

## **TECHNICAL DATA SHEET**

1899-TDS-ENG-2024

VITAMINA C (ACIDO ASCORBICO) (EUR. PH.)			
DESCRIPTION DCI:		DESCRIPTION DOE:	
CAS Nº: 50-81-7	EC Nº: 200-066-2		AEMPS CODE:
MOL. WEIGHT: 176,12	MOL. FORMULA: C6H8O6		ARTICLE CODE: 1899

ATTRIBUTES SHOULD BE

Appearance White or almost white, crystalline powder or colourless crystals, becoming

discoloured on exposure to air and moisture

Solubility Freely soluble in water, sparingly soluble in ethanol (96 %)

Melting point abput 190 °C, with decomposition

Identification BCompliesIdentification CCompliespH2.1 - 2.6

Appearance of solution Clear and not more intensely coloured than ref. sol. BY7

Specific optical rotation +20.5 / +21.5Impurity E = < 0.2 %

Related substances

Impurity C =< 0.15 %Impurity D =< 0.15 %Unspecified impurities =< 0.10 %Total impurities (other than C and =< 0.2 %

D)

Copper =< 5 ppmIron =< 2 ppmSulfated ash =< 0.1 %Assay 99.0 - 100.5 %

## COMPLIES WITH

European Pharmacopoeia 11.2

## STORAGE

Keep the container tightly closed, protected from light, in a dry place and at room temperature.

## **REMARKS**

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

The product is not of animal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.