

Certificate of Analysis

Product name: Testosteronum
Batch number / Weight: 24K06-B09-004108 / 1 g
Producer / Producer Batch Number: Hubei Zhuxi Humanwell Pharmaceutical Co., Ltd / GT240609W1
Analyzed according to: Ph.Eur 11.5
Number of Analysis / Certificate no.: 24K06-B09 / QO0009974

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder or colourless or yellowish-white crystals	Conform		
Particle size	90% <10 um / 99% <25 um	Conform		
Identification	IR spectrum	Conform		
Specific optical rotation	+106 - +114	+111,7		
Related substances	Conform	Conform		
Impurity C	<=0,3	0,09	%	
Impurity I	<=0,2	<0,05	%	
Impurity K	<=0,15	0,049	%	
Unspecified impurities	<=0,10	0,049	%	
Total impurities	<=0,6	0,19	%	
Loss on drying	<=1,0	0,23	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP
Assay	98,0 - 102,0	98,70	%	

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:

20-1-2025
 Ewelina Gadzinowska
 Qualified Person

Expiration: 8-6-2027

Conclusion: APPROVED

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