



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251501

Product:	FLUOCINOLONE ACETONIDE
Lot:	251501
Expiry date:	17/04/2030
Reference:	Cumple PhEur11.8
Synonyms:	Fluancinolona acetónido.
Formula:	C ₂₄ H ₃₀ F ₂ O ₆
Molecular weight:	452,5 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Specific rotation (EtOH, 1%)	+ 101°	(+100°) - (+104°)	=
Related substances (HPLC)	Conform		=
Loss on drying (3h, 105°C)	0,18 %	<= 1,0 %	
Assay	98,4 %	97,5 - 102,0 %	
Impurity D	0,06 %	<= 0,2 %	=
Impurity H	< 0,05 %	<= 0,15 %	=
Impurity I	0,06 %	<= 0,15 %	=
Impurity J	< 0,05 %	<= 0,2 %	=
Impurity K	< 0,05 %	<= 0,3 %	=
Unspecified Impurities	< 0,05 %	<= 0,10 %	=
Total impurities	0,12 %	<= 0,7 %	=
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 08/09/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F01002 FARMABIOS SpA

Manufacturer batch: 2151NM1 B0032523

Product	Name	Capacity	Batch
1145102	FLUOCINOLONA ACETONIDO	0,25 g	251501-B-1
1145102	FLUOCINOLONA ACETONIDO	0,25 g	251501-B-2

1145104	FLUOCINOLONA ACETONIDO	1 g	251501-D-1
1145104	FLUOCINOLONA ACETONIDO	1 g	251501-D-2
1145105	FLUOCINOLONA ACETONIDO	5 g	251501-E-1
1145105	FLUOCINOLONA ACETONIDO	5 g	251501-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

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

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