

Certificate of Analysis

Productname: **Tocoferoli alfa acetas**

Inspection No: 105080/0721/536

Batchnumber: **21C25-T14-087632**

Expiration date: 06.07.2023

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

Original Manuf. Date: 6.7.2020

Sample Unit: 0 x

Batch Size: 26 x 25 ml

Identification of producer: V00709

Batch no. of vendor: 84218824U0

	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	°	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	0,1	%		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 ³	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	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
ASSAY					
Alpha-tocopheryl acetate	96,5 - 102,0	99,3	%	GC	Contract Lab
Excipient					

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Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Pavel Mišák, QC
Ing. Martina Zemanová, QP
Date: 19.07.2021
Conclusion: APPROVED

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