



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 231451**

Product:	ESTRADIOL VALERATE
Lot:	231451
Expiry date:	28/06/2027
Reference:	Cumple PhEur11.0
Synonyms:	
Formula:	C23H32O3
Molecular weight:	356.5 g/mol

Assay	Result	Specification	
Elemental impurities	Conform	Test PhEur	#
Assay	100,4 %	97,5 - 102,0 %	
Impurity D	<0,4 %	<= 0,4 %	=
Impurity C	< 0,05 %	<= 0,2 %	=
Organoleptic properties	Conform	PhEur	
Unspecified Impurities	< 0,10 %	<= 0,10 %	=
Identification	Conform(A,B)	Test PhEur (A,B)	
Impurity E	< 0,15 %	<= 0,15 %	=
Related substances (HPLC)	Conform	Test PhEur	=
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Appearance of solution	Conform	Test PhEur	=
Total impurities	0,14 %	<= 0,5 %	=
Specific rotation	+44	(+41) – (+47)	=
Loss on drying	0,14 %	<= 1,0 %	
Residual solvent: Methanol	< 5000 ppm	<= 5000 ppm	#
Impurity A	< 0,2 %	<= 0,2 %	=

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: 25/04/2023

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00381 STEROID S.P.A.

Manufacturer batch: 057522

Product	Name	Capacity	Batch
1130364	ESTRADIOL VALERATO	1 g	231451-D-1

1130364	ESTRADIOL VALERATO	1 g	231451-D-2
1130366	ESTRADIOL VALERATO	5 g	231451-E-1
1130366	ESTRADIOL VALERATO	5 g	231451-E-2
1130366	ESTRADIOL VALERATO	5 g	231451-E-3
1130367	ESTRADIOL VALERATO	10 g	231451-F-1
1130367	ESTRADIOL VALERATO	10 g	231451-F-2
1130367	ESTRADIOL VALERATO	10 g	231451-F-3
1130368	ESTRADIOL VALERATO	25 g	231451-G-1
1130368	ESTRADIOL VALERATO	25 g	231451-G-2
1130368	ESTRADIOL VALERATO	25 g	231451-G-3

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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