

Certificate of Analysis

Productname: Progesteronum micronisatum
Number of analysis/Inspection Code: 1 / KEUR-195187B
Batchnumber: 22D05-F02-382169
Reference code / No.: 2338 / EU-HTT220202M
Analysed according to: PHEUR10.7+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder or colorless crystals	Conform		
Particle size	99% < 30 µm / 90% < 15µm	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		TLC
Specific optical rotation	+186 - +194	+188		1% <i>m</i> /V EtOH; dried
Related substances	Conform	Conform		HPLC
Impurity I	<=0,6	<0,05	%	
Impurity C	<=0,3	0,1	%	
Impurity B	<=0,2	0,1	%	
Impurity D and E	<=0,15	<0,05	%	
Impurity G	<=0,15	<0,05	%	
Impurity J, K, L, M	<=0,15	<0,05	%	
Impurity H at 286nm	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Sum of impurities other than H	<=1,0	0,2	%	
Loss on drying	<= 0,5	0,1	%	2 h 105 °C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Progesterone	97,0 - 102,0	100,8	% <i>m</i> / <i>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:
 Anthony Amoureux
 Qualified Person

07/25/22

Expiration: 02-2027

Conclusion: APPROVED

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