



# METAPHARMACEUTICA

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## TECHNICAL DATA

004868

### TRETINOINA (ACIDO TRACETICO)

DESCRIPTION DCI: TRETINOIN

CAS N°: 302-79-4

EC N°: 206-129-0

MOL. WEIGHT: 300.42

MOL. FORMULA: C<sub>20</sub>H<sub>28</sub>O

### ATTRIBUTES

Appearance	Yellow or light orange
Solubility	Practically insoluble in ether, slightly soluble in ethanol
Melting point	about 182 °C, with decomposition
Identification A	Complies
Related substances	
Impurity A	= < 0.5 %
Unspecified impurities	= < 0.2 %
Total of impurities	= < 1.0 %

All methods are validated by the official pharmacopoeias and/or by the company.

004868-TDS-ENG-2023



## ICAL DATA SHEET

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## INS-RETINOICO Ph. Eur. ROCHE)

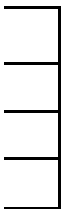
	DESCRIPTION DOE: TRETINOINA
	AEMPS CODE: 155A
0H28O2	ARTICLE CODE: 004868

## SHOULD BE

orange, crystalline powder

luble in water, sparingly soluble in methylene chloride, slightly  
sol (96 %)

with decomposition





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MOL. WEIGHT: 300.42	MOL. FORMULA: C <sub>20</sub> H <sub>28</sub> O

### ATTRIBUTES

Loss on drying	= < 0.5 %
Sulfated ash	= < 0.1%
Assay	98.0 - 102.0 %

### COMPLIES WITH

### STORAGE

It is recommended to be used as quickly as possible once

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## ICAL DATA SHEET

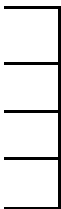
58-TDS-ENG-2023

## INS-RETINOICO Ph. Eur. ROCHE)

	DESCRIPTION DOE: TRETINOINA
	AEMPS CODE: 155A
0H28O2	ARTICLE CODE: 004868

SHOULD BE

» the container is opened and to keep the rest under inert gas. S



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## TECHNICAL DATA

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### TRETINOINA (ACIDO TRACETICO)

DESCRIPTION DCI: TRETINOIN

CAS N°: 302-79-4

EC N°: 206-129-0

MOL. WEIGHT: 300.42

MOL. FORMULA: C<sub>20</sub>H<sub>28</sub>O<sub>2</sub>

### REMARKS

Tretinoin is subjected to the requirements of the ICH Q3E (R2) and EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured in accordance with guidelines EMA/428592/2019 Rev 2 and ICH Q3E (R2).

Certificates of residual solvents, allergens, non-GMO and heavy metals are available upon request.

All methods of analysis are validated by official pharmacopoeias which can be obtained at specific request. The above info is for informational purposes only. Please refer to the product leaflet before use.

All methods are validated by the official pharmacopoeias and/or internal methods.

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## ICAL DATA SHEET

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### INS-RETINOICO Ph. Eur. ROCHE)

	DESCRIPTION DOE: TRETINOINA
	AEMPS CODE: 155A
0H2802	ARTICLE CODE: 004868

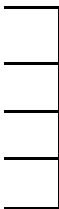
3) "Elemental Impurities" and the requirements of guides

after a risk evaluation according to ICH Q9, ICH M7 and in  
EMA/189634/2019.

BSE-TSE, among others, are available upon request.

procedures or are validated by internal methods of the manufacturer  
information does not exempt from the obligation to identify the proc





Product

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