

Certificate of Analysis

Productname: Tocopherylis acetat (dl-alfa)
Number of analysis/Inspection Code: 1 / KEUR-180728B
Batchnumber: 18H20-B02-366201
Reference code / No.: 3984 / UT18060172
Analysed according to: PH.EUR 9.5

Tests	Requirement	Result	Unit	Standard remark
Appearance	Clear, pale (green-)yellow, viscous oily liquid	Conform Conform		
Identification A	-0,01 - +0,01	-0,01	°	Optical rotation
Identification B	Conform	Conform		IR-spectrum
Related substances	Conform	Conform		GC
Impurity A	<=0,5	0,1	%	
Impurity C	<=0,5	<0,1	%	
Impurity B	<=1,5	0,5	%	
Sum of Impurities D and E	<=1,0	<1,0	%	
Any other impurity	<=0,25	<0,1	%	
Total impurities	<=2,5	<2,5	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay alfa-Tocopherol acetate	96,5 - 102,0	98,1	%m/m	GC
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/25/20

Expiration: 06-2022

Conclusion: APPROVED

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