



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251775

| | |
|-------------------|--|
| Product: | trans-RETINOIC ACID |
| Lot: | 251775 |
| Expiry date: | 11/01/2028 |
| Reference: | Cumple PhEur11.8 |
| 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 | | |
| Elemental impurities | Conform | Test PhEur | # |
| Related substances (HPLC) | Conform | | |
| Loss on drying | 0,11 % | <= 0,5 % | |
| Sulphated ashes | 0,03 % | =< 0,1% | |
| Assay | 99,4 % | 98,0-102,0% | |
| STORE WITHIN 25°C | | | |
| Nitrosamine impurities | Conform | Test PhEur | # |
| Impurity A | < 0,05 % | <= 0,5 % | |
| Unspecified Impurities | < 0,05 % | <= 0,2 % | |
| Total impurities | < 0,05 % | <= 1,0 % | |
| 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: 09/10/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00285 CHONGQING HUAPONT SENGCHEM PHARM. CO. LTD

Manufacturer batch: TRER-20250104

| Product | Name | Capacity | Batch |
|---------|-----------------------|----------|------------|
| 1102521 | ACIDO RETINOICO TRANS | 1 g | 251775-D-1 |
| 1102521 | ACIDO RETINOICO TRANS | 1 g | 251775-D-2 |
| 1102521 | ACIDO RETINOICO TRANS | 1 g | 251775-D-3 |
| 1102528 | ACIDO RETINOICO TRANS | 5 g | 251775-E-1 |
| 1102528 | ACIDO RETINOICO TRANS | 5 g | 251775-E-2 |

| | | | |
|---------|-----------------------|------|------------|
| 1102528 | ACIDO RETINOICO TRANS | 5 g | 251775-E-3 |
| 1102529 | ACIDO RETINOICO TRANS | 25 g | 251775-G-1 |
| 1102529 | ACIDO RETINOICO TRANS | 25 g | 251775-G-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

ACOFARMA DISTRIBUCIÓN, S.A.
C/ Llobregat, 20 - 08223 Terrassa (Barcelona)
Tel./ 93-736.00.88
www.acofarma.com

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