	G.M.P. (EU) *Aut. Prod.* *Provv. 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
260/25	ACIDO FOLICO + VITAMINA B12	NUTRAMIS SRL

Batch Number	Production Date	Expiry Date
AV250331	31/03/25	04/2028

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)

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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: 22/04/2025

Authorized by: Dr Vincenzo Licalsi

Valeo Farma Soc. Coop.
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P. IVA/C.F. 06288220822