



TRIAMCINOLONA ACETONIDO (EUR. PH.)

PRODUCT CODE: 1836	CAS N°: 76-25-5	ANALYSIS N°: 259/24
MANUFACTURER BATCH: NE0996M	CERTIFICATE ID: 43.742	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/04/2024	
METAPH BATCH: 0121024	EXPIRY DATE: 30/04/2029	

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 %	< 0.05 %
Impurity C	= < 0.15 %	< 0.05 %
Unspecified impurities	= < 0.10 %	0.07 %
Total impurities	= < 0.5 %	0.07 %
Water	= < 2.0 %	1.6 %
Assay	97.5 - 102.0 %	98.9 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliances with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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.

(*) Data adapted from the manufacturer's certificate of analysis.

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: 22/11/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000294