

VIOSER S.A
QUALITY CONTROL DPT.

Control Tests on the Finished Product:

SOD. CHLORIDE 0.9% ROMANIA - 250ml

Batch No: 704522
Prod. Date: 04/04/2017
Expiry Date: 04/04/2020

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	5.69
Sodium	154.0 mmol/L \pm 5%	Ph.Eur.2.2.22	flame photometer	153.70
Chloride	154.0 mmol/L \pm 5%	USP Monograph containing assay for chlorides precipitation titration	Volumetric	154.30
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			04/2020
Extractable Volume	> declared volume	Ph.Eur.2.9.17		Conform
Particulate Contamination -nonvisible particles-	$\geq 5 \mu\text{m} \leq 100/\text{ml}$ $\geq 10 \mu\text{m} \leq 25/\text{ml}$ $\geq 25 \mu\text{m} \leq 3/\text{ml}$	Ph.Eur.2.9.19	Light Blockage	4.80 1.20 0.00

EXPERT RESPONSIBLES:

DATE: 11/05/2017

Chemist:

Biologist:

Quality Control Manager

Vasiliki Kefala