METAPHARMACEUTICAL IND SL
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HIDROCORTISONA ACETATO (EUR. PH.)

PRODUCT CODE: 1083	CAS Nº: 50-03-3	ANALYSIS Nº: 003/24	
MANUFACTURER BATCH:	K06M20231106	CERTIFICATE ID:	40.689
SUPPLIER BATCH:	----	MANUFACTURING DATE:	15/11/2023
METAPH BATCH:	0040124	RETEST DATE:	31/10/2028

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder	White crystalline powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Specific optical rotation	+158 / +167	+165
Related substances		
Impurity C	=< 0.6 %	0.14 %
Impurity A	=< 0.5 %	0.11 %
Impurity B	=< 0.3 %	< 0.05 %
Impurity D	=< 0.3 %	< 0.05 %
Impurity E	=< 0.3 %	< 0.05 %
Impurity G	=< 0.15 %	Not Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total of impurities	=< 1.5 %	0.3 %
Loss on drying	=< 0.5 %	0.14 %
Assay	97.0 - 102.0 %	101.5 %

COMPLIES WITH

Euroepan Pharmacopoeia 11.0

REMARKS

Hydrocortisone Acetate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

All 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 containers in a cool and well-ventilated place.

Analysis date: 05/02/2024
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000493
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