



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 212923**

Product:	ESTRADIOL VALERATE
Lot:	212923
Expiry date:	28/04/2025
Reference:	Cumple PhEur 10.4
Synonyms:	
Formula:	C <sub>23</sub> H <sub>32</sub> O <sub>3</sub>
Molecular weight:	356.5 g/mol

Assay	Result	Specification	
Impurity A	<= 0,05 %	<= 0,2 %	
Impurity C	<= 0,05 %	<= 0,2 %	
Impurity D	<= 0,05 %	<= 0,4 %	
Identification	Conform (A,B)	Test PhEur (A,B)	
Impurity E	<= 0,05 %	<= 0,15 %	
Organoleptic properties	Conform	PhEur	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Appearance of solution	Conform	Test PhEur	
Total impurities	NDT	<= 0,5 %	
Related substances (HPLC)	Conform	Test PhEur	
Residual solvent: Ethyl acetate	<=5000 ppm	<= 5000 ppm	#
Loss on drying	0,05 %	<= 1,0 %	
Residual solvent: Methanol	<=5000 ppm	<= 5000 ppm	#
Specific rotation	(+44)	(+41) – (+47)	
Elemental impurities	Conform	Test PhEur	#
Assay	100,3 %	97,5 - 102,0 %	

Organoleptic characteristics: White or almost white, crystalline powder or colourless crystals. Practically insoluble in water, freely soluble in methylene chloride, soluble in ethanol (96 per cent).

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 01/06/2021

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00381 STEROID S.P.A.

Manufacturer batch: 004721

Product	Name	Capacity	Batch
1130364	ESTRADIOL VALERATO	1 g	212923-D-1

1130364	ESTRADIOL VALERATO	1 g	212923-D-2
1130366	ESTRADIOL VALERATO	5 g	212923-E-1
1130366	ESTRADIOL VALERATO	5 g	212923-E-2
1130366	ESTRADIOL VALERATO	5 g	212923-E-3
1130367	ESTRADIOL VALERATO	10 g	212923-F-1
1130367	ESTRADIOL VALERATO	10 g	212923-F-2
1130367	ESTRADIOL VALERATO	10 g	212923-F-3
1130367	ESTRADIOL VALERATO	10 g	212923-F-4
1130368	ESTRADIOL VALERATO	25 g	212923-G-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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