

Certificate of Analysis

Productname: Tocopherol

Inspection No: I04382/0621/536

Batchnumber: 21D06-T06-088532

Expiration date: 07.07.2022

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

Original Manuf. Date: 7.7.2020

Sample Unit: 0 x

Batch Size: 232 x 10 ml

Identification of producer: V01538

Batch no. of vendor: UT20070087

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, colourless or yellowish-brown, 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 B	≤1,5	0,1	%		Contract Lab
Sum of impurities C and D	≤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					
Alfa-tocopherol	96,0 - 102,0	98,2	%	GC	Contract Lab

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Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA
Date: 14.07.2021
Conclusion: APPROVED



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