

VIOSER S.A
QUALITY CONTROL DPT.

Control Tests on the Finished Product:

SOD. CHLORIDE 0.9% ROMANIA - 250ml

Batch No: 705680

Prod. Date: 06/05/2017

Expiry Date: 06/05/2020

| Test for | Nominal Value | According to | Method | Test Results |
|--|---|--|------------------|----------------------|
| Appearance | clear, colorless solution | Ph.Eur.2.2.1 & 2.2.2 Method I | Visually | Conform |
| pH | 5.0-7.0 | Ph.Eur.2.2.3 | potentiometer | 5.71 |
| Sodium | 154.0 mmol/L ± 5% | Ph.Eur.2.2.22 | flame photometer | 154.20 |
| Chloride | 154.0 mmol/L ± 5% | USP Monograph containing assay for chlorides precipitation titration | Volumetric | 154.50 |
| Identification | | | | |
| -Sodium | Quantitative determination serves as proof for identity | | | Conform |
| -Chloride | positive | Ph.Eur.2.3.1 | | Conform |
| Sterility | sterile | Ph.Eur.2.6.1 | Microbiolog. | Conform |
| Bacterial Endotoxins | < 0.25 IU/ml | Ph.Eur.2.6.14 | LAL-test | Conform |
| Expiry Date | shelf life: 3 years | | | 05/2020 |
| Extractable Volume | > declared volume | Ph.Eur.2.9.17 | | Conform |
| Particulate Contamination -nonvisible particles- | ≥ 5 µm ≤ 100/ml ≥ 10 µm ≤ 25/ml ≥ 25 µm ≤ 3/ml | Ph.Eur.2.9.19 | Light Blockage | 3.00 0.50 0.00 |

EXPERT RESPONSIBLES:

Chemist:

Biologist:

DATE: 25/05/2017

Quality Control Manager

Vasiliki Kefala