



SODIO CLORURO (EUR. PH. / USP)

PRODUCT CODE: 001336	CAS Nº: 7647-14-5	ANALYSIS Nº: 029/25
MANUFACTURER BATCH: 434101	CERTIFICATE ID: 45.041	
SUPPLIER BATCH: W0133607	MANUFACTURING DATE: 22/10/2024	
METAPH BATCH: 0030225	RETEST DATE: 21/10/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or colourless crystals or white or almost white pearls	Colourless crystals (*)
Solubility	Freely soluble in water, practically insoluble in anhydrous ethanol	Complies
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Appearance of solution	Clear and colourless	Complies
Acidity or alkalinity	=< 0.5 mL of 0.01 M HCl or 0.01 M NaOH	0.06 mL of 0.01M HCl
Bromides	=< 100 ppm	< 100 ppm
Ferrocyanides	Complies	Complies
Iodides	Complies	Complies
Nitrites	Abs (354 nm) =< 0.01	Complies
Phosphates	=< 25 ppm	< 2.5 ppm
Sulfates	=< 200 ppm	98 ppm
Aluminium	=< 0.2 ppm	< 0.10 ppm
Arsenic	=< 1 ppm	< 0.50 ppm
Barium	Complies	Complies
Iron	=< 2 ppm	< 0.20 ppm
Magnesium and alkaline-earth metals	=< 100 ppm	8.4 ppm
Potassium	=< 500 ppm	84 ppm
Loss on drying	=< 0.5 %	0.06 % (*)
Assay	99.0 - 100.5 %	100.3 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Sodium Chloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data controlled by Metapharmaceutical Industrial SL.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Analysis date: 24/02/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001215
K+S FRANCE SAS
1 rue des Docks Rémois
51100 REIMS
(Francia)



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Keep the container tightly closed in a cool, dry and well-ventilated place.

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