



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 224414

Product:	ESTRADIOL VALERATE
Lot:	224414
Expiry date:	30/05/2027
Reference:	Cumple PhEur 10.8
Synonyms:	
Formula:	C ₂₃ H ₃₂ O ₃
Molecular weight:	356.5 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform	Test PhEur	=
Related substances (HPLC)	Conform	Test PhEur	=
Loss on drying	0,02 %	<= 1,0 %	
Specific rotation	+45	(+41) – (+47)	=
Elemental impurities	Conform	Test PhEur	#
Assay	99,0 %	97,5 - 102,0 %	
Impurity A	< 0,2 %	<= 0,2 %	=
Impurity C	< 0,2 %	<= 0,2 %	=
Impurity D	< 0,4 %	<= 0,4 %	=
Impurity E	< 0,15 %	<= 0,15 %	=
Unspecified Impurities	< 0,10 %	<= 0,10 %	=
Total impurities	< 0,5 %	<= 0,5 %	=
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Methanol	< 5000 ppm	<= 5000 ppm	#

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: 22/09/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00381 STEROID S.P.A.

Manufacturer batch: 048422

Product	Name	Capacity	Batch
1130364	ESTRADIOL VALERATO (BIOIDENTICA)	1 g	224414-D-1

1130366	ESTRADIOL VALERATO (BIOIDENTICA)	5 g	224414-E-1
1130367	ESTRADIOL VALERATO (BIOIDENTICA)	10 g	224414-F-1
1130368	ESTRADIOL VALERATO (BIOIDENTICA)	25 g	224414-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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