

VITAMINA C (ACIDO ASCORBICO) (EUR. PH.)

PRODUCT CODE: 1899	CAS Nº: 50-81-7	ANALYSIS Nº: 057/23
MANUFACTURER BATCH: 012207081	CERTIFICATE ID: 37.606	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 24/07/2022	
METAPH BATCH: 0030323	EXPIRY DATE: 23/07/2025	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or colourless crystals, becoming discoloured on exposure to air and moisture	White crystalline powder
Solubility	Freely soluble in water, sparingly soluble in ethanol (96 %)	Complies (*)
Melting point	about 190 °C, with decomposition	190 °C
Identification B	Complies	Complies
Identification C	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY7	Complies
Specific optical rotation	+20.5 / +21.5	
pH	2.1 - 2.6	2.5
Impurity E	=< 0.2 %	< 0.20 %
Related substances		
Impurity C	=< 0.15 %	< 0.05 %
Impurity D	=< 0.15 %	Not Detected
Unknown impurities	=< 0.10 %	< 0.05 %
Total impurities (other than C and D)	=< 0.2 %	< 0.05 %
Copper	=< 5 ppm	< 0.40 ppm
Iron	=< 2 ppm	< 1.0 ppm
Sulfated ash	=< 0.1 %	0.06 %
Assay	99.0 - 100.5 %	99.3 %
Microbiological control		(*)
TAMC	=< 1000 CFU/g	< 1000 CFU/g
Residual solvents		(*) (**)
Methanol	=< 3000 ppm	< 3000 ppm

COMPLIES WITH

European Pharmacopoeia 11.0

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 manufacturer's certificate of analysis.

(**) According to 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.

Analysis date: 06/04/2023

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Manufacturer: 40000920





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SUPPLIER BATCH:	----	MANUFACTURING DATE:	24/07/2022
METAPH BATCH:	0030323	EXPIRY DATE:	23/07/2025

STORAGE

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

Analysis date: 06/04/2023

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Manufacturer: 40000920