



TECHNICAL DATA SHEET

001336-TDS-ENG-2024

SODIO CLORURO (EUR. PH. / USP)		
DESCRIPTION DCI: SODIUM CHLORIDE		DESCRIPTION DOE: SODIO CLORURO
CAS Nº: 7647-14-5	EC Nº: 321-598-3	AEMPS CODE: 125CL
MOL. WEIGHT: 58.44	MOL. FORMULA: NaCl	ARTICLE CODE: 001336

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

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

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

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.