

**ACIDO RETINOICO 13 CIS (EUR. PH.)**

PRODUCT CODE: 002052		CAS Nº: 4759-48-2	ANALYSIS Nº: 077/25
MANUFACTURER BATCH:	IST-20250104	CERTIFICATE ID:	45.710
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/01/2025
METAPH BATCH:	0290325	RETEST DATE:	31/12/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	Yellow or light orange, crystalline powder	Light orange crystalline powder
Solubility	Practically insoluble in water, soluble in methylene chloride, slightly soluble in ethanol (96 %)	
Identification	Complies	Complies
Related substances		
Impurity A	=< 0.2 %	0.1 %
Unspecified impurities	=< 0.10 %	0.06 % ( RT = 41.11 min)
Total impurities	=< 0.5 %	0.2 %
Loss on drying	=< 0.5 %	0.02 %
Sulfated ash	=< 0.1 %	0.04 %
Assay	98.0 - 102.0 %	99.6 %

**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.

Isotretinoin 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**

Keep the containers tightly closed. Store under nitrogen in a cool, dry and well-ventilated place

Analysis date: 12/06/2025  
Signature: Albert Sánchez López (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000358  
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