



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 215060

Product:	ESTRADIOL VALERATE
Lot:	215060
Expiry date:	15/01/2026
Reference:	Cumple PhEur 10.5
Synonyms:	
Formula:	C ₂₃ H ₃₂ O ₃
Molecular weight:	356.5 g/mol

Assay	Result	Specification	
Assay	98,3 %	97,5 - 102,0 %	
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,20 %	<= 1,0 %	
Residual solvent: Methanol	<= 5000 ppm	<= 5000 ppm	#
Specific rotation	+46	(+41) – (+47)	=
Appearance of solution	Conform	Test PhEur	=
Total impurities	<= 0,5 %	<= 0,5 %	=
Related substances (HPLC)	Conform	Test PhEur	=
Residual solvent: Ethyl acetate	<= 5000 ppm	<= 5000 ppm	#
Identification	Conform (A,B)	Test PhEur (A,B)	
Impurity E	<= 0,15 %	<= 0,15 %	=
Organoleptic properties	Conform	PhEur	
Unspecified Impurities	<= 0,10 %	<= 0,10 %	=
Impurity C	<= 0,2 %	<= 0,2 %	=
Impurity D	<= 0,4 %	<= 0,4 %	=
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: 29/09/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00381 STERIOD S.P.A.

Manufacturer batch: 003721

Product	Name	Capacity	Batch
1130364	ESTRADIOL VALERATO	1 g	215060-D-1

1130364	ESTRADIOL VALERATO	1 g	215060-D-2
1130366	ESTRADIOL VALERATO	5 g	215060-E-1
1130366	ESTRADIOL VALERATO	5 g	215060-E-2
1130367	ESTRADIOL VALERATO	10 g	215060-F-1
1130367	ESTRADIOL VALERATO	10 g	215060-F-2
1130368	ESTRADIOL VALERATO	25 g	215060-G-1
1130368	ESTRADIOL VALERATO	25 g	215060-G-2
1130368	ESTRADIOL VALERATO	25 g	215060-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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