

TECHNICAL DATA SHEET

151371-TDS-ENG-2021

POTASIO CLORURO EP - EUR.GMP			
DESCRIPTION DCI: POTASSIUM CHLORIDE		DESCRIPTION DOE: POTASIO CLORURO	
CAS N°: 7447-40-7	EC N°: 231-211-8		
MOL. WEIGHT: 74.55	MOL. FORMULA: KCI		ARTICLE CODE: 151371

ATTRIBUTES SHOULD BE

Appearance White or almost white, crystalline powder or colourless crystals

Solubility Freely soluble in water, practically insoluble in anhydrous ethanol

Identification ACompliesIdentification BComplies

Appearance of solution Clear and colourless

Acidity or alcalinity = < 0.5 mL of 0.01 M NaOH or HCl

Bromides =< 0.1 % **Iodides** Complies Sulfates =< 300 ppm Barium Complies Iron =< 20 ppm Magnesium and alkaline-earth metals =< 200 ppm Loss on drying =< 1.0 % 99.0 - 101.0 % Assay

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

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

REMARKS

Potassium Chloride is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.