



**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: CRS240320  
Retest date: 24.03.2023  
Production date: 24.03.2020 - 30.03.2020

|  |             | 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    |
|  |             |                                      |        | 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*  
07.04.2020

Qualified Person  
Dipl.-Ing. Birgit Spreitz  
Date: 07.04.2020

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