



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 252242

Product:	TRIAMCINOLONE ACETONIDE
Lot:	252242
Expiry date:	28/02/2029
Reference:	Cumple PhEur12.1
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	+113	(+110) - (+117)	
Moisture - K.F.	1,5 %	<= 2,0 %	
Assay (HPLC)	98,4 %	97,5-102,0%	
Impurity B	0,10 %	<= 0,2 %	
Impurity C	< 0,05 %	<= 0,15 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,10 %	<= 0,5 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform		#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 15/01/2026

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00340 SWATI SPENTOSE PRIVATE LIMITED (UNIT-I)

Manufacturer batch: TCA-125004

Product	Name	Capacity	Batch
1186923	TRIAMCINOLONA ACETONIDO	1 g	252242-D-1
1186923	TRIAMCINOLONA ACETONIDO	1 g	252242-D-2
1186924	TRIAMCINOLONA ACETONIDO	5 g	252242-E-1

1186924	TRIAMCINOLONA ACETONIDO	5 g	252242-E-2
1186925	TRIAMCINOLONA ACETONIDO	10 g	252242-F-1
1186926	TRIAMCINOLONA ACETONIDO	25 g	252242-G-1
1186928	TRIAMCINOLONA ACETONIDO	250 g	252242-N-1
1186928	TRIAMCINOLONA ACETONIDO	250 g	252242-N-2
1200233	TRIAMCINOLONA ACETONIDO	50 g	252242-I-1
1200233	TRIAMCINOLONA ACETONIDO	50 g	252242-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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