



Certificate of Analysis

Productname: Tocoferoli alfa acetat

Inspection No: J00471/0122/536

Batchnumber: 21K03-T06-091784

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: 44 x 25 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 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					
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

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

Performed by: Lenka Morávková

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

Date: 31.01.2022

Conclusion: **APPROVED**

This document has been produced electronically from our quality system and is valid without signature.