

Certificate of Analysis

Productname: Estriolum
Number of analysis/Inspection Code: 1 / KEUR-185338B
Batchnumber: 20G10-F06-372937
Reference code / No.: 4719 / L00047276
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		HPLC
Specific optical rotation	+60 - +65	+65	°	0.8% <i>m/V</i> alcohol; dried
Related substances	Conform	Conform		HPLC
Impurity A	<=0,2	0,1	%	
Impurity D	<=0,2	<0,05	%	
Impurity E	<=0,3	<0,05	%	
Impurity F	<=0,5	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Sum of impurities	<=1,0	0,1	%	
Loss on drying	<=0,5	0,1	%	3H 105°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Estriol	97,5 - 102,0	101,6	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

08/28/20

Expiration: 11-2024

Conclusion: APPROVED

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