



## TECHNICAL DATA SHEET

002226-TDS-ENG-2023

<b>ACIDO CITRICO MONOHIDRATO-EP</b>		
DESCRIPTION DCI: ---		DESCRIPTION DOE: ---
CAS Nº: 5949-29-1	EC Nº: 691-328-9	AEMPS CODE: ---
MOL. WEIGHT: 210.14	MOL. FORMULA: C <sub>6</sub> H <sub>8</sub> O <sub>7</sub> ·H <sub>2</sub> O	ARTICLE CODE: 002226

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder, colourless crystals or granules, efflorescent
Solubility	Very soluble in water, freely soluble in ethanol (96 %)
Identification B	Complies
Identification E	Complies
Appearance of solution	Clear and colourless or not more intensely coloured than ref. sol. Y7, BY7 o GY7
Readily carbonisable substances	The solution is not more intensely coloured than a mixture of 1 mL red primary sol. and 9 mL of yellow primary sol.
Oxalic acid	=< 360 ppm
Sulfates	=< 150 ppm
Water	7.5 - 9.0 %
Sulfated ash	=< 0.1 %
Assay	99.5 - 100.5 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Keep the container tightly closed.

### REMARKS

Citric Acid Monohydrate 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.

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.