SÜDWESTDEUTSCHE SALZ WERKE AG

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Certificate

Sodium chloride Ph.Eur./USP

Art. No.: 16653
Date of production: 02 March 2020
Lot-No.: 20062

Parameter	Specifications (Ph.Eur.)	Test result	Specifications (USP)	Test result
Assay	99.0 – 100.5 %	100.1 %	99.0 – 100.5 %	100.1 %
Identity	chlorides (A.), sodium (B.)	passes test	Positive tests for chlorides and sodium	passes test
Appearance of solution	clear and colourless	passes test	clear and colourless	passes test
Acidity or alkalinity	≤ 0.5 ml (0.01 M) hydrochloric acid or ≤ 0.5 ml (0.01 M) sodium hydroxide	passes test	≤ 0.5 ml (0.01 N) hydrochloric acid or ≤ 0.5 ml (0.01 N) sodium hydroxide	passes test
Bromides	≤ 100 ppm	≤ 50 ppm	≤ 0.010 %	≤ 0.005 %
Ferrocyanides	No blue colour develops (Ph.Eur. test)	passes test	No blue colour develops (USP test)	passes test
Iodides	No blue colour with starch solution	passes test	No blue colour with starch solution	passes test
Nitrites	Absorbance (354 nm) ≤ 0.01	passes test	Absorbance (354 nm) ≤ 0.01	passes test
Phosphates	≤ 25 ppm	≤ 25 ppm	≤ 0.0025 %	≤ 0.0025 %
Sulphates	≤ 200 ppm	≤ 200 ppm	≤ 0.020 %	≤ 0.020 %
Aluminium	≤ 0.2 ppm [1)]	≤ 0.2 ppm	≤ 0.2 µg/g [1)]	≤ 0.2 µg/g
Arsenic	≤ 1 ppm	< 0.5 ppm	≤ 1µg/g	< 0.5 µg/g
Barium	corresponds to opalescence test Ph.Eur.	passes test	corresponds to opalescence test USP	passes test
Iron	≤ 2 ppm	≤ 2 ppm	≤ 2 µg/g	≤ 2 µg/g
Potassium	≤ 500 ppm [1,2)]	≤ 100 ppm	≤ 0.050 % [1,2)]	≤ 0.01 %
Magnesium and alkaline-earth metals	≤ 100 ppm calculated as Ca	≤ 100 ppm	≤ 0.010 % calculated as Ca	≤ 0.01 %
Loss on drying	≤ 0.5 %	< 0.1 %	≤ 0.5 %	< 0.1 %
Bacterial endotoxins	< 5 I.U./g [3)]	not tested	-	not tested
Residual solvents	Ph.Eur.	excluded by production process	USP	excluded by production process

	Internal limits	Test result
Pb	< 1.0 ppm	< 0.5 ppm
Heavy metals	≤ 5 ppm	≤ 3 ppm

[1)] If intended for use in the manufacture of peritoneal dialysis solutions, hemodialysis solutions or hemofiltration solutions.
[2)] If intended for use in the manufacture of parenteral dosage forms.
[3)] If intended for use in the manufacture of parenteral dosage forms without a further appropriate procedure for removal of bacterial endotoxins.

Tests are in accordance to monography 0193 of the European Pharmacopoeia last edition in force or validated methods.
Quality corresponds to Ph. Eur. and USP.
Retest date: 3 years after production date.
Place of manufacture: Saltworks Bad Friedrichshall

03 March 2020
Date of signature

A. Teicht
Proxy Management Quality Control
Analytical laboratory Saline Bad Friedrichshall

Edited: Quality assurance / Dr. Biebinger/go

Version: 01. August 2019
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