



SUPPLEMENT CERTIFIED
BY NRCI WATERFORD IRELAND

Certificate of Analysis

Supplement Certified
Waterford Institute of Technology
Carrigmore house, West Campus
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Certificate number: CoA-22-00-16

Work Order: WO-22-00-04

Customer: MacuHealth LP™, Birmingham, MI 48009 (US)
Product: MacuHealth with Micro-Micelle Technology
Lot number: C2102912
Expiry date: 2024/12
Product description: 90 soft gels in PETE Bottle
Serving: 1/day
Storage conditions: 25.0 ± 0.1 °C; 60.0 ± 0.5 % Rh

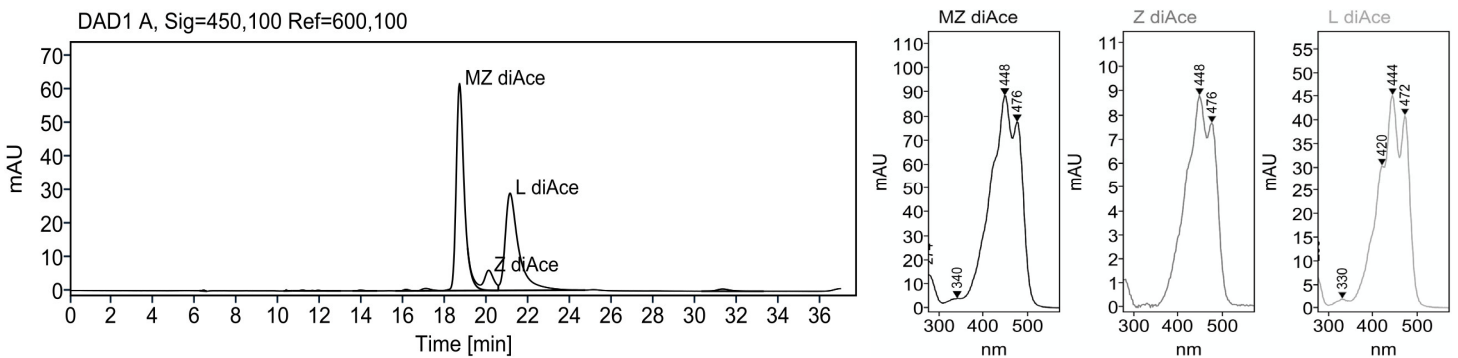
Received: 2022/01/25
Analysed: 2022/01/26
Reported: 2022/01/28
Sampler: Customer
Test: 3 soft gels
Test temp.: 20 °C

Analyte	Method	Declared mg/capsule	Measured* mg/capsule ± U95%	Heterogen. (RSD, %)	Confidence (%)	Conformance
Meso-zeaxanthin	AM-01.1-HPLC-DAD	10	12.87 ± 0.70	2.76	100	Pass
Zeaxanthin	AM-01.1-HPLC-DAD	2	1.78 ± 0.08	2.28	100	Fail
Lutein	AM-01.1-HPLC-DAD	10	13.22 ± 0.94	3.64	100	Pass
Total carotenoids	AM-01.1-HPLC-DAD	22	27.87	-	-	Pass

* The reported expanded measurement uncertainty (U95%) is stated as the combined standard measurement uncertainty multiplied by the coverage factor k = 1.96 such that the coverage probability corresponds to approximately 95%. U95% is not involved in the decision rule. (ILAC Guidelines for Measurement Uncertainty in Testing, ILAC-G17:01/2021).

Quality Control Sample: Micro Mic 5% Lutein Emulsion; Lot 70220; Analyte: Lutein diAce (50 mg/g)					
	Method	Specs. #	Raw value	Value	Result
Within-run Accuracy	AM-01.1-HPLC-DAD	85 - 115 %	Spec: 48.0 ± 0.9; HPLC: 47.9 ± 1.1	101.70%	Conform
Within-run Precision	AM-01.1-HPLC-DAD	RSD < 15 %	-	0.51%	Conform

As defined by the Guideline On Bioanalytical Method Validation (EMA, European Medicines Agency) (EMEA/CHMP/EWP/192217/2009 Rev. 1 Corr. 2**), authored by the Committee for Medicinal Products for Human Use (CHMP) 21 July 2011.



History	Month 0						
Analyte/Report ID	CoA-22-00-16						
Meso-zeaxanthin diAce	12.87 ± 0.36						
Zeaxanthin diAce	1.78 ± 0.04						
Lutein diAce	13.22 ± 0.48						
Total carotenoids	27.87						

Disclaimers: The results in this certificate relate only to the samples described above. This report shall not be altered, modified, supplemented or abstracted in any manner. Any violation of these conditions renders the report void.



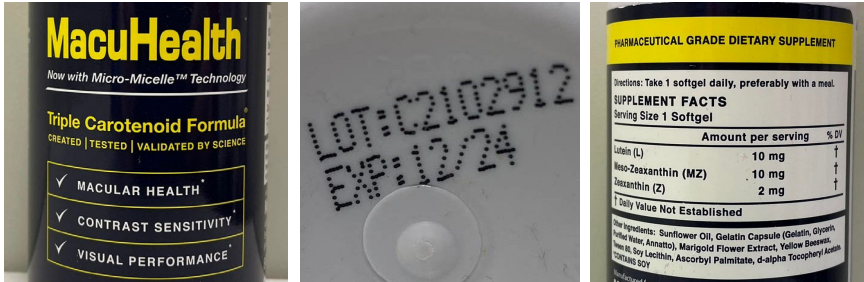
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Product pictures



Comments

To further assure results on zeaxanthin, we have extracted an additional capsule and injected ten times in the HPLC. The results are consistent with those presented in this report, and zeaxanthin fails label claim.

This product does not comply with Supplement Certified analysis criteria for label claim.

Analysis performed by:

Tommy Power, Analyst

Tommy Power (Jan 28, 2022 15:45 GMT)

Report approved by:

Dr Alfonso Prado-Cabrero, Laboratory manager

Alfonso Prado-Cabrero (Jan 28, 2022 15:34 GMT)

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CoA-22-00-16 MacuHealth with Micro-Micelle Technology C2102912 LC

Final Audit Report

2022-01-28

Created:	2022-01-28
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Status:	Signed
Transaction ID:	CBJCHBCAABAAU1p_LusKG68wviz9QbP8ZMbx57zvpnPH

"CoA-22-00-16 MacuHealth with Micro-Micelle Technology C2102912 LC" History

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