

Certificate of Analysis

Productname: Prasteronum
Number of analysis/Inspection Code: 1 / KEUR-186984B
Batchnumber: 20H26-F04-374795
Reference code / No.: 4509 / DHEAH200604W
Analysed according to: PH.FR.2017

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white, crystalline powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Spezifische Drehung	+11,0 - +14,0	+12,6		2% <i>m</i> /V in EtOH; water and solvent free
Related substances	Conform	Conform		HPLC
Impurity A	<=0,1	n.d.	%	
Impurity B	<=0,1	<0,1	%	
Impurity D	<=0,1	n.d.	%	
Impurity E	<=0,1	<0,025	%	
Impurity C	<=0,02	<0,01	%	
Impurity F	<=0,08	<0,025	%	
Any other impurity	<=0,10	0,06	%	
Total impurities	<=0,5	0,1	%	
Hydroxylamine	<=5	Conform	ppm	
Sulphated ash	<=0,1	0,0	%	
Water	<=1,0	<0,1	%	Karl Fischer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Prasterone	97,5 - 102,0	100,0	% <i>m</i> /m	Anhydrous and solvent-free
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

11/11/20

Expiration: 06-2022

Conclusion: APPROVED

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