



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 217177

Product:	TESTOSTERONE
Lot:	217177
Expiry date:	01/10/2025
Reference:	Cumple PhEur10.7
Synonyms:	17-Hydroxyandrost-4-en-3-one
Formula:	C ₁₉ H ₂₈ O ₂
Molecular weight:	288,4 g/mol

Assay	Result	Specification	
Assay (HPLC)	99,0 %	98,0 - 102,0 % sps	
Impurity I	<=0,05 %	<= 0,2 %	
Impurity C	<=0,05 %	<= 0,3 %	
Total impurities	<=0,05 %	<= 0,6 %	
Any other impurity	<=0,05 %	<= 0,10 %	
Impurity K	<=0,05 %	<= 0,15 %	
Methanol (GC)	<=3000 ppm	<= 3000 ppm	#
Dichloromethane	<=600 ppm	<= 600 ppm	#
Triethylamine	<=320 ppm	<= 320 ppm	#
Elemental impurities	Conform		#
Ethanol	<=5000 ppm	<= 5000 ppm	#
Acetone	<=5000 ppm	<= 5000 ppm	#
Organoleptic properties	Conform	PhEur	
Identification	Conform	Test PhEur	
Loss on drying (2h, 105°C)	0,95 %	<= 1,0 %	
Related substances (HPLC)	Conform	Complies	
Specific rotation	+108	(+106) - (+114)	

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: 29/04/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00330 SYMBIOTEC PHARMALAB LIMITED

Manufacturer batch: ZTSTCY20004

Product	Name	Capacity	Batch
1184512	TESTOSTERONA BASE (INACTIVO)	1 g	217177-D-1
1184513	TESTOSTERONA BASE (INACTIVO)	5 g	217177-E-1
1184514	TESTOSTERONA BASE (INACTIVO)	10 g	217177-F-1
1184515	TESTOSTERONA BASE	25 g	217177-G-1
1184516	TESTOSTERONA BASE (INACTIVO)	100 g	217177-J-1
1184517	TESTOSTERONA BASE	1 kg	217177-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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Date of edition: 30/06/2025

