

TECHNICAL DATA SHEET

0083-TDS-ENG-2025

ACIDO SALICILICO POLVO 99,5 % (EUR. PH.)				
DESCRIPTION DCI: SALICYLIC ACID		DESCRIPTION DOE: SALICILICO ACIDO		
CAS Nº: 69-72-7	EC Nº: 200-712-3		AEMPS CODE: 136A	
MOL. WEIGHT: 138,10	MOL. FORMULA: C7H6O3		ARTICLE CODE: 0083	

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 =< 0.5 % Loss on drying Sulfated ash =< 0.1 % 99.0 - 100.5 % Assay

COMPLIES WITH

European Pharmacopeia 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.

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