



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240971

Product:	FLUOCINOLONE ACETONIDE
Lot:	240971
Expiry date:	19/02/2029
Reference:	Cumple PhEur11.4
Synonyms:	Fluancinolona acetónido.
Formule:	C ₂₄ H ₃₀ F ₂ O ₆
Poids moléculaire:	452,5 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Specific rotation (EtOH, 1%)	+104°	(+100°) - (+104°)	=
Related substances (HPLC)	Conform		=
Loss on drying (3h, 105°C)	0,31 %	<= 1,0 %	
Assay	99,3 %	97,5 - 102,0 %	
Impurity D	0,05 %	<= 0,2 %	=
Impurity H	< 0,05 %	<= 0,15 %	=
Impurity I	0,06 %	<= 0,15 %	=
Impurity J	ND	<= 0,2 %	=
Impurity K	0,09 %	<= 0,3 %	=
Unspecified Impurities	0,06 %	<= 0,10 %	=
Total impurities	0,26 %	<= 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: 12/06/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F01002 FARMABIOS SpA

Manufacturer batch: 2151NM1 B0012423

Produit	Nom	Capacité	Lot
1145102	FLUOCINOLONA ACETONIDO	0,25 g	240971-B-1
1145102	FLUOCINOLONA ACETONIDO	0,25 g	240971-B-2

1145102	FLUOCINOLONA ACETONIDO	0,25 g	240971-B-3
1145104	FLUOCINOLONA ACETONIDO	1 g	240971-D-1
1145104	FLUOCINOLONA ACETONIDO	1 g	240971-D-2
1145104	FLUOCINOLONA ACETONIDO	1 g	240971-D-3
1145105	FLUOCINOLONA ACETONIDO	5 g	240971-E-1
1145105	FLUOCINOLONA ACETONIDO	5 g	240971-E-2
1145105	FLUOCINOLONA ACETONIDO	5 g	240971-E-3
1145105	FLUOCINOLONA ACETONIDO	5 g	240971-E-4

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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