

TECHNICAL DATA SHEET

1836-TDS-ENG-2026

| TRIAMCINOLONA ACETONIDO (EUR. PH.) | | |
|---|---|--|
| DESCRIPTION DCI: TRIAMCINOLONE ACETONIDE | | DESCRIPTION DOE: TRIAMCINOLONA ACETONIDO |
| CAS N°: 76-25-5 | EC N°: 200-948-7 | AEMPS CODE: 1171AD |
| MOL. WEIGHT: 434,49 | MOL. FORMULA: C ₂₄ H ₃₁ FO ₆ | ARTICLE CODE: 1836 |

| ATTRIBUTES | SHOULD BE |
|---------------------------|---|
| Appearance | White or almost white, crystalline powder |
| Solubility | Practically insoluble in water, sparingly soluble in ethanol (96 %) |
| Identification A | Complies |
| Identification C | Complies |
| Specific optical rotation | +110 / +117 |
| Related substances | |
| Impurity B | =< 0.2 % |
| Impurity C | =< 0.15 % |
| Unspecified impurities | =< 0.10 % |
| Total impurities | =< 0.5 % |
| Water | =< 2.0 % |
| Assay | 97.5 - 102.0 % |

COMPLIES WITH

European Pharmacopoeia 12.2

STORAGE

Keep the container tightly closed in a dry, cool and well-ventilated place.

REMARKS

It shows polymorphism.

Triamcinolone Acetonide is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline 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.