

Certificate of Analysis

Product name: Progesteronum micronisatum
Batch number / Weight: 25E15-B06-010871 / 5 g
Producer / Producer Batch Number: Hubei Gedian Humanwell Pharmaceutical Co. Ltd. / NHTT250312M2
Analyzed according to: Ph.Eur.11.7
Number of Analysis / Certificate no.: 25E15-B06 / Q00015998

	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)	+189,9		
Related substances	Conform	Conform		
Impurity I (sum of the 2 epimers)	≤ 0,6	0,12	%	
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	0,022	%	
Unspecified impurities	≤ 0,10	0,065	%	
Sum of impurities other than H	≤ 1,0	0,19	%	
Loss on drying	≤ 0,5	0,03	%	
Assay	97,0 - 102,0	99,09	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
TAMC	≤ 10 ³		cfu/g	
TYMC	≤ 10 ²		cfu/g	

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 lab

Release:

28-5-2025
 Dominika Sołtysik
 Qualified Person

Certificate of Analysis

Requirement	Result	Unit	Standard remark
Expiration: 7-3-2030			
Conclusion: APPROVED			

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