



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251496

Product:	TESTOSTERONE
Lot:	251496
Expiry date:	30/05/2030
Reference:	Cumple PhEur11.8
Synonyms:	17-Hydroxyandrost-4-en-3-one
Formula:	C ₁₉ H ₂₈ O ₂
Molecular weight:	288,4 g/mol

Assay	Result	Specification	
Identification	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Specific rotation	+111	(+106) - (+114)	
Related substances (HPLC)	Conform	Complies	
Loss on drying	0,10 %	<= 1,0 %	
Assay (HPLC)	100,3 %	98,0 - 102,0 % sps	
Impurity C	< 0,05 %	<= 0,3 %	
Impurity I	0,02 %	<= 0,2 %	
Impurity K	< 0,05 %	<= 0,15 %	
Any other impurity	< 0,05 %	<= 0,10 %	
Total impurities	0,02 %	<= 0,6 %	
Residual solvent: Triethylamine	< 320 ppm	<= 320 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Elemental impurities	Conform		#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white crystalline powder, or colourless or yellowish-white crystals. Practically insoluble in water, freely soluble in ethanol 96%l and in methylene chloride, practically insoluble in fatty oils.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 07/08/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00330 SYMBIOTEC PHARMALAB LIMITED

Manufacturer batch: ZTSTCY-U5CL-25013-M1

Product	Name	Capacity	Batch
1184517	TESTOSTERONA BASE	1 kg	251496-P-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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