

**ACIDO FOLICO WHO-GMP (EUR. PH.)**

PRODUCT CODE: 151377	CAS Nº: 59-30-3	ANALYSIS Nº: 213/24
MANUFACTURER BATCH: COS022407002	CERTIFICATE ID: 43.257	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 04/07/2024	
METAPH BATCH: 0070824	RETEST DATE: 03/07/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	Yellowish or orange, crystalline powder	Orange crystalline powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification D	Complies	Complies
Specific optical rotation	+18 / +22	+20
Related substances		
Impurity A	=< 0.5 %	0.2 %
Impurity D	=< 0.4 %	0.3 %
Impurity C	=< 0.3 %	< 0.05 %
Impurity E	=< 0.3 %	0.07 %
Impurity G	=< 0.3 %	0.05 %
Impurity H	=< 0.15 %	0.07 %
Impurity I	=< 0.15 %	0.06 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.2 %	0.8 %
Water	5.0 - 8.5 %	8.3 %
Sulfated ash	=< 0.2 %	0.08 %
Assay	96.0 - 102.0 %	99.6 %

**COMPLIES WITH**

European Pharmacopoeia 11.0

**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.

All data controlled by Metapharmaceutical Industrial SL.

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.

**STORAGE**

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

Analysis date: 07/10/2024  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40001123