

**TRIAMCINOLONA ACETONIDO (EUR. PH.)**

PRODUCT CODE: 1836	CAS Nº: 76-25-5	ANALYSIS Nº: 158/23
MANUFACTURER BATCH: ND1254M	CERTIFICATE ID: 38.572	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/04/2023	
METAPH BATCH: 0010623	EXPIRY DATE: 30/04/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder (*)
Solubility	Practically insoluble in water, sparingly soluble in ethanol (96 %)	Complies
Identification A	Complies	Complies (*)
Identification C	Complies	Complies (*)
Specific optical rotation	+110 / +117	+ 113
Related substances		
Impurity B	=< 0.2 %	< LoQ
Impurity C	=< 0.15 %	0.06 %
Unspecified impurities	=< 0.10 %	< LoQ
Total impurities	=< 0.5 %	0.06 %
Water	=< 2.0 %	1.8 % (*)
Assay	97.5 - 102.0 %	100.2 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

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.

(*) Data controlled by Metapharmaceutical Industrial SL.

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

STORAGE

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

Analysis date: 13/06/2023
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000294
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