

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:

CRS220818

Retest date:

22.08.2021

Production date:

22.08.2018

25.08.2018

		Specification	Unit	Result	Unit
Identification	Na+	positive			
Identification	Cl-	positive		conforms	-
Assay	NaCl	99,5 - 100,5	%	conforms	-
Bromides	Br-	<= 100		99,97	%
Iodides	I-	<= 10	ppm	<= 100	ppm
		1-10	ppm	<= 10	ppm
Sulfate	SO4 2-	<= 200	71 P. WA	conforms Ph. Eur	
Phosphate	PO4 3-	<= 25	ppm	<= 200	ppm
Nitrite	NO2-	<= 0,01	ppm	<= 25	ppm
Heavy metals	as Pb	<= 3	abs.	<= 0,01	abs.
Iron	Fe	<= 2	ppm	<= 3	ppm
Aluminium	Al	-	ppm	<= 2	ppm
Arsenic	As	<= 0,2 <= 1	ppm	<= 0,2	ppm
Potassium	K	-	ppm	<= 1	ppm
Barium	Ba	<= 500	ppm	<= 500	ppm
	Da	<= 10	ppm	<= 10	ppm
Magnesium & alkaline-earth metals	sale as C-			conforms Ph. Eur	
errocyanides	calc. as Ca	<= 100	ppm	<= 100	ppm
insoluble matters	[Fe(CN)6]4-	conforms	-	conforms	-
oss on drying		<= 50	ppm	<= 50	ppm
Appearance of solution		<= 0,5	%	<= 0,5	%
Acidity or Alkalinity		clear, colourless		conforms	-
according to the regulations		conforms		conforms	-
Residual Solvents		Impaccible due to			
ccording ICH-guideline		Impossible due to production process		conforms	-
Sacterial Endotoxins		< 5			
AMC			I.U./g	< 5	I.U./g
		<= 10	CFU/g	<= 10	CFU/g
YMC		<= 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 alinen Austria AG solutions, hemodialysis solutions and hemofiltration solutions.

Bign / Spreat

Qualified Person Dipl.-Ing.Birgit Spreitz Date:10.09.2018 Labor Steinkogelstraße 30 4802 Ebensee Tel. +43 6132 / 200-0