SALINEN AUSTRIA

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: CRS030120
Retest date: 03.01.2023
Production date: 03.01.2020 - 07.01.2020

		Specification	Unit	Result	Unit
Identification	Na+	positive		conforms	-
Identification	Cl-	positive		conforms	-
Assay	NaCl	99,5 - 100,5	%	99,96	%
Bromides	Br-	<= 100	ppm	<= 100	ppm
Iodides	I-	<= 10	ppm	<= 10	ppm
				conforms Ph. Eur	
Sulfate	SO4 2-	<= 200	ppm	<= 200	ppm
Phosphate	PO4 3-	<= 25	ppm	<= 25	ppm
Nitrite	NO2-	<= 0,01	abs.	<= 0,01	abs.
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
				conforms Ph. Eur	
Magnesium & 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	I.U./g	< 5	I.U./g
TAMC		<= 10	CFU/g	<= 10	CFU/g
TYMC		<= 10	CFU/g	<= 10	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.

It is suitable for the use in the manufacture of injectable dosage forms, peritoneal dialysis solutions, hemodialysis solutions and hemofiltration solutions.

Birgit Spreitz
14.01.2020

Qualified Person
Dipl.-Ing.Birgit Spreitz
Date:14.01.2020

Salinen Austria AG
Labor
Steinkogelstraße 30
4802 Ebensee
Tel +43 6132 / 200-0