



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 200958

Product:	TRIAMCINOLONE ACETONIDE
Lot:	200958
Expiry date:	01/06/2025
Reference:	Cumple PhEur10.2
Synonyms:	
Formula:	C ₂₄ H ₃₁ FO ₆
Molecular weight:	434,5 g/mol

Assay	Result	Specification	
Assay (HPLC)	100,9 %	97,5-102,0%	
Moisture - K.F. (s/0,5g)	1,3 %	<= 2,0 %	
Specific rotation (0,5% EtOH)	+ 115 °	(+110°)-(+117°)	=
Residual solvent: methylene chloride	<= 600 ppm	<= 600 ppm	#
Related substances (HPLC)	Conform		=
Residual solvent: acetone	<= 5000 ppm	<= 5000 ppm	#
Organoleptic properties	Conform		
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Identification	Conform (A,C)		
Total impurities	0,11 %	<= 0,5 %	=
Unspecified Impurities	0,01 %	<= 0,10 %	=
Impurity C	<= 0,15 %	<= 0,15 %	=
Impurity B	<= 0,2 %	<= 0,2 %	=

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 02/09/2020

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01002 FARMABIOS SpA

Manufacturer batch: 2196NM4 B0022021

Product	Name	Capacity	Batch
1186922	TRIAMCINOLONA ACETONIDO (INACTIVO)	0.5 g	200958-C-1
1186923	TRIAMCINOLONA ACETONIDO	1 g	200958-D-1
1186923	TRIAMCINOLONA ACETONIDO	1 g	200958-D-2
1186924	TRIAMCINOLONA ACETONIDO	5 g	200958-E-1
1186925	TRIAMCINOLONA ACETONIDO	10 g	200958-F-1

1186926	TRIAMCINOLONA ACETONIDO	25 g	200958-G-1
1186928	TRIAMCINOLONA ACETONIDO	250 g	200958-N-1
1200233	TRIAMCINOLONA ACETONIDO	50 g	200958-I-1
M0019090	TRIAMCINOLONA ACETONIDO	g	200958

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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