



## TECHNICAL DATA SHEET

00081-TDS-ENG-2023

TRETINOINA (Ac.trans-Retinoico) (PH.EUR-GMP EUR)		
DESCRIPTION DCI: TRETINOIN		DESCRIPTION DOE: TRETINOINA
CAS N°: 302-79-4	EC N°: 206-129-0	AEMPS CODE: 155A
MOL. WEIGHT: 300.42	MOL. FORMULA: C <sub>20</sub> H <sub>28</sub> O <sub>2</sub>	ARTICLE CODE: 00081

ATTRIBUTES	SHOULD BE
Appearance	Yellow or light orange, crystalline powder
Solubility	Practically insoluble in water, sparingly soluble in methylene chloride, slightly soluble in ethanol (96 %)
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 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1%
Assay	98.0 - 102.0 %
Residual solvents	
Isopropyl alcohol	=< 2000 ppm
Methanol	=< 100 ppm
Ethyl acetate	=< 100 ppm
Chloroform	=< 50 ppm

### COMPLIES WITH

European Pharmacopoeia 11.0

### 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 i

### REMARKS

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.