



TECHNICAL DATA SHEET

002052-TDS-ENG-2023

| ACIDO RETINOICO 13 CIS (EP - GMP EUR) BASF | | |
|--|--|--------------------------------|
| 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 ₂₀ H ₂₈ O ₂ | ARTICLE CODE: 002052 |

| 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 % |
| Residual solvents | |
| Dioxan | = < 50 ppm |
| Acetone | = < 100 ppm |
| Ethanol | = < 100 ppm |
| Ethyl acetate | = < 100 ppm |
| Methanol | = < 100 ppm |
| n-Heptane | = < 1000 ppm |
| Isopropyl alcohol | = < 2000 ppm |
| Particle size | |
| D (10 %) | = < 40 µm |
| D (50 %) | 75 - 150 µm |
| D (90 %) | = < 450 µm |

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.