



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240503

Product:	trans-RETINOIC ACID
Lot:	240503
Expiry date:	19/01/2027
Reference:	Cumple PhEur11.3
Synonyms:	Tretinoína. Vitamina A ácida.
Formula:	C ₂₀ H ₂₈ O ₂
Molecular weight:	300,42 g/mol

Assay	Result	Specification	
Identification	Conform (A)		
Organoleptic properties	Conform		
Melting point (dec) (Mettler)	182 ° C	Approx. 182°C (dec)	
Elemental impurities	Conform	Test PhEur	#
Related substances (HPLC)	Conform		
Loss on drying	0,02 %	<= 0,5 %	
Sulphated ashes	0,00 %	=< 0,1%	
Assay	100,7 %	98,0-102,0%	
STORE WITHIN 25°C			
Nitrosamine impurities	Conform	Test PhEur	#
Impurity A	0,08 %	<= 0,5 %	
Unspecified Impurities	0,15 %	<= 0,2 %	
Total impurities	0,29 %	<= 1,0 %	
Residual solvent: Acetaldehyde	< 15 ppm	<= 15 ppm	#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics:

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

Date of analysis: 15/03/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00285 CHONGQING HUAPON T SENGCHEM PHARM. CO. LTD

Manufacturer batch: TRER-20240101

Product	Name	Capacity	Batch
1102521	ACIDO RETINOICO TRANS	1 g	240503-D-1
1102521	ACIDO RETINOICO TRANS	1 g	240503-D-2
1102521	ACIDO RETINOICO TRANS	1 g	240503-D-3

1102521	ACIDO RETINOICO TRANS	1 g	240503-D-4
1102521	ACIDO RETINOICO TRANS	1 g	240503-D-5
1102528	ACIDO RETINOICO TRANS	5 g	240503-E-1
1102528	ACIDO RETINOICO TRANS	5 g	240503-E-2
1102528	ACIDO RETINOICO TRANS	5 g	240503-E-3
1102529	ACIDO RETINOICO TRANS	25 g	240503-G-1
1102529	ACIDO RETINOICO TRANS	25 g	240503-G-2
1102529	ACIDO RETINOICO TRANS	25 g	240503-G-3

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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Date of edition: 09/05/2026

