

A080.02.ENG

TECHNICAL DATA SHEET

002388-TDS-ENG-2023

ACIDO FERULICO					
DESCRIPTION DCI: ÁCIDO FERÚLICO		DESCRIPTION DOE: FERULIC ACID			
CAS N°: 1135-24-6	EC N°: 214-490-0		AEMPS CODE:		
MOL. WEIGHT: 194.18	MOL. FORMULA: C10H10O4		ARTICLE CODE: 002388		

ATTRIBUTES SHOULD BE

Almost white crystalline powder Appearance

Identification A Complies Identification B Conforme 173 - 176 °C Melting point =< 0.5 % Loss on drying Sulfated ash =< 0.1 %

Related substances

Total impurities =< 1.0 % Assav >= 99.0 %

Residual solvents

Ethanol =< 5000 ppm

Microbiological control

TAMC =< 1000 CFU/q **TYMC** =< 100 CFU/q Escherichia coli Absence/1g Candida Albicans Absence/1g Pseudomonas aeruginosa Absence/1g Staphylococcus aureus Absence/1g Salmonella Absence/1g

COMPLIES WITH

Manufcaturer specifications

STORAGE

Keep tightly closed. Store in a cool dry place.

REMARKS

Excipient suitable for cosmetic and/or nutraceutical use.

Ferulic Acid is subjected to the requirements of the ICH Q3D "Elemental Impurities" 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, are available upon request.

All methods are validated by the official pharmacopoeias and/or by the authorized manufacturer

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.

Properties

It is an antioxidant that neutralizes free radicals, responsible for oxidative stress in cell membranes and DNA.



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It helps protect the skin from the damage caused by ultraviolet radiation.

Prevents aging caused by the sun.

Protects the dermal layer (which contains elastin and collagen) and capillaries.

Applications

It is used in solar preparations.

It is used in pharmacy for its anti-inflammatory properties.