



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251707

Product:	17-alpha ESTRADIOL
Lot:	251707
Expiry date:	16/06/2030
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	0,06 %	<= 0,5 %	
Specific rotation	(+56)	(+51,0) - (+56,0)	=
Sulphated ashes	0,1 %	=< 0,1%	=
Related substances (HPLC)	Conform	Test	=
Elemental impurities	Conform	Test	#
Assay	101,3 %	97,0 - 102,0 %	
Impurity A	ND	<= 0,2 %	=
Impurity B	ND	<= 0,15 %	=
Impurity C	ND	<= 0,2 %	=
Impurity D	ND	<= 0,3 %	=
Unspecified Impurities	ND	<= 0,10 %	=
Total impurities	ND	<= 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: 24/09/2025

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00343 CHIRACON GmbH

Manufacturer batch: 35-24-I-76P5189

Product	Name	Capacity	Batch
1130262	ESTRADIOL 17-alfa (BIOIDENTICA)	0,25 g	251707-B-1
1130262	ESTRADIOL 17-alfa (BIOIDENTICA)	0,25 g	251707-B-2
1130263	ESTRADIOL 17-alfa (BIOIDENTICA)	0,5 g	251707-C-1
1130263	ESTRADIOL 17-alfa (BIOIDENTICA)	0,5 g	251707-C-2
1130264	ESTRADIOL 17-alfa (BIOIDENTICA)	1 g	251707-D-1
1130264	ESTRADIOL 17-alfa (BIOIDENTICA)	1 g	251707-D-2
1130265	ESTRADIOL 17-alfa (BIOIDENTICA)	5 g	251707-E-1
1130265	ESTRADIOL 17-alfa (BIOIDENTICA)	5 g	251707-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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