



TECHNICAL DATA SHEET

010792-TDS-ENG-2023

ACIDO SALICILICO POLVO EP 99,5%		
DESCRIPTION DCI: SALICYLIC ACID		DESCRIPTION DOE: SALICILICO ACIDO
CAS N°: 69-72-7	EC N°: 200-712-3	AEMPS CODE: 136A
MOL. WEIGHT: 138.10	MOL. FORMULA: C7H6O3	ARTICLE CODE: 010792

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or white or colourless, acicular crystals
Solubility	Slightly soluble in water, freely soluble in ethanol (96 %), sparingly soluble in methylene chloride
Melting point	158 - 161 °C
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and colourless
Related substances	
Impurity A	=< 0.1 %
Impurity B	=< 0.05 %
Impurity C	=< 0.02 %
Unspecified impurities	=< 0.05 %
Total impurities	=< 0.2 %
Chlorides	=< 100 ppm
Sulfates	=< 200 ppm
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 100.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

In a tightly closed container protected from light.

REMARKS

Salicylic Acid 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.