

**ACIDO TRANS RETINOICO (EUR. PH.) EU-GMP**

PRODUCT CODE: 00081	CAS N°: 302-79-4	ANALYSIS N°: 008/25
MANUFACTURER BATCH: 0024101291	CERTIFICATE ID: 44.753	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 24/06/2024	
METAPH BATCH: 0080125	RETEST DATE: 24/06/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	Yellow or light orange, crystalline powder	Yellow crystalline powder
Melting point	about 182 °C, with decomposition	182.2 °C
Identification A	Complies	Complies
Related substances		
Impurity A	=< 0.5 %	0.15 %
Unspecified impurities	=< 0.2 %	< 0.05 %
Total of impurities	=< 1.0 %	0.15 %
Loss on drying	=< 0.5 %	< 0.01 %
Sulfated ash	=< 0.1%	0.01 %
Assay	98.0 - 102.0 %	99.2 %

**COMPLIES WITH**

European Pharmacopoeia 11.0

**REMARKS**

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Tretinoin is subjected to the requirements of the ICH Q3D "Elemental Impurities" and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

**STORAGE**

It is recommended to be used as quickly as possible once the container is opened and to keep the rest under inert gas. Store in a cool, dry place. Protect from light and heat.

Analysis date: 18/02/2025  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000353  
OLON s.p.a.  
Stabilimento di Garbagnate Milanese  
Via Milano, 186  
20024 Garbagnate Milanese (MI)