



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 232455

Product:	17-alpha ESTRADIOL
Lot:	232455
Expiry date:	22/03/2026
Reference:	Especificaciones de fabricante
Synonyms:	Alfatradiol.
Formule:	C18H24O2
Poids moléculaire:	272,37 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test (A,B)	
Impurity D	ND	<= 0,3 %	
Impurity C	ND	<= 0,2 %	
Impurity B	0,03%	<= 0,15 %	
Impurity A	ND	<= 0,2 %	
Assay	100,1 %	97,0 - 102,0 %	
Elemental impurities	Conform	Test	#
Nitrosamine impurities	Conform	Test	#
Related substances (HPLC)	Conform	Test	
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Sulphated ashes	0,00 %	=< 0,1%	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Specific rotation	+53,3	(+51,0) - (+56,0)	
Residual solvent: Cyclohexane	< 3880 ppm	<= 3880 ppm	#
Loss on drying	0,08%	<= 0,5 %	
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Melting point	224 °C	222 - 226 °C	
Total impurities	0,03%	<= 1,0 %	
Organoleptic properties	Conform		
Unspecified Impurities	ND	<= 0,10 %	

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: 24/05/2023

Judgement:
APPROVED

Responsible: M.Mesa

Technical director: Montserrat Enrique

Manufacturer: F00343 CHIRACON GmbH

Manufacturer batch: 35-23-I10P4767

Produit	Nom	Capacité	Lot
1130262	ESTRADIOL 17-alfa	0,25 g	232455-B-1
1130262	ESTRADIOL 17-alfa	0,25 g	232455-B-2
1130263	ESTRADIOL 17-alfa	0,5 g	232455-C-1
1130263	ESTRADIOL 17-alfa	0,5 g	232455-C-2
1130263	ESTRADIOL 17-alfa	0,5 g	232455-C-3
1130264	ESTRADIOL 17-alfa	1 g	232455-D-2
1130264	ESTRADIOL 17-alfa	1 g	232455-D-5
1130264	ESTRADIOL 17-alfa	1 g	232455-D-7
1130265	ESTRADIOL 17-alfa	5 g	232455-E-1
1130265	ESTRADIOL 17-alfa	5 g	232455-E-2
1130265	ESTRADIOL 17-alfa	5 g	232455-E-3
1370175	ESTRADIOL 17-alfa (FLB) (INACTIVO)	1 g	232455-D-1
1370175	ESTRADIOL 17-alfa (FLB) (INACTIVO)	1 g	232455-D-3
1370175	ESTRADIOL 17-alfa (FLB) (INACTIVO)	1 g	232455-D-4
1370175	ESTRADIOL 17-alfa (FLB) (INACTIVO)	1 g	232455-D-6

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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