



## TECHNICAL DATA SHEET

151377-TDS-ENG-2024

ACIDO FOLICO WHO-GMP (EUR. PH.)		
DESCRIPTION DCI: FOLIC ACID HYDRATE		DESCRIPTION DOE: ACIDO FOLICO HIDRATO
CAS Nº: 59-30-3	EC Nº: 200-419-0	AEMPS CODE: 149H
MOL. WEIGHT: 441,40	MOL. FORMULA: C19H19N7O6	ARTICLE CODE: 151377

ATTRIBUTES	SHOULD BE
Appearance	Yellowish or orange, crystalline powder
Solubility	Practically insoluble in water and in most organic solvents. It dissolves in dilute acids and in alkaline solutions
Identification A	Complies
Identification B	Complies
Identification D	Complies
Specific optical rotation	+18 / +22
Related substances	
Impurity A	=< 0.5 %
Impurity D	=< 0.4 %
Impurity C	=< 0.3 %
Impurity E	=< 0.3 %
Impurity G	=< 0.3 %
Impurity H	=< 0.15 %
Impurity I	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 1.2 %
Water	5.0 - 8.5 %
Sulfated ash	=< 0.2 %
Assay	96.0 - 102.0 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Keep in the original container in a cool, well-ventilated place.

### REMARKS

It contains a variable quantity of water.

Folic Acid is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline 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, among others, are available upon request.

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.