



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 202222

Product:	TRIAMCINOLONE ACETONIDE
Lot:	202222
Expiry date:	01/09/2025
Reference:	Cumple PhEur10.2
Synonyms:	
Formule:	C ₂₄ H ₃₁ FO ₆
Poids moléculaire:	434,5 g/mol

Assay	Result	Specification	
Moisture - K.F. (s/0,5g)	1,2 %	<= 2,0 %	
Assay (HPLC)	100,2 %	97,5-102,0%	
Impurity B	<=0,05 %	<= 0,2 %	
Impurity C	<=0,05 %	<= 0,15 %	
Unspecified Impurities	<=0,05 %	<= 0,10 %	
Identification	Conform (A,C)		
Total impurities	<=0,05 %	<= 0,5 %	
Organoleptic properties	Conform		
Residual solvent: Methanol	<=3000 ppm	<= 3000 ppm	#
Related substances (HPLC)	Conform		
Residual solvent: acetone	<=5000 ppm	<= 5000 ppm	#
Specific rotation (0,5% EtOH)	+112°	(+110°)-(+117°)	
Residual solvent: methylene chloride	<=600 ppm	<= 600 ppm	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 15/12/2020

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01002 FARMABIOS SpA

Manufacturer batch: 2196NM4 B0142021

Produit	Nom	Capacité	Lot
1186922	TRIAMCINOLONA ACETONIDO (INACTIVO)	0.5 g	202222-C-1
1186923	TRIAMCINOLONA ACETONIDO	1 g	202222-D-1
1186923	TRIAMCINOLONA ACETONIDO	1 g	202222-D-2
1186924	TRIAMCINOLONA ACETONIDO	5 g	202222-E-1
1186924	TRIAMCINOLONA ACETONIDO	5 g	202222-E-2

1186925	TRIAMCINOLONA ACETONIDO	10 g	202222-F-1
1186926	TRIAMCINOLONA ACETONIDO	25 g	202222-G-1
1186926	TRIAMCINOLONA ACETONIDO	25 g	202222-G-2
1186928	TRIAMCINOLONA ACETONIDO	250 g	202222-N-1
1186928	TRIAMCINOLONA ACETONIDO	250 g	202222-N-2
1200233	TRIAMCINOLONA ACETONIDO	50 g	202222-I-1
1200233	TRIAMCINOLONA ACETONIDO	50 g	202222-I-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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