

Certificate of Analysis

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Certificate number: CoA-21-01-46

Requested by: MacuHealth LP™
401 S Old Woodward Ave., Suite 308
Birmingham, MI 48009 (US)

Storage temp: 25.12 ± 0.48 °C

Storage hum: 42.12 ± 8.06 %

Date analysed: 2021/12/02

Date received: 2021/04/12

Date reported: 2021/12/07

Product name: MacuHealth with Micro-Micelle Technology

Expiry date: 2024/03

Lot number: C2100532

Serving size: 1/Day

Distributor: MacuHealth LP™, Birmingham, MI (US)

Formulation: Soft gel

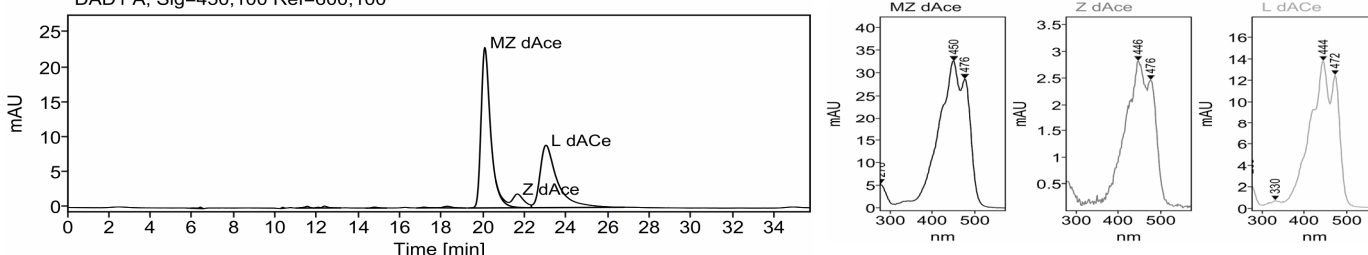
Analyte	Declared mg/capsule	Measured* mg/capsule ± U _{95%}	Heterogeneity (RSD, %)	Confidence (%)	Method	Conformance
Meso-zeaxanthin	10	14.63 ± 0.91	3.18	100	AM-HPLC-1807v2	Pass
Zeaxanthin	2	2.00 ± 0.10	2.68	52.8	AM-HPLC-1807v2	Pass
Lutein	10	13.07 ± 0.88	3.45	100	AM-HPLC-1807v2	Pass
Total carotenoids	22	29.69	-	-	AM-HPLC-1807v2	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% (ILAC Guidelines for Measurement Uncertainty in Testing, ILAC-G17:01/2021).

Quality Control Sample	Micro Mic 5% Lutein Emulsion; Lot 70220; Analyte: Lutein diAce (20 mg/g)				
	Specifications#	Raw value	Value	Method	Result
Within-run Accuracy	85 - 115 %	Spec: 42.8 ± 0.7; HPLC: 41.2 ± 1.3	92.60%	AM-HPLC-1807v2	Conform
Within-run Precision	RSD < 15 %	-	0.73%	AM-HPLC-1807v2	Conform

As defined by the Guideline On Bioanalytical Method Validation (EMA, European Medicines Agency) (EMA/CHMP/EWP/192217/2009 Rev. 1 Corr. 2**), authored by the Committee for Medicinal Products for Human Use (CHMP) 21 July 2011. LQC, MQC and HQC: Low, Medium and High Quality Control sample.

DAD1 A, Sig=450,100 Ref=600,100

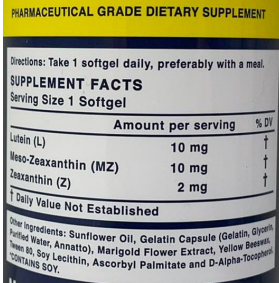


History	Month 0	Month 6
Analyte/Report ID	CoA-21-00-37	CoA-21-01-46
Meso-zeaxanthin	13.5 ± 0.12	14.63 ± 0.91
Zeaxanthin	1.7 ± 0.03	2.00 ± 0.10
Lutein	9.91 ± 0.11	13.07 ± 0.88
Total carotenoids	25.11	29.69



SUPPLEMENT CERTIFIED
BY NRCI WATERFORD IRELAND

Product pictures



Comments

Compared to the initial analysis (CoA-21-00-37), the substantial increase in lutein in the present analysis is due to the use of a new calibration line made with lutein diAce. This standard is more accurate than the one used to date, where lutein diAce was quantified using a calibration line built with free lutein.

Conclusions

This product complies with label claim and heterogeneity based on Supplement Certified criteria for Meso-zeaxanthin

This product complies with label claim based on Supplement Certified criteria for Zeaxanthin

This product complies with label claim and heterogeneity based on Supplement Certified criteria for Lutein

Conclusion: This product complies with Supplement Certified analysis criteria for label claim



SUPPLEMENT CERTIFIED
BY NICK WALE & OUID BILANJ

Supplement Certified criteria: Supplement Certified, performed by the Nutrition Research Centre Ireland, means that the supplement product analysed has undergone independent 3rd party analysis to confirm that each active ingredient (carotenoid and/or omega-3 fatty acid) present in the dietary supplement matches 100% of quantity label claim, excluding expanded uncertainty of 95% (U95%). Also, heterogeneity of each measurand must be below 10% (relative standard deviation, RSD).

Quality control criteria (Within-run accuracy): Closeness of the determined value obtained by the method to the nominal concentration of the analyte (expressed in percentage). Three quality control (QC) samples, representative of the external calibration line's low, medium, and high concentrations, are quantified by spectrophotometry (nominal concentration) and by HPLC (using the current external calibration line). Concentration of the analyte obtained by both techniques is averaged and shown (Raw value). The QC sample whose value is farthest from its nominal value is taken as the within-run accuracy (Value). This value must be within 15% of its nominal value to conform.

Quality control criteria (Within-run precision): Closeness of repeated individual measures of one of the analytes assessed. The QC sample representative of the high concentration of the external calibration line is analysed at the beginning, middle and end of the run. The resulting RSD (Value) must be below 15% to conform.

Disclaimers and Terms: The testing results in this certificate relate only to the samples described above. Unless otherwise stated, all results are expressed on an as received basis. This report shall not be altered, modified, supplemented or abstracted in any manner. Any violation of these conditions renders the report and its results void.

Analysis performed by: Tommy Power

Tommy Power (Dec 8, 2021 00:10 GMT)

Approved by: Dr Alfonso Prado-Cabrero

Alfonso Prado-Cabrero (Dec 7, 2021 09:22 GMT)







CoA-21-01-46 MacuHealth with Micro-Micelle Technology C2100532 LC

Final Audit Report

2021-12-08

Created:	2021-12-07
By:	Alfonso Prado-Cabrero (aprado-cabrero@wit.ie)
Status:	Signed
Transaction ID:	CBJCHBCAABAAszvBJqZgM9Nd0K65w6GE_EIMrYUatnoc

"CoA-21-01-46 MacuHealth with Micro-Micelle Technology C2100532 LC" History

-  Document created by Alfonso Prado-Cabrero (aprado-cabrero@wit.ie)
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