



## TECHNICAL DATA SHEET

009590-TDS-ENG-2023

### ACIDO 13 CIS RETINOICO (EP- GMP EUR) - OLON - (ISOTRETINOINA)

DESCRIPTION DCI: ISOTRETINOIN		DESCRIPTION DOE: ISOTRETINOINA
CAS N°: 4759-48-2	EC N°: 225-296-0	AEMPS CODE: 37A
MOL. WEIGHT: 300.42	MOL. FORMULA: C <sub>20</sub> H <sub>28</sub> O <sub>2</sub>	ARTICLE CODE: 009590

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

### COMPLIES WITH

European Pharmacopoeia 10.0

### STORAGE

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

### REMARKS

Isotretinoin 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.