



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 231912

Product:	13-cis-RETINOIC ACID
Lot:	231912
Expiry date:	22/04/2027
Reference:	Cumple PhEur11.1
Synonyms:	Isotretinoína.
Formula:	C ₂₀ H ₂₈ O ₂
Molecular weight:	300,4 g/mol

Assay	Result	Specification	
Identification	Conform (A)		
Organoleptic properties	Conform	PhEur	
Elemental impurities	Conform	Test PhEur	#
Related substances (HPLC)	Conform	Test PhEur	=
Loss on drying	0,00 %	<= 0,5 %	
Sulphated ashes	< 0,1 %	<= 0,1%	=
Assay (PFP)	99,9 %	98,0-102,0%	
STORE WITHIN 25°C			
Impurity A	<0,05 %	<= 0,2 %	=
Unspecified Impurities	< 0,10 %	<= 0,10 %	=
Total impurities	< 0,05 %	<= 0,5 %	=
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Heptane	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
	< 380 ppm	<= 380 ppm	#

Organoleptic characteristics:

Conservation: Keep in tightly closed containers, in N₂ atmosphere. Protect from light.

Date of analysis: 10/05/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00368 SIEGFRIED PHARMACHEMICKALIEN MINDEN GmbH

Manufacturer batch: 22162129

Product	Name	Capacity	Batch
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1102517	ACIDO RETINOICO 13 CIS	1 g	231912-D-1
1102517	ACIDO RETINOICO 13 CIS	1 g	231912-D-2
1102517	ACIDO RETINOICO 13 CIS	1 g	231912-D-3
1102518	ACIDO RETINOICO 13 CIS	10 g	231912-F-1
1102518	ACIDO RETINOICO 13 CIS	10 g	231912-F-2
1102519	ACIDO RETINOICO 13 CIS	25 g	231912-G-1
1102519	ACIDO RETINOICO 13 CIS	25 g	231912-G-2
1102519	ACIDO RETINOICO 13 CIS	25 g	231912-G-3
1102535	ACIDO RETINOICO 13 CIS	100 g	231912-J-1
1102535	ACIDO RETINOICO 13 CIS	100 g	231912-J-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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