Fagron personalizing medicine

Certificate of Analysis

Productname: **Tocopherol**

Inspection No: I08765/1121/536
Batchnumber: **21J01-T03-089877**
Expiration date: 08.06.2023
Analysed according to: ČL 2017-Dopl.2020,Ph.Eur.10.0
Original Manuf. Date: 8.6.2021

Sample Unit: 0 x
Batch Size: 68 x 10 ml

Identification of producer: V01538
Batch no. of vendor: UT21060057

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear,colourless or yellowish-brown, viscous, oily liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	-0,01 - +0,01	+0	°	Optical rotation	Fagron CZ
Identification B	Conform	Conform		IR - spectrum	Fagron CZ
TESTS					
Related substances	Conform	Conform		GC	Contract Lab
Impurity A	<=0,5	0,1	%		Contract Lab
Impurity B	<=1,5	0,4	%		Contract Lab
Sum of impurities C and D	<=1,0	0,2	%		Contract Lab
Any other impurity	<=0,25	0,20	%		Contract Lab
Total impurities	<=2,5	0,9	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 103	<10	CFU/g		Contract Lab
TYMC	<=2 x 102	<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					
Alfa-tocopherol	96,0 - 102,0	100,5	%	GC	Contract Lab

Excipient

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

The product conforms to ČL 2017-Dopl.2020,Ph.Eur.10.0.

Performed by:	Lucie Kubáňová DiS.
Responsible:	Ing. Pavel Mišák, QC MVDr. Zdenka Borská, QA
Date:	08.12.2021
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.

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