

Certificate of Analysis

Productname: Estradiolum (17 alfa-)
Number of analysis/Inspection Code: 1 / KEUR-194150B
Batchnumber: 22A10-F02-381372
Reference code / No.: 1317 / 5122244
Analysed according to: DAC 2021/2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Specific optical rotation	+51 - +56	+55		10% <i>m/V</i> EtOH 96%; dried
Related substances	Conform	Conform		HPLC
Impurity A	<=0,2	0,1	%	
Impurity B	<=0,15	n.d.	%	
Impurity C	<=0,2	n.d.	%	
Impurity D	<=0,3	0,1	%	
Any other impurity	<=0,10	<0,05	%	
Total impurities	<=1,0	0,2	%	
Loss on drying	<=0,5	0,0	%	105°C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay 17-alfa-Estradiol	97,0 - 102,0	100,2	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:
 Anthony Amoureux
 Qualified Person

03/29/22

Expiration: 10-2024

Conclusion: APPROVED

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