



# Certificate of Analysis

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

**Product name:** MacuPrime Plus

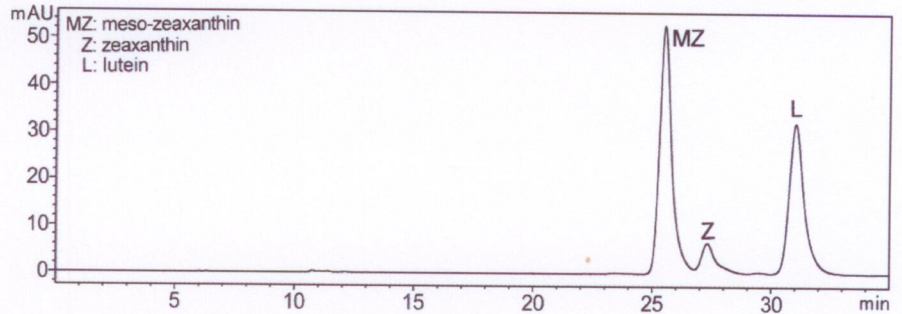
**Lot number:** 200405-A8

**Expiry date:** Jun/22

**Date received:** 2020.02.26

**Date analysed:** 2020.03.23

**Analysis ID:** 200008



Analyte	Declared (mg/capsule)	Measured (mg/capsule ± U <sub>95%</sub> ) <sup>a</sup>	% Achieved (95% confidence)	Result <sup>b</sup>
Lutein	10.00	10.951 ± 0.592	110 ( 104 - 115 )	Exceeds
Zeaxanthin	2.00	2.450 ± 0.124	122 ( 116 - 129 )	Exceeds
Meso-zeaxanthin	10.00	15.241 ± 0.892	152 ( 143 - 161 )	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%	101.04 %	Conform
Precision <sup>e</sup>	RSD <sup>d</sup> < 15%	0.54 %	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)

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

Capsules analyzed: 3

## Report Summary

This product complies with label claim

*Tommy Power*

**Analyzed By:** Tommy Power

*Alfonso Prado-Cabrero*

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