



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 240803**

Product:	17-alpha ESTRADIOL
Lot:	240803
Expiry date:	04/04/2029
Reference:	Especificaciones de fabricante
Synonyms:	Alfatradiol.
Formula:	C18H24O2
Molecular weight:	272,37 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test (A,B)	
Organoleptic properties	Conform		
Melting point	225 °C	222 - 226 °C	
Loss on drying	0,08 %	<= 0,5 %	
Specific rotation	+ 53,0	(+51,0) - (+56,0)	
Sulphated ashes	0,00%	=< 0,1%	
Related substances (HPLC)	Conform	Test	
Elemental impurities	Conform	Test	#
Assay	100,1%	97,0 - 102,0 %	
Impurity A	< 0,05 %	<= 0,2 %	
Impurity B	< 0,05 %	<= 0,15 %	
Impurity C	ND	<= 0,2 %	
Impurity D	ND	<= 0,3 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 1,0 %	
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Cyclohexane	< 3880 ppm	<= 3880 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Nitrosamine impurities	Conform	Test	#

Organoleptic characteristics: White or almost white, crystalline powder. Practically insoluble in water, freely soluble in ethanol and in hot alkaline solution.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 10/05/2024

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00343 CHIRACON GmbH

Manufacturer batch: 21-22-I-91P6527

Product	Name	Capacity	Batch
1130262	ESTRADIOL 17-alfa (BIOIDENTICA)	0,25 g	240803-B-1
1130262	ESTRADIOL 17-alfa (BIOIDENTICA)	0,25 g	240803-B-2
1130263	ESTRADIOL 17-alfa (BIOIDENTICA)	0,5 g	240803-C-1
1130263	ESTRADIOL 17-alfa (BIOIDENTICA)	0,5 g	240803-C-2
1130264	ESTRADIOL 17-alfa (BIOIDENTICA)	1 g	240803-D-1
1130264	ESTRADIOL 17-alfa (BIOIDENTICA)	1 g	240803-D-2
1130265	ESTRADIOL 17-alfa (BIOIDENTICA)	5 g	240803-E-1
1130265	ESTRADIOL 17-alfa (BIOIDENTICA)	5 g	240803-E-2

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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