

	G.M.P. (EU) Food Supplements 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. 4	Emission date: 25/09/2023

Certificate of Analysis of finished product

Certificate Number	Product Name	Owner of Product
197/24	Biotina	Nutramis Srl

Batch Number	Expiry date
BT240325	04.2027

APPEARANCE

Pharmaceutical form	Tablet
Primary Packaging	pill bottle HDPE
Secondary Packaging	-

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 (TAMC) in 1 g or 1 ml	c.f.u./g	ISO 4833-1	0	≤ 2000
Total Moulds-Yeasts (TYMC) in 1 g or 1 ml	c.f.u./g	ISO 21527-2	0	≤ 200
Escherichia coli in 1 g or 1 ml	c.f.u./g	ISO 16649-2	Absent	Absent

* In accordance to acceptance criteria for microbiological quality of non-sterile dosage forms (Compliant F.U.I. Table 5.1.4-1)

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 benzo(a)pyrene, < 50 ppm IPA4
- And other contaminants.
- Compliant to Reg. UE 1169/2011 about allergens and nanomaterials.

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

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- Compliant to Reg. CE 396/2005 and 839/2008 about residual pesticides.
 - Compliant to Reg. 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.
- Product does not contain, and it is not manufactured from OMG components.

Rating: Suitable

Date of release: 03/04/2024

Authorized by: Dr Vincenzo Licalsi

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