



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 231683**

Product:	FLUOCINOLONE ACETONIDE
Lot:	231683
Expiry date:	07/12/2027
Reference:	Cumple PhEur11.0
Synonyms:	Fluancinolona acetónido.
Formula:	C <sub>24</sub> H <sub>30</sub> F <sub>2</sub> O <sub>6</sub>
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%)	+104°	(+100°) - (+104°)	=
Related substances (HPLC)	Conform		=
Loss on drying (3h, 105°C)	0,26 %	<= 1,0 %	
Assay	100,8 %	97,5 - 102,0 %	
Impurity D	< 0,05 %	<= 0,2 %	=
Impurity H	< 0,05 %	<= 0,15 %	=
Impurity I	0,08 %	<= 0,15 %	=
Impurity J	< 0,2 %	<= 0,2 %	=
Impurity K	< 0,3 %	<= 0,3 %	=
Unspecified Impurities	ND	<= 0,10 %	=
Total impurities	0,08 %	<= 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: 13/04/2023

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01002 FARMABIOS SpA

Manufacturer batch: 2151NM1B0052223

Product	Name	Capacity	Batch
1145102	FLUOCINOLONA ACETONIDO	0,25 g	231683-B-1
1145102	FLUOCINOLONA ACETONIDO	0,25 g	231683-B-2

1145102	FLUOCINOLONA ACETONIDO	0,25 g	231683-B-3
1145102	FLUOCINOLONA ACETONIDO	0,25 g	231683-B-4
1145104	FLUOCINOLONA ACETONIDO	1 g	231683-D-1
1145104	FLUOCINOLONA ACETONIDO	1 g	231683-D-2
1145104	FLUOCINOLONA ACETONIDO	1 g	231683-D-3
1145104	FLUOCINOLONA ACETONIDO	1 g	231683-D-4
1145105	FLUOCINOLONA ACETONIDO	5 g	231683-E-1
1145105	FLUOCINOLONA ACETONIDO	5 g	231683-E-2
1145105	FLUOCINOLONA ACETONIDO	5 g	231683-E-3
1145105	FLUOCINOLONA ACETONIDO	5 g	231683-E-4
1145105	FLUOCINOLONA ACETONIDO	5 g	231683-E-5

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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