

<b>ACIDO TRANS RETINOICO (EUR. PH.) EU-GMP</b>			
PRODUCT CODE: 00081		CAS Nº: 302-79-4	ANALYSIS Nº: 336/25
MANUFACTURER BATCH:	0025101527	CERTIFICATE ID:	48.845
SUPPLIER BATCH:	----	MANUFACTURING DATE:	04/08/2025
METAPH BATCH:	0271025	RETEST DATE:	03/08/2030

ATTRIBUTES	SHOULD BE	IS
Appearance	Yellow or light orange, crystalline powder	Yellow crystalline powder
Melting point	about 182 °C, with decomposition	180 °C
Identification A	Complies	Complies
Related substances		(*)
Impurity A	=< 0.5 %	< 0.05 %
Unspecified impurities	=< 0.2 %	0.05 %
Total of impurities	=< 1.0 %	0.05 %
Loss on drying	=< 0.5 %	0.02 %
Sulfated ash	=< 0.1%	0.06 %
Assay	98.0 - 102.0 %	99.6 %

#### COMPLIES WITH

European Pharmacopoeia 11.0

#### REMARKS

Product fully analyzed within the EU, in compliance with the currents 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.

(\*) Data adapted from the manufacturer's certificate of analysis.

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.

Release date: 17/12/2025  
Signature: Albert Sánchez López (QP)  
Conclusion: Complies



Manufacturer: 40000353  
OLON s.p.a.  
Via della Vittoria, 89  
26837 Mulazzano  
Lodi (Italia)

Original certificate available upon request

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