



Certificate of Analysis

Productname: Tocopherol

Inspection No: I08798/1221/536

Batchnumber: 21J01-T03-091193

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: 16 x 1 l

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 10 ³	<10	CFU/g		Contract Lab
TYMC	≤2 x 10 ²	<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)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
	Kontrolní laboratoř č. 536	Post Code	779 00	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.

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