

Certificate of Analysis

Product name: Progesteronum micronisatum
Batch number / Weight: 25H13-B05-015812 / 1 kg
Producer / Producer Batch Number: Hubei Gedian Humanwell Co. Ltd / HG-NHTT250601M2
Analyzed according to: Ph. Eur. 11.8
Number of Analysis / Certificate no.: 25H13-B05 / QO0023350

	Requirement	Result	Unit	Standard remark
Appearance	white or almost white, crystalline powder or colourless crystals	Conform		
Identification	A, B	Conform		
Particle size	100% ≤ 20 µm	Conform		
Specific optical rotation	(+186) - (+194)	+191,3		
Related substances	Conform	Conform		
Impurity I (sum of the 2 epimers)	≤ 0,6	0,10	%	
Impurity C	≤ 0,3	<0,05	%	
Impurity B	≤ 0,2	<0,05	%	
Sum of impurities D and E	≤ 0,15	0,000	%	
Impurity G	≤ 0,15	0,000	%	
Impurity J	≤ 0,15	<0,05	%	
Impurity K	≤ 0,15	<0,05	%	
Impurity L	≤ 0,15	<0,05	%	
Impurity M	≤ 0,15	<0,05	%	
Impurity H at 286 nm	≤ 0,15	<0,05	%	
Unspecified impurities	≤ 0,10	<0,05	%	
Sum of impurities other than H	≤ 1,0	0,10	%	
Loss on drying	≤ 0,5	0,42	%	
Assay	97,0 - 102,0	100,19	%	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE

Release:

28-10-2025
 Ewelina Gadzinowska
 Qualified Person

Expiration: 24-6-2027

Conclusion: APPROVED

Certificate of Analysis

Requirement	Result	Unit	Standard remark
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