



TECHNICAL DATA SHEET

1836-TDS-ENG-2023

TRIAMCINOLONA ACETONIDO (PH.EUR)		
DESCRIPTION DCI: TRIAMCINOLONE ACETONIDE		DESCRIPTION DOE: TRIAMCINOLONA ACETONIDO
CAS Nº: 76-25-5	EC Nº: 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 11.0

STORAGE

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

REMARKS

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.