

VITAMINA C (ACIDO ASCORBICO) (EUR. PH.)						
PRODUCT CODE: 1899		CAS Nº: 50-81-7	ANAI	LYSIS Nº: 124/24		
MANUFACTURER BATCH	:		CERTIFICATE ID:	42.111		
SUPPLIER BATCH:	W0373101		MANUFACTURING DATE:	28/09/2023		
МЕТАРН ВАТСН:	0080524		EXPIRY DATE:	27/09/2027		

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or	White crystalline powder
	colourless crystals, becoming discoloured on	becoming discoloured on
	exposure to air and moisture	exposure to air and moisture
Melting point	abput 190 °C, with decomposition	191 °C
Identification B	Complies	Complies
Identification C	Complies	Complies
рН	2.1 - 2.6	2.4
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY7	Complies
Specific optical rotation	+20.5 / +21.5	+21.0 (*)
Impurity E	=< 0.2 %	< 0.2 % (*)
Related substances		(*)
Impurity C	=< 0.15 %	< 0.15 %
Impurity D	=< 0.15 %	< 0.15 %
Unspecified impurities	=< 0.10 %	< 0.10 %
Total impurtites (other thanC	=< 0.2 %	< 0.20 %
and D)		
Copper	=< 5 ppm	< 5 ppm (*)
Iron	=< 2 ppm	< 2 ppm (*)
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	99.0 - 100.5 %	99.3 %
COMPLIES WITH		

European Pharmacopoeia 11.2

## 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.

(\*) Data adapted from the supplier's certificate of analysis.

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.

## **STORAGE**

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

Analysis date: 22/05/2024

Signature: Albert Sanchez Lopez (QP)

Conclusion: Complies

AT MILL

Manufacturer: 40000406

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