

# Certificate of Analysis

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**Certificate number:** CoA-21-01-24

**Requested by:** Pharma Marine  
Terøy Industriområde 3  
6280 Sjøvik, Norway

**Date received:** 2021/09/23

**Product name:** PAO GOLD

**Lot number:** K2108024

**Distributor:** Pharma Marine, Sjøvik (Norway)

**Storage temp:** 8 °C

**Storage hum:** Nd

**Date analysed:** 2021/09/30

**Date reported:** 2021/10/29

**Expiry date:** Nd

**Serving size:** Nd

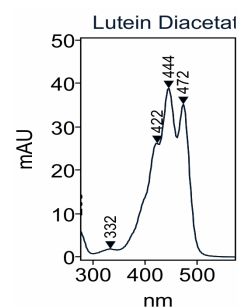
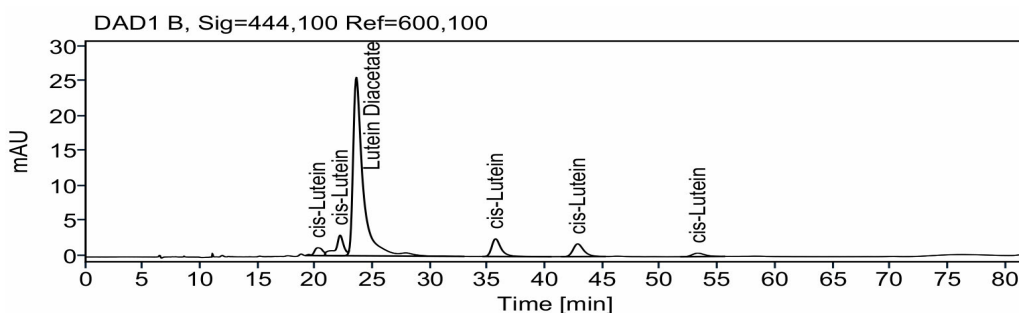
**Formulation:** Bottle

Analyte	Declared mg/g	Measured* mg/g ± U95%	Heterogeneity (RSD, %)	Confidence (%)	Method	Conformance
cis-Lutein	0	3.89 ± 0.06	0.8	-	AM-HPLC-1807v2	-
Lutein	50	12.25 ± 1.42	5.9	100	AM-HPLC-1807v2	Fail
Total carotenoids	50	16.14	-	-	AM-HPLC-1807v2	Fail

\* 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% Zeaxanthin Emulsion; Lot ; Analyte: Zeaxanthin diAce (50 mg/g)				
	Specifications#	Raw value	Value	Method	Result
Within-run Accuracy	85 - 115 %	Spec: 55.6 ± 3.5; HPLC: 55.7 ± 2.2	102.80%	AM-HPLC-1807v2	Conform
Within-run Precision	RSD < 15 %	-	0.40%	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.





**SUPPLEMENT CERTIFIED**  
BY NRCI WATERFORD IRELAND

## Product pictures

## Comments

## Conclusions

- This product does not comply with label claim based on Supplement Certified criteria for Lutein diAce

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



**SUPPLEMENT CERTIFIED**  
BY NICKI WALE & ORU BILIANJ

**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 (Oct 29, 2021 11:15 GMT+1)

**Approved by: Dr Alfonso Prado-Cabrero**

Alfonso Prado-Cabrero (Oct 29, 2021 11:11 GMT+1)







# CoA-21-01-24 PAO Gold K2108024 LC 2021.09.30

Final Audit Report

2021-10-29

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## "CoA-21-01-24 PAO Gold K2108024 LC 2021.09.30" History

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