



ACIDO TRANS RETINOICO (EUR. PH.)

PRODUCT CODE: 000223	CAS Nº: 302-79-4	ANALYSIS Nº: 275/24
MANUFACTURER BATCH: TRER-20240303	CERTIFICATE ID: 44.016	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 26/03/2024	
METAPH BATCH: 0291024	RETEST DATE: 25/03/2027	

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 %	< 0.05 %
Unspecified impurities	=< 0.2 %	0.08 %
Total impurities	=< 1.0 %	0.08 %
Loss on drying	=< 0.5 %	0.07 %
Sulfated ash	=< 0.1 %	0.05 %
Assay	98.0 - 102.0 %	101.3%

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.

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

Store the containers in a dry and well-ventilated place, away from sources of heat and direct sunlight.

Analysis date: 20/02/2025
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000358
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