



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 226633

Product:	17-beta ESTRADIOL
Lot:	226633
Expiry date:	29/04/2027
Reference:	Cumple PhEur11.0
Synonyms:	Estradiol hemihydrate.
Formula:	C ₁₈ H ₂₄ O ₂ ·0,5H ₂ O
Molecular weight:	281,39 g/mol

Assay	Result	Specification	
Impurity A	< 0,05 %	<= 0,3 %	
Impurity B	< 0,05 %	<= 0,3 %	
Impurity C	0,07 %	<= 0,3 %	
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#
Related substances (HPLC)	Conform		
Specific rotation	+82,1	(+76,0) - (+83,0)	
Water	3,2 %	2,9-3,5%	
Assay	98,8 %	97,0-103,0% o.d.m.	
Impurity D	< 0,05 %	<= 0,3 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Identification	Conform (B)		
Total impurities	0,07 %	<= 0,5 %	
Organoleptic properties	Conform		

Organoleptic characteristics: White or almost white, crystalline powder or colourless crystals. Practically insoluble in water, soluble in acetone, quite soluble in ethanol 96% and slightly soluble in methylene chloride.
Conservation: In tightly closed containers. Protect from light.

Date of analysis: 16/03/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00344 BAYER AG

Manufacturer batch: UN80A4L

Product	Name	Capacity	Batch
1130281	ESTRADIOL 17-beta HEMIHDRATO	1 g	226633-D-2
1130281	ESTRADIOL 17-beta HEMIHDRATO	1 g	226633-D-3

1130281	ESTRADIOL 17-beta HEMIHDRATO	1 g	226633-D-4
1130282	ESTRADIOL 17-beta HEMIHDRATO	25 g	226633-G-1
1130282	ESTRADIOL 17-beta HEMIHDRATO	25 g	226633-G-2
1130282	ESTRADIOL 17-beta HEMIHDRATO	25 g	226633-G-3
1130282	ESTRADIOL 17-beta HEMIHDRATO	25 g	226633-G-4
1370135	ESTRADIOL 17-beta HEMIHDRATO (FLB) (INACTIVO)	1 g	226633-D-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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