



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 213298**

Product:	FLUOCINOLONE ACETONIDE
Lot:	213298
Expiry date:	01/10/2025
Reference:	Cumple PhEur10.4
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	
Residual solvent: methylene chloride	<=600 ppm	<= 600 ppm	#
Assay	100,4 %	97,5 - 102,0 %	
Residual solvent: acetone	<=5000 ppm	<= 5000 ppm	#
Loss on drying (3h, 105°C)	0,26 %	<= 1,0 %	
Residual solvent: Methanol	<=3000 ppm	<= 3000 ppm	#
Related substances (HPLC)	Conform		=
Total impurities	<= 0,7 %	<= 0,7 %	=
Impurity H	<= 0,15 %	<= 0,15 %	=
Impurity D	<= 0,2 %	<= 0,2 %	=
Specific rotation (EtOH, 1%)	+101°	(+100°) - (+104°)	=
Unspecified Impurities	<= 0,10 %	<= 0,10 %	=
Organoleptic properties	Conform	PhEur	
Impurity K	<= 0,3 %	<= 0,3 %	=
Identification	Conform (A,B)	Test PhEur (A,B)	
Impurity J	<= 0,2 %	<= 0,2 %	=
Impurity I	<= 0,15 %	<= 0,15 %	=

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 01/07/2021

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01002 FARMABIOS SpA

Manufacturer batch: 2151NM1 B0092030

Product	Name	Capacity	Batch
1145102	FLUOCINOLONA ACETONIDO	0,25 g	213298-B-1
1145102	FLUOCINOLONA ACETONIDO	0,25 g	213298-B-2

1145102	FLUOCINOLONA ACETONIDO	0,25 g	213298-B-3
1145104	FLUOCINOLONA ACETONIDO	1 g	213298-D-1
1145104	FLUOCINOLONA ACETONIDO	1 g	213298-D-2
1145104	FLUOCINOLONA ACETONIDO	1 g	213298-D-3
1145105	FLUOCINOLONA ACETONIDO	5 g	213298-E-1
1145105	FLUOCINOLONA ACETONIDO	5 g	213298-E-2
1145105	FLUOCINOLONA ACETONIDO	5 g	213298-E-3

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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