METAPHARMACEUTICAL IND SL
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ACIDO TRANS RETINOICO (EUR. PH.) EU-GMP

PRODUCT CODE: 00081	CAS Nº: 302-79-4	ANALYSIS Nº: 283/24	
MANUFACTURER BATCH:	0024101291	CERTIFICATE ID:	44.089
SUPPLIER BATCH:	----	MANUFACTURING DATE:	24/06/2024
METAPH BATCH:	0081124	RETEST DATE:	24/06/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	Yellow or light orange, crystalline powder	Yellow crystalline powder
Melting point	about 182 ºC, with decomposition	182 ºC
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 %	0.01 %
Sulfated ash	=< 0.1%	0.04 %
Assay	98.0 - 102.0 %	100.7 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliances 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.

Analysis date: 22/11/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000353