

## Certificate of Analysis

**Productname:** Tocopheryl acetate (dl-alfa)

**Inspection No:** I06290/0821/536

**Batchnumber:** 21C26-T07-088299

**Expiration date:** 25.04.2024

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

**Original Manuf. Date:** 26.4.2020

**Sample Unit:** 0 x

**Batch Size:** 152 x 10 g

**Identification of producer:** V01538

**Batch no. of vendor:** UT20050107

	Requirement	Result	Unit	Standard remark	Insp. Site
<b>CHARACTERS</b>					
Appearance	Clear, colourless or slightly greenish-yellow, viscous oily liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
<b>IDENTIFICATION</b>					
Identification A	-0,01 - +0,01	0	°	Optical rotation	Fagron CZ
Identification B	Conform	Conform		IR - spectrum	Fagron CZ
<b>TESTS</b>					
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	<0,1	%		Contract Lab
Total impurities	≤2,5	<0,1	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	≤2 x 10 <sup>3</sup>	Conform	CFU/g		Contract Lab
TYMC	≤2 x 10 <sup>2</sup>	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
<b>ASSAY</b>					
Alpha-tocopheryl acetate	96,5 - 102,0	98,5	%	GC	Contract Lab
Alpha-tocopheryl acetate	Calculated value	942,13	mg/ml		Fagron CZ
Drop content	Calculated value	29,9	mg (IU)		Fagron CZ

**Name** Fagron a.s. (CZ)  
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**Performed by:** Lucie Kubáňová DiS.  
**Responsible:** Ing. Pavel Mišák, QC  
MVDr. Zdenka Borská, QA  
**Date:** 31.08.2021  
**Conclusion:** **APPROVED**



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