 06132 / 200-0
 Fax 06132 / 200-4100

Qualified Person
 Dipl.-Ing. Birgit Spreitz
 Date: 2014-11-10

Birgit Spreitz

10.11.2014