



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 216653

Product:	TRIAMCINOLONE ACETONIDE
Lot:	216653
Expiry date:	01/05/2026
Reference:	Cumple PhEur10.6
Synonyms:	
Formula:	C ₂₄ H ₃₁ FO ₆
Molecular weight:	434,5 g/mol

Assay	Result	Specification	
Identification	Conform (A,C)		
Organoleptic properties	Conform		
Related substances (HPLC)	Conform		=
Specific rotation (0,5% EtOH)	+ 111°	(+110°)-(+117°)	=
Moisture - K.F. (s/0,5g)	1,1 %	<= 2,0 %	
Assay (HPLC)	99,8 %	97,5-102,0%	
Impurity B	<= 0,2 %	<= 0,2 %	=
Impurity C	<= 0,15 %	<= 0,15 %	=
Unspecified Impurities	<= 0,10 %	<= 0,10 %	=
Total impurities	<= 0,5 %	<= 0,5 %	=
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: 13/01/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01002 FARMABIOS SpA

Manufacturer batch: 2196NM4 B0262121

Product	Name	Capacity	Batch
1186922	TRIAMCINOLONA ACETONIDO (INACTIVO)	0.5 g	216653-C-1
1186923	TRIAMCINOLONA ACETONIDO	1 g	216653-D-1
1186924	TRIAMCINOLONA ACETONIDO	5 g	216653-E-1
1186925	TRIAMCINOLONA ACETONIDO	10 g	216653-F-1
1186926	TRIAMCINOLONA ACETONIDO	25 g	216653-G-1

1186928 TRIAMCINOLONA ACETONIDO

250 g

216653-N-1

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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