

Certificate of Analysis

Productname: Vitamini A palmitas 1g=1ME

Inspection No: I09786/1221/536
Batchnumber: 21K03-T07-085709
Expiration date: 30.03.2023
Analysed according to: Ph.Eur.10.3
Original Manuf. Date: 30.3.2021

Sample Unit: 1 x 5 ml
Batch Size: 215 x 25 ml

Identification of producer: V01538
Batch no. of vendor: UT21030209

	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	0,54			Fagron CZ
Peroxide value	≤10,0	1,91			Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	≤2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	≤2 x 10 ²	Conform	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	1102883	IU/g	HPLC	Contract Lab
Vitamin A	≥500000	1102883	IE/G(UI/G)	HPLC	Contract Lab
Vitamin A	Calculated value	1014652	IU/ml		Fagron CZ
Vitamin A (% decl.content)	95,0 - 110,0	101,2	%		Contract Lab
Weight of drop		0,036	g		Fagron CZ
Content Vitamin A in a drop	Calculated value	39704	IU		Fagron CZ

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

Performed by: Mgr. Zdeňka Šinclová

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 13.12.2021

Conclusion: **APPROVED**

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