



## Certificate of Analysis

**Productname:** Tocoferoli alfa acetat

**Inspection No:** J00473/0122/536

**Batchnumber:** 21K03-T06-091809

**Expiration date:** 19.12.2024

**Analysed according to:** ČL 2017-Dopl.2020, Ph.Eur. 10.0

**Original Manuf. Date:** 20.12.2020

**Sample Unit:** 1 x 10 ml

**Batch Size:** 34 x 100 ml

**Identification of producer:** V01538

**Batch no. of vendor:** UT21010022

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, colourless or slightly greenish-yellow, viscous oily liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	-0,01 - +0,01	0,00	°	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 C	<=0,5	<0,1	%		Contract Lab
Impurity B	<=1,5	0,5	%		Contract Lab
Sum of impurities D and E	<=1,0	0,1	%		Contract Lab
Any other impurity	<=0,25	0,14	%		Contract Lab
Total impurities	<=2,5	1,0	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<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					
Alpha-tocopheryl acetate	96,5 - 102,0	99,7	%	GC	Contract Lab
Alpha-tocopheryl acetate	Calculated value	954,73	mg/ml		Fagron CZ
Drop content	Calculated value	30,0	mg (IU)		Fagron CZ

Quality: API

<b>Name</b>	Fagron a.s. (CZ)	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
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**Performed by:** Lenka Morávková

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

**Date:** 31.01.2022

**Conclusion:** **APPROVED**

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