



## Certificate of Analysis

**Productname:** alpha-Tocopherylis acetat

**Inspection No:** K06526/0923/536

**Sample Unit:** 1 x 10 ml

**Batchnumber:** 23H04-T16-108050

**Batch Size:** 16 x 100 ml

**Expiration date:** 17.12.2026

**Analysed according to:** ČL2017-Dopl.2020, Ph.Eur.11.0

	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	<0,1	%		Contract Lab
Total impurities	<=2,5	0,6	%		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	ICH Q3C	Conform			Data Producer
Heavy metals	Conform	Conform			Data Producer
ASSAY					
Alpha-tocopheryl acetate	96,5 - 102,0	101,6	%	GC	Contract Lab
Alpha-tocopheryl acetate	Calculated value	965,1	mg/ml		Fagron CZ
Cont.Alpha-tocoph.acet.in drop	Calculated value	34,3	mg (IU)		Fagron CZ

**Name**  
Fagron a.s. (CZ)  
Kontrolní laboratoř č. 536

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**Performed by:** Ludmila Burianová

**Responsible:** Mgr. Zdeňka Šinclová, QC  
MVDr. Zdenka Borská, QP

**Date:** 07.09.2023

**Conclusion:** **APPROVED**

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