

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 CRS230610
Retest date 23.06.2013
Production date 23.06.10 - 25.06.10

| | | Specification | Unit | Result | Unit |
|---|-------------|---|-------------|---------------|-------------|
| Identification | Na+ | positive | | conforms | - |
| Identification | Cl- | positive | | conforms | - |
| Assay | NaCl | 99,5 - 100,5 | % | 99,98 | % |
| Bromides | Br- | <= 100 | ppm | <= 100 | ppm |
| Iodides | J- | <= 10 | ppm | <= 10 | ppm |
| Sulphates | SO42- | <= 200 | ppm | <= 200 | ppm |
| Phosphates | PO43- | <= 25 | ppm | <= 25 | ppm |
| Nitrites | NO2- | <= 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- | <= 1 | ppm | <= 1 | ppm |
| Insoluble matters | | <= 50 | ppm | <= 50 | ppm |
| Loss on drying | | <= 0,5 | % | <= 0,5 | % |
| pH solution 10 % | | 4,5 - 7,0 | | conforms | - |
| 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.

Qualified Person
DI Herbert Stieb
Date: 2010-07-07

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