



LAB N° 0699 L



Test Report n. 24LA06121 of the day 09/04/2024

Sample matrix: Dietary supplements
Sample description: MAGISNAT DR BERTELLI'S - IMMUNE SYSTEM CAPSULES - CAMPIONE 45/24 - LOTTO 074
SCADENZA 03/2027 #
Customer: UDEM PHARMA SRL
VIA G. G. PRIAROGGIA N.83
00054 FIUMICINO RM - IT
Sampling by: Customer
Sampling site: Via Gazzana Priaroggia 83, Fiumicino, RM
Sampling date: 27/03/2024
Delivered by: Courier
Sample receipt date: 28/03/2024
Analysis start date: 28/03/2024
Analysis end date: 08/04/2024

Microbiological Analytical Results

Parameter	U.M.	Results	Uncertainty »
<i>Analytical Methods</i>			
* Enumeration of microorganisms at 30°C ISO 4833-1:2013/Amd 1. 2022	CFU/g	Present but < 40	N.A. ±1
Enumeration of moulds EU PHARMA 01/2021:20612	CFU/g	Present but < 40	N.A. ±1
Enumeration of yeasts EU PHARMA 01/2021:20612	CFU/g	< 10	N.A. ±1
Total yeasts and moulds EU PHARMA 01/2021:20612	CFU/g	Present but < 40	N.A. ±1
* § Clostridium perfringens count ISO 7937:2004	CFU/g	< 10	N.A.
Detection of Listeria monocytogenes UNI EN ISO 11290-1:2017	25 g	Not detected	N.A.
Detection of Escherichia coli EU PHARMA 01/2021: 20612 + 01/2021:20613	g	Absent	N.A.
Detection of Salmonella spp EU PHARMA 01/2021: 20612 + 01/2021:20613 + 01/2014:20631	25 g	Absent	N.A.

Chemical Analytical Results

Parameter	U.M.	Results	Uncertainty »
<i>Analytical Methods</i>			
Cadmium UNI EN 13805:2014 + UNI EN 15763:2010	mg/kg	< 0,005	
METALS			
Mercury UNI EN 13805:2014 + UNI EN 15763:2010	mg/kg	0,0057	±0,0012
Lead UNI EN 13805:2014 + UNI EN 15763:2010	mg/kg	0,0440	±0,0088



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Chemical Analytical Results

Parameter <i>Analytical Methods</i>	U.M.	Results	Uncertainty »
Arsenic UNI EN 13805:2014 + UNI EN 15763:2010	mg/kg	0,059	±0,011
OTHER PARAMETERS			
Gluten MI_613_2023_Rev.2	mg/kg	< 4,0	
* § Lactose MP 2125 rev 4 2023	mg/kg	nd	

* test not accredited by ACCREDIA

â1 Approach ISO 19036: 2019 option (b): expanded uncertainty determined as a standard deviation of reproducibility with coverage factor k=2 (95% confidence level)

» expanded uncertainty U, coverage factor K=2 (confidence level 95%), unless otherwise specified.

N.A. Not Applicable

§ test performed by an external qualified laboratory, according to PG 010

U.M. Unit of Measurement

information provided by the customer. Where sample information are provided by the customer and sampling is performed by the customer as well, all the sampling details are to be considered customer's responsibility. Where sampling is not performed by the laboratory, all the results are to be considered related to the sample as received and the laboratory declines all responsibility on results calculated using sampling information provided by the Customer.

This TEST REPORT refers only to tested samples and can not be partially reproduced unless written approval of the laboratory. / Samples storage time: samples are stored for 30 days after certificate's issue (except for perishable products which are disposed at the end of the analysis or on the date of expiry). Longer storages are allowed only on specific request, / Records storage time: copies of the certificate and of the analysis' records are stored by the laboratory for 4 years, unless otherwise specified; all the documents concerning products authorisation are stored for 10 years. / Unless otherwise specified, judgements of compliance/non compliance eventually reported apply exclusively to analysed parameters and relate on the comparison of the result with Reference values without considering measure's confidence interval.

Note: MI_613_2023 Rev2 ELISA method derived from AOAC 2014.03, limit of quantification (LOQ) 4 mg/kg.

For the method MP 2125 rev 4 2023 the limit of quantification (LOQ) corresponds to 20 mg/kg and the limit of detection (LOD) to 10 mg/kg.

LoD: limit of detection, identifies a confidence interval equal to zero at a probability level of 99%. LoQ: limit of quantification;

"nd": not detected, indicates a value lower than LoD;

"Traces": indicates a value between LoD and LoQ, this value is purely indicative;

"<x" or "> x" respectively indicate a value lower or higher than the measuring range of the test.

Person in Charge of Chemical and Biological Tests
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Biologist - Order of Biologist
Registration n° Tri_A3269 Sez. A

End of test report n° 24LA06121