



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-22-00-04

Customer: MacuHealth LP™, Birmingham, MI 48009 (US)
Product: MacuHealth Plus+ with LMZ3
Lot number: 26050-F9
Expiry date: 2021/11
Product description: 360 soft gels in 90 sachets
Serving: 4/day
Storage conditions: 25.0 ± 0.1 °C; 60.0 ± 0.5 % Rh

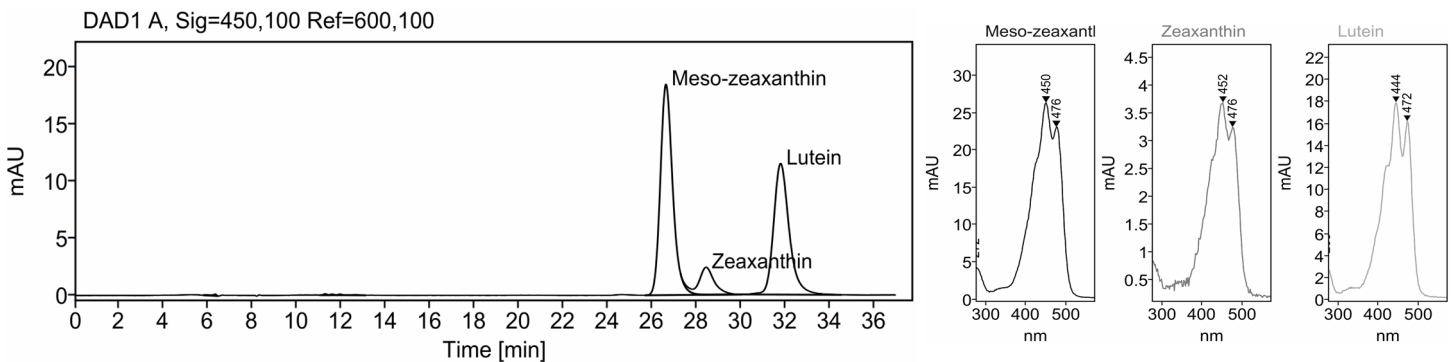
Received: 2019/03/19
Analysed: 2022/01/04
Reported: 2021/01/07
Sampler: Customer
Test: 3 soft gels
Test temp.: 20.0 °C

Analyte	Method	Declared mg/capsule	Measured* mg/capsule ± U95%	Heterogen. (RSD, %)	Confidence (%)	Conformance
Meso-zeaxanthin	AM-01.1-HPLC-DAD	10	14.77 ± 0.31	1.08	100	Pass
Zeaxanthin	AM-01.1-HPLC-DAD	2	2.65 ± 0.05	1.01	100	Pass
Lutein	AM-01.1-HPLC-DAD	10	11.31 ± 0.16	0.74	100	Pass
Total carotenoids	AM-01.1-HPLC-DAD	22	28.72	-	-	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: Natures Plus UltraLutein; Lot 1346590; Analyte: Lutein (20 mg/capsule)					
	Method	Specs. #	Raw value	Value	Result
Within-run Accuracy	AM-01.1-HPLC-DAD	85 - 115 %	Spec: 21.3 ± 0.5; HPLC: 20.5 ± 0.7	94.90%	Conform
Within-run Precision	AM-01.1-HPLC-DAD	RSD < 15 %	-	0.65%	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	Month 6	Month 12	Month 18	Month 24	Month 30	Month 33	
Analyte/Report ID	CoA-19-00-09	CoA-19-00-44	CoA-20-00-19	CoA-20-00-45	CoA-21-00-30	CoA-21-01-10	CoA-22-00-04	
Meso-zeaxanthin	13.07 ± 0.13	12.96 ± 0.11	14.29 ± 0.30	13.92 ± 0.57	13.38 ± 0.37	13.39 ± 0.30	14.77 ± 0.16	
Zeaxanthin	2.11 ± 0.02	2.11 ± 0.03	2.26 ± 0.04	2.20 ± 0.09	2.15 ± 0.06	2.40 ± 0.08	2.65 ± 0.03	
Lutein	10.50 ± 0.11	10.32 ± 0.24	11.34 ± 0.21	11.23 ± 0.41	10.59 ± 0.31	10.27 ± 0.25	11.31 ± 0.08	
Total carotenoids	25.68	25.39	27.89	27.35	26.12	26.07	28.72	

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

This product complies with Supplement Certified analysis criteria for label claim.

Analysis performed by:

Tommy Power, Analyst


Tommy Power (Jan 7, 2022 18:32 GMT)

Report approved by:

Dr Alfonso Prado-Cabrero, Laboratory manager


Alfonso Prado-Cabrero (Jan 7, 2022 16:50 GMT)

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CoA-22-00-04 MacuHealth Plus+ with LMZ3 26050-F9 LC

Final Audit Report

2022-01-07

Created:	2022-01-07
By:	Alfonso Prado-Cabrero (aprado-cabrero@wit.ie)
Status:	Signed
Transaction ID:	CBJCHBCAABAAhKnQbLwrEf0M2LZLs08doEc7q8I-HuVU

"CoA-22-00-04 MacuHealth Plus+ with LMZ3 26050-F9 LC" History

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