

Certificate of Analysis

Productname: Vitamini A palmitas 1g=1ME

Inspection No: I05672/0721/536
Batchnumber: 21E27-T03-085793
Expiration date: 30.03.2023
Analysed according to: Ph.Eur.10.3
Original Manuf. Date: 30.3.2021

Sample Unit: 0 x
Batch Size: 8 x 250 ml

Identification of producer: V01538
Batch no. of vendor: UT21030208

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Yellow or brownish-yellow liquid. Partial crystallisation may occur in highly concentrated solutions.	Conform			
Solubility	Conform	Conform			
IDENTIFICATION					
Identification	Conform	Conform		TLC	
TESTS					
Acid value	$\leq 2,0$	0,34			
Peroxide value	$\leq 10,0$	0,112			
Microbiology	Conform	Conform			
TAMC	$\leq 2 \times 10^3$	Conform	CFU/g		
TYMC	$\leq 2 \times 10^2$	Conform	CFU/g		
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			
Residual solvents	CPMP/ICH/82 260/2006	Conform			
Metallic residues	ICH Q3D on elemental impurities	Conform			
ASSAY					
Vitamin A	≥ 500000	1093854	IU/g	HPLC	
Vitamin A	Calculated value	1005252	IU/ml		
Vitamin A (% decl.content)	95,0 - 110,0	109,4	%		
Weight of drop		0,032	g		
Content Vitamin A in a drop	Calculated value	35003	IU		

Name	Fagron a.s. (CZ)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521

Performed by: Lucie Kubáňová DiS.
Responsible: Lenka Morávková, QC
MVDr. Zdenka Borská, QA
Date: 10.08.2021
Conclusion: **APPROVED**

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Name	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
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