

	G.M.P. (EU) Aut. Prod. Prov. Ric. n. CE IT AIP 19038	Valeo Farma soc. Coop. C/da Canne Masche s.n.c. 90018 Z. I. Termini Imerese, Italy P. Iva (VAT) 06288220822
Prepared by: Dr. Francesco Gullo	Verified by: Dr. Giuseppe Farina	Approved by: Dr. Vincenzo Licalsi
Code: Release_CoA	Rev. 7	Emission date: 01/11/2024

CERTIFICATE OF ANALYSIS OF FINISHED PRODUCT

Certificate Number	Product Name	Owner of Product
136/25	ACIDO FOLICO + VITAMINA B12	NUTRAMIS SRL
Batch Number	Production Date	Expiry Date
AB250225	25/02/25	03/2028
Product Category	FOOD SUPPLEMENT FOR HUMAN USE	
Storage Conditions	15-25°C, 35-60% RH	

APPEARANCE

Pharmaceutical form	TABLET
Primary Packaging	BLISTER
Secondary Packaging	CARDBOARD BOX WITH LEAFLET
Accessories	N.A.

Declaration of Compliance

Here we declare that this product is a Food Supplement as defined by directive 2002/46/EC of the European parliament and of the council of 10 June 2002. This product is compliant with the specification of Codex Alimentarius, European Food Law, HACCP, GMP and GHP criteria and Test labs are aligned to UNI CEI EN ISO 17025:2018.

MICROBIOLOGICAL TESTS

Test	U.M.	Method	Result	Limits*
Total Aerobic Microorganisms	c.f.u./g	ISO 4833-1	< 30	≤20.000
Total Moulds-Yeasts	c.f.u./g	ISO 21527-2	< 10	≤200
Enterobacteriaceae	c.f.u./g	ISO 21528-2	< 10	≤200
E. coli	c.f.u./g	ISO 16649-3	Absent	Absent
Salmonella	c.f.u./g	EU.PH	Absent	Absent
Staphylococcus aureus	c.f.u./g	EU.PH	Absent	Absent

*In accordance to acceptance criteria for microbiological quality of non-sterile dosage forms (Eu.Ph)

Valeo Farma is an Italian Contract Manufacturing Company operating in accordance with EU GMP and HACCP criteria.

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ADDITIONAL TESTS (tests performed in an external laboratory)				
Test	U.M.	Method	Result	Limits*
Gluten	mg/Kg	[MI] PPA-287 rev3 2022	< 5,0	< 20
Lactose	mg/Kg	[MI] PPA-297 rev2 2022	< 5	N.A
* Gluten limit in accordance to REG.(EC) N. 828/2014				

OTHER INFORMATION PROVIDED ON RAW MATERIALS AND PACKAGING MATERIALS
- Compliant to Reg. UE 2023/915 < 10 ppm Heavy Metals (Pb < 3 ppm; Cd < 1 ppm; Hg < 0,1 ppm). < 5 ppb aflatoxin B1 < 10 ppb total aflatoxin (sum of B1, B2, G1, G2). < 400 ppb Pyrrolizidine alkaloids < 10 ppm benzoapyrene, < 50 ppm IPA4 - And other contaminants. - Compliant to Reg. UE 1169/2011 about nanomaterials. - Compliant to Reg. CE 396/2005 and 839/2008 about residual pesticides. - Compliant to Dir. CE 1999/2/CE and 1999/3 about product not irradiated. - Compliant to Dir. 2009/32/CE about residual solvents. - Compliant to Reg. CE 1935/2004 about packaging materials. - Compliant to Reg. CE 2073/2005 about microbiological criteria Product does not contain, and it is not manufactured from OMG components.

Rating: Suitable
Date of release: 10/03/2025

Authorized by: Dr Vincenzo Licalsi

Valeo Farma Soc. Coop.
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