

Control Tests on the Finished Product:

SOD. CHLORIDE 0.9% ROMANIA - 250ml

Batch No: 704587
Prod. Date: 19/04/2017
Expiry Date: 19/04/2020

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	5.74
Sodium	154.0 mmol/L ± 5%	Ph.Eur.2.2.22	flame photometer	154.70
Chloride	154.0 mmol/L ± 5%	USP Monograph containing assay for chlorides precipitation titration	Volumetric	154.80
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-	≥ 5 µm ≤ 100/ml ≥ 10 µm ≤ 25/ml ≥ 25 µm ≤ 3/ml	Ph.Eur.2.9.19	Light Blockage	0.20 0.20 0.10

EXPERT RESPONSIBLES:

Chemist:

Biologist:

DATE: 11/05/2017

Quality Control Manager

Vasiliki Kefala