



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: CRS060917
Retest date: 06.09.2020
Production date: 06.09.2017 - 09.09.2017

| | | 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 |
| 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 |
| 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 | | conforms | | conforms | - |
| according to the regulations | | | | | |
| Residual Solvents | | Impossible due to | | conforms | - |
| according ICH-guideline | | production process | | | |
| 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
20.09.2017

Qualified Person
Dipl.-Ing. Birgit Spreitz
Date: 20.09.2017

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