

Certificate of Analysis

Product name: Estriolum
Batch number / Weight: 25L03-B04-017967 / 1 g
Producer / Producer Batch Number: Qinhuangdao Zizhu Pharmaceutical Co., Ltd. / 818008802506002
Analyzed according to: Ph. Eur. 11.8
Number of Analysis / Certificate no.: 25L03-B04 / QQ0026117

	Requirement	Result	Unit	Standard remark
Appearance	White or almost white, crystalline powder	Conform		
Identification	A, B	Conform		
Specific optical rotation	(+60) - (+65)	+62,0		
Related substances	Conform	Conform		
impurity F	<= 0,5	< 0,05	%	
Impurity E	<= 0,3	0,05	%	
Impurity A	<= 0,2	< 0,05	%	
Impurity D	<= 0,2	0,06	%	
Unspecified impurities	<= 0,10	< 0,05	%	
Total impurities	<= 1,0	0,11	%	
Loss on drying	<= 0,5	0,12	%	
Assay	97,5 - 102,0	99,22	% m/m	
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
TAMC	<= 10 ³		cfu/g	
TYMC	<= 10 ²		cfu/g	
Particle size	90% <10 µm	Conform	%	

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:

31-12-2025
 Ewelina Gadzinowska
 Qualified Person

Expiration: 18-6-2028

Conclusion: APPROVED

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