

<b>HIDROCORTISONA BASE (EUR. PH.)</b>			
PRODUCT CODE: 1084		CAS Nº: 50-23-7	ANALYSIS Nº: 075/21
MANUFACTURER BATCH:	K05M20201111	CERTIFICATE ID:	31.345
SUPPLIER BATCH:	----	MANUFACTURING DATE:	24/11/2020
METAPH BATCH:	0230321	RETEST DATE:	24/10/2025

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, sparingly soluble in acetone and in ethanol (96 %), slightly soluble in methylene chloride	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Specific optical rotation	+162 / +168	+167
Related substances		
Impurity C	=< 0.5 %	< 0.05 %
Impurity D	=< 0.5 %	0.08 %
Impurity E	=< 0.5 %	Not Detected
Impurity I	=< 0.5 %	< 0.05 %
Impurity G	=< 0.4 %	< 0.05 %
Impurity F	=< 0.3 %	< 0.05 %
Impurity A	=< 0.2 %	0.09 %
Impurity B	=< 0.2 %	Not Detected
Impurity H	=< 0.15 %	Not Detected
Impurity N	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 2.0 %	0.17 %
Loss on drying	=< 1.0 %	0.08 %
Assay	97.0 - 103.0 %	100.9 %
Residual solvents		(*) (**)
Acetone	=< 3000 ppm	39 ppm
Methanol	=< 1500 ppm	1562 ppm
Methylene Chloride	=< 100 ppm	Not Detected

#### COMPLIES WITH

European Pharmacopoeia 10.0

#### REMARKS

It shows polymorphism (5.9).

Hydrocortisone 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 controlled by Metapharmaceutical Industrial SL-

(\*\*) 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.

Analysis date: 29/04/2021

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000493

HENAN LIHUA Ph. Co., Ltd.

Middle Of Huanghe Street, Hi-Tech Industry

Development Zone

455000 Anyang



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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

Protect from the light. Keep the container tightly closed in a dry and well-ventilated place.

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