

## Certificate of Analysis

**Productname:** Progesteronum micronisatum  
**Number of analysis/Inspection Code:** 1 / KEUR-195838B  
**Batchnumber:** 22A31-F02-383203  
**Reference code / No.:** 2338 / EU-HTT211213M  
**Analysed according to:** PHEUR10.6+

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	+191		1% <i>m/V</i> EtOH; dried
Related substances	Conform	Conform		HPLC
Impurity I	<=0,6	<0,05	%	
Impurity C	<=0,3	0,2	%	
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	0,3	%	
Loss on drying	<= 0,5	0,0	%	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	98,8	% <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:  
 Anthony Amoureux  
 Qualified Person

09/28/22

Expiration: 12-2026

Conclusion: APPROVED

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