



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 260492

Product:	FLUDROCORTISONE ACETATE
Lot:	260492
Expiry date:	01/08/2030
Reference:	Cumple PhEur12.2
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	(+134)	(+126) - (+138)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,00%	<= 1,0 %	
Assay	99,7 %	98,0 - 102,0 %	
Impurity A	< 0,05 %	<= 0,5 %	
Any other impurity	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 1,0 %	
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	< 5000 ppm	<= 5000 ppm	#
Elemental impurities	Conform		#
Nitrosamine impurities	Conform		#

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: 13/04/2026

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F01002 FARMABIOS SpA

Manufacturer batch: 2142AM0 B0022523

Product	Name	Capacity	Batch
1145041	FLUDROCORTISONA ACETATO	1 g	260492-D-2
1145042	FLUDROCORTISONA ACETATO	5 g	260492-E-1
1370274	FLUDROCORTISONA ACETATO (FLB)	1 g	260492-D-1
1370274	FLUDROCORTISONA ACETATO (FLB)	1 g	260492-D-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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