



## Certificate of Analysis

**Productname:** Vitamini A palmitas 1g=1ME

**Inspection No:** K06295/1123/536

**Batchnumber:** 23H04-T18-106049

**Expiration date:** 12.04.2025

**Analysed according to:** ČL 2017-Dopl.2021,Ph.Eur.11.0

**Original Manuf. Date:** 13.4.2023

**Sample Unit:** 1 x 1 ml

**Batch Size:** 120 x 25 ml

**Identification of producer:** V01538

**Batch no. of vendor:** UT23040227

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Yellow or brownish-yellow liquid.Partial crystallisation may occur in highly concentrated solutions.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification	Conform	Conform		TLC	Fagron CZ
TESTS					
Acid value	<=2,0	0,11			Fagron CZ
Peroxide value	<=10,0	3,50			Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<10	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer
ASSAY					
Vitamin A	>=500000	1057662	IU/g	HPLC	Contract Lab
Vitamin A	>=500000	1057662	IE/G(UI/G)	HPLC	Contract Lab
Vitamin A	Calculated value	972203	IU/ml		Fagron CZ
Vitamin A (% decl.content)	95,0 - 110,0	96,4	%		Contract Lab
Weight of drop		0,035	g		Fagron CZ
Content Vitamin A in a drop	Calculated value	37018	IU		Fagron CZ

**Name** Fagron a.s. (CZ)  
Kontrolní laboratoř č. 536

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**Performed by:** Ludmila Burianová

**Responsible:** Mgr. Zdeňka Šinclová, QC  
MVDr. Zdenka Borská, QP

**Date:** 13.09.2023

**Conclusion:** **APPROVED**

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