



# Certificate of Analysis

**Report Issued to:** MacuHealth LLC™(USA)

**Product name:** MacuHealth

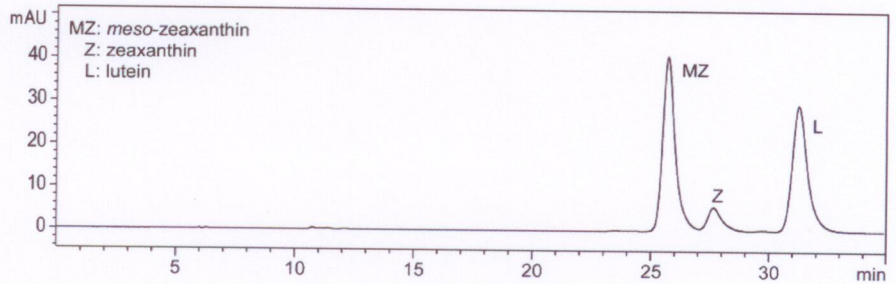
**Lot number:** C1801644

**Expiry date:** Aug/21

**Date received:** 2019.03.19

**Date analysed:** 2019.09.30

**Analysis ID:** 190045



Analyte	Declared (mg/capsule)	Measured (mg/capsule ± U <sub>95%</sub> ) <sup>a</sup>	% Achieved (95% confidence)	Result <sup>b</sup>
Lutein	10.00	10.24 ± 0.68	102 ( 96 - 109 )	Pass
Zeaxanthin	2.00	2.19 ± 0.13	109 ( 103 - 116 )	Exceeds
Meso-zeaxanthin	10.00	12.69 ± 1.18	127 ( 115 - 139 )	Exceeds

<sup>(a)</sup> U<sub>95%</sub> = 1.96 Standard Deviation. NIST 1297 (1993)

<sup>(b)</sup> % Achieved (95% confidence) is equal (pass), below (fail) or above (excess) to 100%

Quality Control	Specification <sup>c</sup>	Value	Result
Accuracy <sup>d</sup>	85 - 115%	94.93 %	Conform
Precision <sup>e</sup>	RSD <sup>d</sup> < 15%	0.55 %	Conform

<sup>(c)</sup> European Medicines Agency (EMA). Guideline on Bioanalytical Method Validation (2011)

<sup>(d)</sup> Closeness (Relative Standard Deviation, RSD) of determined concentration of lutein control sample to nominal lutein concentration

<sup>(e)</sup> Within-run variability (RSD) of lutein peak area in control sample

## Method

Technique: HPLC-DAD, column Daicel Chiralpak® IA-3

Method: Prado-Cabrero et al. Eur Food Res Technol, 242, 599-608 (2016); 3 capsules analysed.

Conditions: Isocratic run with hexane:isopropanol (90:10, v/v), flow rate of 0.5 mL min<sup>-1</sup>. Column temperature 25°C.

## History

Date analyzed	Mar-19	Sep-19	Mar-20	Sep-20	Mar-21	Sep-21
# Report	190013	190045				
Lutein	10.66 ± 0.60	10.24 ± 0.68				
Zeaxanthin	2.22 ± 0.12	2.19 ± 0.13				
Meso-zeaxanthin	12.89 ± 0.77	12.69 ± 1.18				

*Tommy Power*

**Analyzed By:** Tommy Power

*Alfonso Prado-Cabrero*

**Authorized By:** Alfonso Prado-Cabrero, PhD