

HIDROCORTISONA ACETATO (EUR. PH.)

PRODUCT CODE: 1083	CAS Nº: 50-03-3	ANALYSIS Nº: 224/22
MANUFACTURER BATCH: K06M20220902	CERTIFICATE ID: 36.220	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 06/09/2022	
METAPH BATCH: 0081022	RETEST DATE: 06/08/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, slightly soluble in anhydrous ethanol and in methylene chloride	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Specific optical rotation	+158 / +167	+164
Related substances		
Impurity C	=< 0.6 %	0.16 %
Impurity A	=< 0.5 %	0.19 %
Impurity B	=< 0.3 %	< 0.05 %
Impurity D	=< 0.3 %	< 0.05 %
Impurity E	=< 0.3 %	< 0.05 %
Impurity G	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	0.05 % (RT = 16.64 min)
Total of impurities	=< 1.5 %	0.40 %
Loss on drying	=< 0.5 %	< 0.01 %
Assay	97.0 - 102.0 %	99.2 %
Residual solvents [In-house]		(*) (**)
Acetone	=< 5000 ppm	412 ppm
Methanol	=< 3000 ppm	Not Detected
Methylene chloride	=< 600 ppm	Not Detected
Particle size		(*)
=< 30 µm	85 %	Complies

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

Hydrocortisone Acetate is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.

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

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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: 23/11/2022

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000493

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