

## Certificate of Analysis

**Productname:** Estradiolum (17 alfa-)  
**Number of analysis/Inspection Code:** 1 / KEUR-185326B  
**Batchnumber:** 20F18-F01-372924  
**Reference code / No.:** 1317 / 5122243  
**Analysed according to:** DAC 2020/1

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</i> /V EtOH 96%; dried
Related substances	Conform	Conform		HPLC
Impurity A	<=0,2	0,1	%	
Impurity B	<=0,15	<0,05	%	
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	<0,1	%	105°C
Sulphated ash	<=0,1	<0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay 17-alfa-Estradiol	97,0 - 102,0	99,7	% <i>m</i> /m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:  
Paul Hofman  
Pharmacist - Qualified Person

08/27/20

Expiration: 10-2024

Conclusion: APPROVED

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