Fagron personalizing medicine

Certificate of Analysis

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

Inspection No:	I09784/1221/536	**Sample Unit:**	0 x
Batchnumber:	**21K03-T07-090170**	**Batch Size:**	20 x 250 ml
Expiration date:	30.03.2023		
Analysed according to:	Ph.Eur.10.3		
Original Manuf. Date:	30.3.2021		
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 103	Conform	CFU/g		Contract Lab
TYMC	<=2 x 102	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** **Post Code**	Holická 1098/31m, Olomouc 779 00	**Phone No.** **Fax No.**	+420585222590 +420 585 226 521

The product conforms to Ph.Eur.10.3.

Performed by:	Mgr. Zdeňka Šinclová
Responsible:	Ing. Pavel Mišák, QC MVDr. Zdenka Borská, QA
Date:	13.12.2021
Conclusion:	**I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.**

This document has been produced electronically from our quality system and is valid without signature.

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