



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 221134

Product:	FLUDROCORTISONE ACETATE
Lot:	221134
Expiry date:	01/09/2026
Reference:	Cumple PhEur10.6
Synonyms:	
Formula:	C ₂₃ H ₃₁ FO ₆
Molecular weight:	422,5 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Specific rotation	+152	(+148) - (+156)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,04 %	<= 1,0 %	
Assay	99,9 %	97,0 - 103,0 %	
Any other impurity	0,06 %	<= 1,0 %	
Total impurities	0,06 %	<= 1,5 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Tetrahydrofuran	< 720 ppm	<= 720 ppm	#
Residual solvent: Pyridine	< 200 ppm	<= 200 ppm	#
Residual solvent: Dimethylformamide	< 880 ppm	<= 880 ppm	#
Residual solvent: Ethanol	< 200 ppm	<= 200 ppm	#

Organoleptic characteristics: White or almost white, slightly hygroscopic crystalline powder. Practically insoluble in water, sparingly soluble in anhydrous ethanol. It shows polymorphism

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 25/03/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F01002 FARMABIOS SpA

Manufacturer batch: 2142AM0B0012123

Product	Name	Capacity	Batch
1145041	FLUDROCORTISONA ACETATO	1 g	221134-D-1
1145041	FLUDROCORTISONA ACETATO	1 g	221134-D-2

1145041	FLUDROCORTISONA ACETATO	1 g	221134-D-3
1145041	FLUDROCORTISONA ACETATO	1 g	221134-D-4
1145041	FLUDROCORTISONA ACETATO	1 g	221134-D-5
1145042	FLUDROCORTISONA ACETATO	5 g	221134-E-1
1145042	FLUDROCORTISONA ACETATO	5 g	221134-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

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