



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 252224

Product:	17-alpha ESTRADIOL
Lot:	252224
Expiry date:	18/09/2030
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	0,03 %	<= 0,5 %	
Specific rotation	+55	(+51,0) - (+56,0)	=
Sulphated ashes	< 0,05 %	=< 0,1%	=
Related substances (HPLC)	Conform	Test	=
Elemental impurities	Conform	Test	#
Assay	100,3 %	97,0 - 102,0 %	
Impurity A	<= 0,15 %	<= 0,2 %	=
Impurity B	<= 0,15 %	<= 0,15 %	=
Impurity C	<= 0,15 %	<= 0,2 %	=
Impurity D	<= 0,15 %	<= 0,3 %	=
Unspecified Impurities	<= 0,10 %	<= 0,10 %	=
Total impurities	<= 1,0 %	<= 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: 09/01/2026

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00343 CHIRACON GmbH

Manufacturer batch: 35-25-I-10P5257

Product	Name	Capacity	Batch
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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

ACOFARMA DISTRIBUCIÓN, S.A.
C/ Llobregat, 20 - 08223 Terrassa (Barcelona)
Tel./ 93-736.00.88
www.acofarma.com

Date of edition: 04/04/2026

